SELF-ADMINISTERED COGNITIVE BEHAVIOURAL THERAPY FOR WOMEN WITH CHRONIC PELVIC PAIN: DESIGN AND PILOT EVALUATION

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This thesis was submitted in partial fulfilment of the requirements for Doctor of Philosophy/Master of Psychology
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Abstract

Chronic pain is a complex, costly, and distressing condition that is associated with depression, anxiety, and functional impairment. Affecting approximately one in five women, chronic pelvic pain (CPP) can be particularly debilitating and is the most common cause of referral to women's health services. Medical interventions for this condition are generally limited to short-term symptom relief, while psychological interventions, although effective, are often not utilised or available. Stigma, mobility, cost, and lack of resources are among the barriers women face when considering psychological interventions for CPP.

These barriers are common among many chronic pain and mental health conditions, for which technology-based interventions are sometimes utilised. Some of these interventions, such as self-administered cognitive behavioural therapy (CBT) have shown to be as effective as face-to-face therapies. The almost ubiquitous adoption of mobile smartphones provides opportunities to deliver self-administered CBT to a wider range of people, and at relatively low cost. Unfortunately, there are no technology-based psychological interventions currently available for women experiencing CPP.

The aim of the research reported in this thesis was to develop and pilot-test a technology-based CBT intervention for women experiencing CPP utilising a co-design approach. In the first phase of this project, outpatients and clinicians from the CPP Clinic of the Royal Women’s Hospital in Melbourne (Australia) took part in a series of focus groups and interviews. This provided a rich understanding of the condition and helped determine the suitability of a technology-based CBT intervention for women with CPP. The data from this phase were then used to create a set of design specifications which informed the development of a smartphone app, appEase.

The smart-phone intervention delivered a 28-day CBT intervention involving mindfulness relaxation, cognitive restructuring, and pain education which women experiencing CPP would use daily. The final phase of the project involved pilot-testing appEase. Twenty-four women completed a series of baseline measures and took part in a screening interview. Of these women, eighteen completed post-intervention measures, and participated in mid- and post-intervention interviews. Survey and usage data were also collected from within the app while participants were engaging with the therapy.
Two women underwent surgery during the pilot study, and of the sixteen women who met the full criteria for data inclusion, twelve (75%) completed all 28 sessions. Although the app was designed to be used over 28 days, the mean completion time was 64 days. Most women found it difficult to find 15 minutes every day to utilise the app. Nevertheless, ten participants (63%) experienced clinically significant reductions in Pain Catastrophising, and nine (56%) experienced clinically significant increases in Pain Self-Efficacy.

The co-design methodologies utilised produced some useful insights into how women engaged with the therapy, and what mechanisms may have led to favourable outcomes. Interviews with participants during and after the pilot study confirmed that appEase was engaging, simple to use, and provided helpful tools and strategies for managing CPP. Furthermore, some participants reported that they felt a therapeutic relationship between themselves and the intervention. These results suggest that a self-administered technology-based CBT intervention may be suitable for women experiencing CPP and could play a role in helping them manage their pain.

This project is the first to apply co-design methodologies to the treatment of CPP in women. Furthermore, the app created, appEase, is the first technology-based CBT intervention developed for this population. Using co-design methodologies also yielded some rich insights into the personal experiences and complexities of CPP in women. It provided some helpful information into how intervention could be evaluated and has produced a sound empirical basis for testing the efficacy of appEase in a randomised control trial.
Declaration

I, Arthur Stabolidis, declare that this thesis is my own work, except where acknowledged, and that the research reported in this thesis was conducted in accordance with the principles for the ethical treatment of human subjects as stated by the University of Melbourne Human Research Ethics Committee and the Royal Women’s Hospital Human Research Ethics Committee. This thesis is less than 100,000 words in length, exclusive of tables, figures, references, and appendices, and has not been previously accepted in any substance for any other degree.

Signed: _______________________________ Date: January 26, 2018
Acknowledgements

I would like to thank my supervisors for their guidance and patience throughout this project. Their expertise and temperament were both motivating and inspiring. I would also like to thank the Collier Charitable Fund for providing the financial support for the research program, the clinical and administrative staff of the Royal Women’s hospital for their help and perseverance, and Associate Professor Martin Healey and Professor Stephen Bowden for initiating discussions about this project. I would also like to thank the patients from the hospital for their generous insights, and all the study participants for their enthusiastic contributions. Finally, I thank my wife and Tonie Thiele for their enduring encouragement and support, and for making this endeavour possible.

Ask not what disease the patient has, but rather who the patient is that has the disease.

William Osler
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Appendix I: LoFrisco (2010) Review
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<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>APA</td>
<td>American Psychiatric Association</td>
</tr>
<tr>
<td>BPI</td>
<td>Brief Pain Inventory</td>
</tr>
<tr>
<td>CPP</td>
<td>Chronic Pelvic Pain</td>
</tr>
<tr>
<td>CBT</td>
<td>Cognitive Behavioural Therapy</td>
</tr>
<tr>
<td>DASS</td>
<td>Depression Anxiety and Stress Scale</td>
</tr>
<tr>
<td>DSM-5</td>
<td>Diagnostic and Statistical Manual (5th ed.)</td>
</tr>
<tr>
<td>DSM-IV</td>
<td>Diagnostic and Statistical Manual (4th ed.)</td>
</tr>
<tr>
<td>IASP</td>
<td>International Association for the Study of Pain</td>
</tr>
<tr>
<td>LOC</td>
<td>Locus of Control</td>
</tr>
<tr>
<td>PSOCQ</td>
<td>Pain Stages of Change Questionnaire</td>
</tr>
<tr>
<td>PTSD</td>
<td>Post-Traumatic Stress Disorder</td>
</tr>
<tr>
<td>PC</td>
<td>Pain Catastrophising</td>
</tr>
<tr>
<td>PSE</td>
<td>Pain Self-Efficacy</td>
</tr>
<tr>
<td>RCT</td>
<td>Randomised Control Trial</td>
</tr>
<tr>
<td>RWH</td>
<td>Royal Women’s Hospital</td>
</tr>
<tr>
<td>SF-12</td>
<td>12-Item Short Form Health Survey</td>
</tr>
<tr>
<td>SOC</td>
<td>Transtheoretical Stages of Change</td>
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Chapter 1.

Introduction

Almost everyone understands the experience of acute pain, such as toothache, headache, burn, or physical injury. Pain, particularly when it is intense, is highly distressing and can diminish the enjoyment of life (Butler & Moseley, 2013). For most people, once healing has occurred, pain passes and life returns to normal. For one in five, the experience of intense and debilitating pain can linger for months, or even decades (Blyth et al., 2001).

Pain that persists for more than three to six months is referred to as chronic pain (Breivik, Collett, Ventafridda, Cohen, & Gallacher, 2006). Although it is also present in males, this study is concerned with chronic pelvic pain (CPP) in women. The International Association for the Study of Pain (IASP) defines CPP as ‘chronic or recurrent pelvic pain that has a gynaecological origin but for which no definite lesion or cause is found’ (Merskey & Bogduk, 2007, p. 170).

CPP is a prevalent and costly condition. Community-based studies estimate the prevalence of CPP to be between 14% and 24% (Latthe, Latthe, et al., 2006). The annual direct out-of-pocket costs to physicians treating women with CPP, not including diagnostic procedures or hospitalisation, was estimated at $2.8 billion in 1997 in the US alone (Weijenborg, Greeven, Dekker, Peters, & ter Kuile, 2007). The World Health Organisation considers CPP to be a condition with high disease burden (Latthe, Mignini, Gray, Hills, & Khan, 2006).

CPP in women is the most common cause of referral to women’s health services (Engeler et al., 2013; Zondervan & Barlow, 2000). Like all forms of chronic pain, CPP has a profound impact on many aspects of life. For some women experiencing CPP, it can not only cause distress and disability, it can also affect identity; the ability to be intimate; fertility; and the ability to care for children (LoFrisco, 2011; Werner, Isaksen, & Malterud, 2004).

The causes of CPP are complex, and physical pathology does not always clearly correlate to the amount of pain and distress experienced (Dalpiaz et al., 2008; Weijenborg et al., 2007). Adding to this complexity, CPP is often comorbid with anxiety, depression, PTSD symptoms, and personality disorders (Ghaly & Chien, 2000;
Savidge & Slade, 1997). In cases where pain is not responsive to treatment, trauma and abuse are sometimes implicated in the aetiology and maintenance of the condition (Heim, Ehlert, Hanker, & Hellhammer, 1998; McGowan, Clark-Carter, & Pitts, 1998). Given these complexities, CPP is a difficult condition to treat (Ghaly & Chien, 2000; Price et al., 2006). It is common for patients to feel dissatisfied with medical diagnosis and treatments (McGowan, Luker, Creed, & Chew-Graham, 2007). Some pharmacological and surgical interventions can have debilitating side-effects, and in some cases, can make the condition worse in the long run (Brandsborg, Nikolajsen, Kehlet, & Jensen, 2008).

Psychological factors, such as fear and catastrophising, are known to be implicated in the experience of and maintenance of CPP (Samwel, Evers, Crul, & Kraaimaat, 2006; Quartana, Campbell, & Edwards, 2009). Therefore, Cognitive Behavioural Therapy (CBT) is sometimes used to help women manage CPP (Ferreira et al., 2013; LoFrisco, 2011; Martin, Garske, & Davis, 2000) as it is widely used in the management of many chronic pain conditions (Morley, 2011).

CBT interventions for chronic pain generally include relaxation exercises, skill building, pain education and cognitive restructuring (Bradley, 1996; Turk & Gatchel, 2002). Frequently, these interventions target pain-related distress and disability by seeking to reduce pain catastrophising (PC) or negative thoughts the person has about their pain (Sullivan et al., 2001), and increase pain self-efficacy (PSE) which can be defined as the ability to feel empowered and engage in aspects of their life despite the pain condition (Buckelew, Murray, Hewett, Johnson, & Huysen, 1995).

CBT interventions for chronic pain have not only proven to be effective in limiting distress and disability (Bradley, 1996; Turk & Gatchel, 2002) but have also been associated with favourable reorganisation of cortical structures within the brain (Shpaner et al., 2014). Although CBT may not necessarily be effective in lowering perceived pain levels (Williams, Eccleston, & Morley, 2012), it has been shown to be effective in addressing low mood and disability associated with chronic pain, and is considered by the IASP to be the first line of treatment for chronic pain conditions (Ehde, Dillworth & Turner, 2014; Gatchel, Peng, Peters, Fuchs, & Turk, 2007).

CBT interventions are most effective when utilised in the context of multi-disciplinary settings involving other professionals, such as social workers, pain doctors,
and physical therapists (Flor, Fydrich, & Turk, 1992; Kames, Rapkin, Naliboff, Afifi, & Ferrer-Brechner, 1990; Okifuji, 2003; Peters et al., 1991; Turk & Gatchel, 2002). Although considered to be the gold standard approach for treating chronic pain conditions, there are several barriers to accessing such services. First, demand for these services outstrips supply. In some regional areas these services are not available at all (Hogg, Gibson, Helou, DeGabriele, & Farrell, 2012). Second, some people with chronic pain experience reduced mobility and cannot attend sessions (Carpenter, Stoner, Mundt, & Stoelb, 2012). Third, some persons with chronic pain may not be able to work and therefore cannot afford to pay for treatment (Silvemark, Källmén, Portala & Molander, 2008). Fourth, some do not want to engage in psychotherapy because they feel a sense of stigma associated with seeking psychological help (Turk, Swanson, & Tunks, 2008).

To overcome some of these barriers, self-administered CBT interventions have been developed, in some cases showing clinical efficacy similar to face-to-face therapy (Fitria, 2017; Grist & Cavanagh, 2013; Richardson, Stallard, & Velleman, 2010). Recent technological advances, such as the widespread use of smartphones, have provided further opportunities to improve access, engagement, and effectiveness of these interventions, with growing evidence for their efficacy in many clinical areas (Bender, Radhakrishnan, Diorio, Englesakis, & Jadad, 2011; Mohr, Burns, Schueller, Clarke & Klinkman, 2013; Rosser & Eccleston, 2011).

Despite their advantages and known effectiveness, self-administered CBT interventions, such as those delivered through smartphones, have some limitations. Developers of these technologies rarely consult with end users or clinicians, and few embody evidence-based practices (Donker et al., 2013). Few apps for chronic pain have been rigorously evaluated in randomised control trials (RCT), or tested for their safety (Lalloo, Jibb, Rivera, Agarwal, & Stinson, 2015; Rosser & Eccleston, 2011). In studies assessing their clinical efficacy, drop-out rates are high, particularly when these interventions are utilised without clinician guidance (Geraghty, Wood, & Hyland, 2010; Rini, Williams, Broderick, & Keefe, 2012). At the time of this review, there were no technology-based CBT interventions available for managing CPP in women.

This research sought to overcome these shortcomings by utilising a co-design approach in the development and evaluation of a self-administered CBT intervention for women experiencing CPP. Co-design methodologies involve end users and specialist
clinicians in the design and evaluative process (Dabbs et al., 2009). Researchers have advocated the use of co-design (Hagen et al., 2012) and some have published guidelines for applying it to technology based psychological interventions (Doherty, Coyle & Matthews, 2010). This research explored the potential utility of adopting a co-design approach for women experiencing CPP.

**Summary of the Project**

Utilising co-design methodologies involving patients and clinicians, this project developed a CBT intervention in the form of a mobile phone app called appEase. The intervention delivered a 28-day course of pain education, cognitive restructuring and mindfulness skills for women experiencing CPP. It sought to reduce PC, thereby reducing pain-related distress, and increase PSE to help women feel confident in performing activities despite being in pain (Cheong, Smotra, & Williams, 2014; Weijenborg, ter Kuile, & Stones, 2009). The final phase of this project involved evaluating appEase in a pilot study.

Initially, a group of patients and clinicians took part in a series of focus group workshops and interviews as part of a co-design process. These data were used to create an intervention which was evaluated in a pilot study with a sample of twenty-four women. As part of the evaluation, a series of psychometric measures were taken at baseline and post-intervention which included pain catastrophising and pain self-efficacy as the primary variables of interest. Usage and survey data were also collected through the app, and participants were interviewed before, during, and after the pilot study to help understand mechanisms of change, and verify the app’s acceptability, usability and effectiveness. Suggestions for design improvements were also collected for modifying the intervention and testing it in a future RCT.

**Outline of This Thesis**

This thesis comprises nine chapters. Following this introduction, Chapter 2 presents a review of the literature on chronic pain and outlines the challenges involved in both classifying and quantifying the condition. It examines theories around the aetiology and maintenance of chronic pain and discusses psychological and behavioural factors that mediate the experience of chronic pain within an individual. It seeks to explain why medical pathology is often not linearly related to distress, and why some women with
gynaecological conditions go on to experience CPP for many years, while others remain asymptomatic. The latter part of the chapter presents a discussion on the treatments clinicians use, such as CBT, to help minimise PC and highlights the challenges involved in delivering CBT to women experiencing CPP.

Chapter 4 begins by examining alternative ways in which CBT can be delivered outside of face-to-face contexts. It examines how technological advances, such as Internet devices and smartphone apps, can be utilised to make self-administered CBT accessible and engaging. The chapter then outlines some of the challenges involved in utilising smartphone technologies in clinical settings, and reviews ways in which these challenges and limitations might be overcome by utilising a co-design approach. Chapter 5 presents an outline of the overall aim and rationale for the project and presents the research questions which will be addressed within the investigative and pilot phases.

The investigative phase of the research program is presented in Chapter 6. The chapter presents the findings of the investigation, along with a discussion of how they answered the research questions proposed, and how their responses will inform the design of the intervention. Chapter 7 then describes the development phase of the project. It discusses the important principles and features of the intervention and summarises the range of topics that make up the 28-day CBT program. The chapter concludes with a description of the mobile phone app that was created and describes how usage and survey data would be collected from participants through the app.

Chapter 8 describes the pilot phase of the study. It begins by outlining the methods of investigation, instruments used, and ethical considerations involved with the study. It then presents the quantitative and qualitative findings that addressed the research questions proposed. Chapter 9 concludes the thesis by providing an integrative analysis of the three phases of the study given the literature reviewed and research questions proposed. It highlights the contributions of the research and suggests opportunities for further investigation. This is followed by a brief summary of the strengths and weaknesses of the study, a presentation of some design improvements, and details of a planned future RCT.
Chapter 2.
Chronic Pain

This chapter presents a review of the key concepts and theories relevant to the aetiology and management of chronic pain. It begins with a working definition of chronic pain and discusses the challenges involved in classifying and quantifying the condition. It then reviews psychological and behavioural factors that mediate the experience of pain, and the cost chronic pain can impose on society, the individual and significant others. The chapter then concludes with a survey of the literature on psychological and multi-disciplinary interventions for chronic pain.

### 2.1 Definition, Classification and Prevalence

**Pain and Nociception**

Pain is defined as ‘an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage’ (Loeser & Treede, 2008, p. 475). The primary function of pain is to protect an organism against injury. The nervous system’s response to harm, referred to as ‘nociception’, is often the cause of what is ordinarily considered to be pain. In this process, cells called nociceptors are stimulated chemically, mechanically or thermally (Butler & Moseley, 2013). This activation then produces a signal that travels along nerve fibres to the spinal cord, then up through the spinal cord into the brain. The brain interprets those signals as pain. The resulting pain that is experienced is not always linearly related to the signal produced as many factors influence processing along the path from the site of harm to the brain (McMahon, Koltzenburg, Tracey, & Turk, 2013). Some of these factors include cognitions, emotions, central sensitisation, and brain plasticity. These will be discussed in more detail later in the chapter.

**Chronic Pain**

In most cases, pain diminishes when healing occurs, or when the cause of pain is averted. When pain lasts more than three to six months, or beyond ‘natural healing’, it is generally referred to as chronic pain (Merskey & Bogduk, 2007). The relationship between pathology, healing and chronic pain is complex. In many conditions, such as rheumatoid arthritis, spinal stenosis and osteoarthritis, it is difficult to determine if...
normal healing has, in fact, occurred. In some cases, such as those involving amputation or scar tissue around nerves, healing in the ordinary clinical sense may not occur at all (McMahon et al., 2013). Adding to this complexity, painful lesions may be present, but not detectable by current imaging technologies (Bonica, Fishman, Ballantyne, & Rathmell, 2010). In other conditions that cause chronic pain, such as migraine and endometriosis, these symptoms might abate but then recur (Chapron et al., 2003). In cases such as these where pain persists, the adaptive function of pain is less clear, as chronic pain often diminishes a person’s health and well-being; and can cause considerable long-term suffering.

**Classifications**

Considering the complex and diverse circumstances in which chronic pain can arise, the IASP created an international task force of pain experts to work with the World Health Organisation to create a classification system that more adequately represents the complexities of the condition in its varying forms (Treede et al., 2015). The taskforce argued that chronic pain affects an estimated 20% of people worldwide and accounts for up to one-fifth of physician visits, yet it is represented in a highly unsystematised manner in the International Classification of Diseases. They believe that with proper classification, chronic pain will receive greater attention, understanding and priority within the health system. They report that some diagnoses of pain that defy these classification principles, such as fibromyalgia, will be correctly classified with the new system to be ratified by the World Health Assembly in 2018.

According to the most recent version of the Diagnostic and Statistical Manual (DSM-5) of the American Psychiatric Association (APA, 2013), persons who experience somatic symptoms associated with significant distress and impairment are classified under a new diagnostic category called Somatic Symptom and Related Disorders (APA, 2013; Katz, Rosenbloom, & Fashler, 2015). The APA also removed the diagnostic criteria for Pain Disorders and moved those criteria within this new classification. Diagnosis involving conditions with somatic symptoms are now made based on signs and symptoms that are present, rather than on the basis of medical explanations that are absent in the face of somatic complaints (APA, 2013.) These changes were made in response to criticisms that the previous DSM-IV categorisation of Somatization Disorder was too specific and rigorous, resulting in too few diagnoses.
Some critics now argue that the new diagnosis is too sensitive resulting in over-diagnosis and this may impede medical investigations in instances where the somatic symptoms are prematurely labelled as having a psychological basis (Frances & Chapman, 2013; Katz et al., 2015).

2.2 Prevalence and Impact

Prevalence

Variations in prevalence rates are common across chronic pain studies, largely due to the subjective nature chronic pain, and differences in the definition (i.e., 3 months versus 6 months of continuous or intermittent pain). In Australia, a prevalence study involving 17,543 interviews with randomly selected adults from the general population showed the prevalence rate for males to be 17.1% and females 20% (Blyth et al., 2001). For females in the oldest age group (80 – 84 years), the prevalence rate peaked at 31% (Blyth et al., 2001). Most chronic pain studies in the literature quote a community prevalence figure of 20% (Breivik et al., 2006; Ehde et al., 2014).

The most recent study to report prevalence rates for chronic pain is a 2016 systematic review conducted in the UK (Fayaz, Croft, Langford, Donaldson, & Jones, 2016). By pooling population data comprising 139,933 male and female UK residents from 19 matched studies, the review reported a prevalence rate that ranged from 35% to 50%. A similar prevalence study from a US adult population reported a prevalence rate for chronic pain that ranged between 11% and 64% (Watkins, Wollan, Melton, & Yawn, 2008).

Economic Cost

In many developed countries it has been reported that costs for chronic pain conditions account for up to 14% of a country’s GDP (Nachemson & Jonsson, 2000). In 2008, the US conducted a medical expenditure survey and found that the annual cost of chronic pain was greater than the annual cost of heart disease, cancer or diabetes (Gaskin & Richard, 2012). In 2007, Access Economics conducted a comprehensive report in conjunction with the University of Sydney Pain Management Research institute, and found the total annual cost associated chronic pain in Australia was $AU34.3 billion (Access Economics, 2007). This report included costs associated with assessment, treatment and lost productivity. In an earlier Australian review, Leeuwen,
Blyth, March, Nicholas, and Cousins (2006) noted that many chronic pain studies underestimate the cost as the data does not include hidden costs such as reduced work effectiveness and loss of taxation revenue. Some argue that many of the costs associated with chronic pain conditions are cumulative and increase exponentially over time (Schofield et al., 2016). Using a microsimulation model projecting the cumulative costs of chronic back pain, Schofield et al. (2016) predicted that welfare payments between 2015 and 2030 would increase by 16.9%, lost taxation revenue was projected to increase by 43.2% and loss of annual income was predicted to increase by 60%. The study highlighted that research needs to incorporate costs to the individual (loss of productive life years), governments (reduced taxation revenue) and society (loss of gross domestic product) if they are to accurately reflect the economic impact of chronic pain conditions.

**Physical Health**

Chronic pain imposes a significant cost on an individual’s health and well-being. Persons with chronic pain can end up in a cycle of inactivity and avoidance that can precipitate and perpetuate other health conditions. It is common for persons with chronic pain to have problems with sleep, issues with mobility and fatigue, and it can also be associated with a high body mass index (Jakobsson, 2010). Chronic pain has also known to be associated with high stress and cortisol levels in the body (McBeth et al., 2005). Furthermore, prolonged activation of the pain and stress system increases the risk of developing other long-term conditions, such as heart and respiratory diseases (Torrance, Elliott, Lee, & Smith, 2010). Persons who experience chronic pain for extended periods of time generally have lower overall quality of life ratings compared with healthy controls (Silvemark, Källmén, Portala, & Molander, 2008). Drug dependency is also a concern regarding persons who experience chronic pain (van Hecke, Torrance & Smith, 2013). In a systematic review of opioid use, Højsted and Sjøgren (2007) found some studies report a prevalence rate of drug addiction in up to 50% of persons experiencing chronic pain.

**Social Impact**

Chronic pain can also be an isolating condition for the individual experiencing it. In the absence of a cure, individuals with chronic pain may become isolated, lose their jobs and withdraw from society (Charmaz, 1983). They may feel that their body, their loved ones, and their doctors have let them down (Ghaly & Chien, 2000; Price et al.,
2006). For some, the experience of chronic pain is associated with feelings of shame (Werner et al., 2004). Chronic pain affects everyone with whom the individual is in close contact. Family members and significant others often feel helpless as their loved one relentlessly searches for medical cures that rarely provide long term relief (Engeler et al., 2013). As medical costs increase, along with an inability to work or contribute to the commitments of family life, relationships can become strained. Friendships can also become difficult to manage as socialising becomes more difficult with increased disability. Treatment modalities are increasingly involving relationships, including family members (Martire, Lustig, Schulz, Miller, & Helgeson, 2004; Riffin, Suitor, Reid, & Pillemer, 2012) and social networks (Byrne & Hochwarter, 2006).

**Psychological Cost**

When pain is persistent and overwhelming, it can affect a person’s psychological well-being. It can lead to feelings of helplessness and low self-worth (Frischenschlager & Pucher, 2002; Jelovsek, Walters, & Barber, 2008; van Hecke et al., 2013). People with chronic pain can end up in a cycle of fear, anxiety, inactivity and avoidance. They are therefore more likely to experience low mood, depression, and anxiety (van Hecke et al., 2013). In a US national comorbidity study, McWilliams, Cox, and Enns (2003) found that persons with chronic pain were 200% more likely to have a mood or anxiety disorder relative to persons in the general population. Low mood and depressive symptoms associated with chronic pain can also contribute to lack of motivation and mobility, which perpetuates and maintains chronic pain symptoms (Jensen, Jensen, Turner, Romano, & Karoly, 1991). Heightened anxiety associated with chronic pain can also be associated with greater subjective feelings of pain distress, and greater levels of pain monitoring and vigilance (Samwel et al., 2006). It is speculated that individuals who develop a fear of pain may be more likely to engage in maladaptive ways of avoiding that pain such as avoidance behaviours and inappropriate use of substances (Passik & Weinreb, 2000).

### 2.3 Theories and Perspectives on Chronic Pain

For chronic pain theorists and researchers, the major challenge is to account for the following observations: (1) the relationship between pain and injury is variable; (2) pain can be experienced in the absence of noxious stimuli; (3) the location of damage and pain can be inconsistent and can change over time; (4) the distress and disability
associated with pain has many factors (including physiological factors); and (5) treatments for chronic pain are often only partially successful. This section will present key theories that have sought to explain the origin and maintenance of chronic pain. Although the theories presented are not intended to be an exhaustive list, and some still widely debated, they have informed a range of therapies and treatment approaches relevant to the psychological management of chronic pain.

**Psychodynamic and Early Theories of Pain**

Early models of chronic pain were dichotomised in their view of its origins: pain was either medical in origin, or it was caused entirely by psychological factors such as ‘emotional turbulence’ (Melzack, 2005). Psychodynamic conceptualisations of unexplained pain posited that its causes were psychological in origin, and caused by factors such as childhood abuse, parental quarrels, trauma, early responsibilities or unrelenting high standards imposed by parents. In these instances, psychological distress was assumed to be ‘somatised’ into a physical sensation, such as chronic pain (Frischenschlager & Pucher, 2002). It was expected that when the psychological mechanisms were resolved, the pain would in turn resolve. Empirical evidence supporting this view is scarce. Furthermore, insight-oriented psychotherapy has not been shown to be effective for treating chronic pain conditions (Bonica et al., 2010). Although there are some empirical links between childhood trauma and chronic pain, most notably through Engel’s conceptualisation of the “pain prone patient” (Adler, Zlot, Hürny, & Minder, 1989), there is little consistent evidence supporting a causal link between childhood experiences and long-term pain (Davis, 2005).

**Gate Control Theory**

One early attempt to incorporate both psychological and physiological processes into an integrated model of chronic pain is Gate Control Theory (Melzack & Wall, 1967). This model gave rise to new clinical treatments reflecting a view that pain is not explained exclusively by physiological factors (Fordyce, Roberts, & Sternbach, 1985). According to this theory, nociceptive pain signals are modulated by a spinal gate control system before they are transmitted to the brain. Inputs into this gate can be either physiological or psychological and they either potentiate or moderate the pain signal. After analysing phantom limb pain, Melzack (1999) later concluded that Gate Control
Theory was insufficient to explain why pain can still be present in limbs that have been removed, and proposed Neuromatrix theory.

**Neuromatrix Theory**

This revision of Gate Control Theory proposed that pain is a multi-faceted experience that is produced by a widely distributed neurophysiological network called the body-self Neuromatrix (Melzack, 2005). This neural network integrates cognitive, sensory, behavioural, motivational and affective components which together inform the brain’s perception of pain that is occurring within the body. According to the theory, there are cases where the body-self Neuromatrix requires no sensory input in order to produce the experience of pain in the body. Although Gate Control and Neuromatrix theories are still debated (Mouraux, Diukova, Lee, Wise, & Iannetti, 2011), they can be credited for giving rise to a large amount of diverse clinical research and applications in the area of controlling and managing pain (Bonica et al., 2010). Furthermore, both Neuromatrix and Gate-Control Theory form the theoretical basis for many CBT interventions (McCracken & Turk, 2002).

**Sensitised Pain System**

More recent research has highlighted the importance of central nervous system processes in explaining why some injuries result in sustained levels of pain beyond what is normally expected (Siddall & Cousins, 2004). Brain imaging studies of persons who experience chronic pain have shown alterations in some sensory brain centres such as somatosensory cortices, cingulate cortex and insula and prefrontal cortex (Apkarian, Hashmi, & Baliki, 2011; Hunt & Mantyh, 2001); and shown alterations in spinal cord regions (Siddall & Cousins, 2004) relative to healthy controls. These alterations are both chemical and physiological, and result in an efficiency for producing pain signals that is far greater than for those who do not experience chronic pain. This phenomenon has been referred to as “central sensitisation” (Woolf, 2011) and is also thought to be the reason why chronic pain for some people can be experienced in multiple anatomical sites simultaneously (Schmidt & Baumeister, 2007; Woolf, 2011).

**Neuroplasticity and Cortical Restructuring**

Brain plasticity refers to the central nervous system’s ability to physically modify or reorganise itself and its neuronal-connections in response to events, behaviours and
learning (Green & Bavelier, 2008). The phenomenon has received widespread interest in recent years, both in academic (Apkarian et al., 2011) and lay circles (Doidge, 2016). Neuroimaging studies of persons with long standing pain show that the extent of reorganisation increases with the chronicity of the pain condition, and the magnitude of pain experienced (As-Sanie et al., 2012; Fenton, 2007). In a study examining changes in brain matter in 23 women with chronic pelvic pain, As-Sanie et al. (2012) found that for patients with endometriosis and chronic pain, decreases in grey matter were present in brain regions involved in pain perception, whereas for women with endometriosis and no chronic pain, those regions were no different from those of healthy controls.

Some researchers believe that neuroplasticity studies not only increase our understanding of chronic pain, but they can inform treatment modalities, and create strategies to help prevent chronic pain conditions (Flor, 2009). In a review on cortical reorganisation and pain, Flor (2009) reported that cognitive and behavioural strategies that focus on the extinction of pain behaviours, acquisition of new healthy ways of behaving and relating to pain, as well as education and cognitive reappraisal can help reorganise the brain in more adaptive ways for people who experience chronic pain. This is supported by emerging studies suggesting that brain matter can change in response to CBT for some people with chronic pelvic pain and chronic fatigue syndrome (De Lange et al., 2008; Moseley & Flor, 2012; Seminowicz et al., 2013).

2.4 Risk and Moderating Factors

Clinicians who treat medical conditions associated with chronic pain often report considerable variations in symptom presentation, distress and functional impairment, even between individuals presenting with similar physiological pathology (Engeler et al., 2013; Turk & Gatchel, 2002). Studies that have examined the relationship between physical symptoms and functioning have shown that the factors involved are complex, unclear, and do not provide consistent causal links (Geisser, Robinson, Keefe, & Weiner, 1994). This section will present a review of the literature examining risk and moderating factors of chronic pain. It will review how far studies have come in understanding the complexities of chronic pain presentations and how some pain studies have sought to explain why responses to nociceptive pain signals vary so much between individuals with seemingly similar diagnoses.
The biopsychosocial perspective

Psychological, social and cultural factors can all influence the experience, impact and maintenance of chronic pain. The simplistic conceptualisation that chronic pain is either psychological or physiological in origin has now been replaced by a biopsychosocial perspective (Gatchel, 2004). This conceptualisation takes into account the complexities of the intertwined and interactive processes involved in the aetiology, maintenance and experience of chronic pain conditions (Grace, 2000). Furthermore, comprehensive treatments that endorse this biopsychosocial perspective have shown to be more effective than those treatments that just target physiological factors alone (Bendix et al., 1995; Gatchel & Epker, 1999).

Anxiety, Fear and The Fear-Avoidance Model

Vlaeyen and Linton (2000) developed the fear-avoidance model to explain why medical conditions can lead to experiences of long-standing pain in some individuals, but not others. The model states that fear, anxiety and associated avoidance behaviours contribute to a person’s experience of pain and their on-going disability more so than physiological causes. These fear-based factors also contribute to the maintenance of chronic pain as physical activity and movement decreases, perpetuating the pain and causing it to become chronic. Verbunt et al. (2003) tested the assumption that fear of injury leads to disability in a cross-sectional survey of patients with lower back pain. They found that fear-avoidance behaviour was correlated to hypervigilance to illness information, muscular reactivity, physical deconditioning and guarded movements; all of which contribute to pain chronicity. Despite these findings, determining the causal relationship between physical activity and chronic pain is a still a challenge since lower levels of physical activity may be both a risk factor and a consequence of chronic pain (Wicksell et al., 2008).

Persons who are pre-disposed to feeling anxious or those who are prone to worrying excessively are more likely to experience greater levels of distress associated with their pain than those individuals who are less anxious (McCracken & Turk, 2002; Turk & Gatchel, 2002). Pain sensations, by their nature, are an indication that the body is under threat. For an already sensitised anxiety system, anxious thoughts can trigger fear and stress responses, which in turn exacerbate the physiological pain sensation (Woolf, 2011). To understand the mechanisms behind the anxiety, fear and pain relationship,
Crombez, Vlaeyen, Heuts, and Lysens (1999) conducted a study involving measures of pain-related fear and muscle extension exercises with weight lifting tasks. They found that anxiety and pain-related fear affected physical performance and a person’s perception of their own physical ability to lift weights. This study also showed that the fear of pain, driven by excessive anxiety and the anxious appraisal of the anticipation of pain, can predict stronger avoidance behaviours than the sensory experience of pain itself. In another experiment using electromyography recordings of lower back muscles, Vlaeyen et al. (1999) found that participants who reported high levels of pain-related fear also showed significantly higher muscular reactivity readings under physical load than those with low fear ratings. Collectively, these studies suggest that fear and negative affect can have an influence on muscles and physical ability at both physiological and behavioural levels.

Within the context of chronic pain, anxiety is a significant factor that not only predicts performance and perceived disability, but predicts the severity of the pain experience (McWilliams et al., 2003). The fight-or-flight response, when triggered, causes contraction in the muscles and blood vessels, and precipitates pain-inducing chemicals that all work together to increase the severity of pain (Korte, Koolhaas, Wingfield, & McEwen, 2005). Therefore, in some cases anxiety and tension can trigger pain, while in some other cases, pain can trigger anxiety. Individuals who experience persistent pain often report feeling anxious and worried, particularly if their symptoms are unexplained and their prognosis is uncertain. In a large study of patients with chronic widespread pain, approximately 50% of patients reported feelings of anxiety (Wolfe et al., 1990). Therefore, techniques that reduce sensitivity and activity in the autonomic nervous system, such as breathing exercises and relaxation training are essential tools in any psychological pain management strategy (Rhodin, 2013).

Unhelpful beliefs around the distress and fear of pain are cognitive factors that also play an important role in the development and maintenance of chronic pain (Vlaeyen & Linton, 2012). Some persons who experience chronic pain hold beliefs that certain activities will increase their pain or create further injury. Failure to engage in activities or movement prevents the person from obtaining any feedback that challenges this belief, which further reinforces the negative associations of movement with activity, pain and injury (Crombez et al., 1999). Physiologically, the lack of movement can increase tension in the body and heighten the pain sensation (Vlaeyen et al., 1999).
Unhelpful beliefs around pain have also been shown to add to the distress caused by the sensation of pain, as they make a person anxious about the meaning of their symptoms for the future (Verbunt, Seelen, Vlaeyen, van der Heijden, & Knottnerus, 2003). Persons who endorse fear-avoidance beliefs question their physical capacity and believe it is progressively diminishing, and this in turn enhances threat perception further feeding the catastrophic appraisal of a pain sensation.

**Pain Catastrophising (PC)**

A person’s maladaptive cognitive style and exaggerated negative concepts around the experience and prognosis of pain is seen to be an important factor in the development of long term chronic pain conditions (Leeuw et al., 2007). Pain Catastrophising (PC) describes the tendency of some patients to forecast painful events in an irrational negative manner. Persons who catastrophise about their pain imagine that the pain they will experience in the future will be excessive, they ruminate on those thoughts, and at the same time they also imagine they do not have the resources to cope with that pain. So in anticipation of pain, they feel anxious, distressed and vigilant (Roselie & Vlaeyen, 2017).

PC has both physiological and behavioural consequences. As a person catastrophises and moves their attention towards painful stimuli, their sensitivity to pain increases. Laboratory studies involving cold-pressure sensitivity have found that PC reliably predicts perceived pain intensity and pain threshold levels (Geisser et al., 1994; Tracey, 2010). PC also has been linked to disability and increased use of opioids (Gracely et al., 2004; M. K. Jensen, Thomsen, & Højsted, 2006; Quartana et al., 2009). PC has also been shown to predict substance abuse and slower recovery after surgical interventions (Martel, Wasan, Jamison, & Edwards, 2013; Pavlin, Sullivan, Freund, & Roesen, 2005).

The term catastrophising was formally introduced in the behavioural sciences by Albert Ellis and later developed by Aaron Beck (Quartana et al., 2009). Factor analysis has revealed three dimensions of catastrophising: magnification, rumination and helplessness (Sullivan et al., 2001). These factors are also relevant for PC which is conceptualised as an exaggerated negative orientation towards anticipated or actual pain (Quartana et al., 2009). The psychological management of pain usually involves teaching persons how to become aware of PC and challenge those cognitions and
unhelpful beliefs (Turk & Gatchel, 2002). Chronic pain studies commonly use reductions in PC as markers for determining the effectiveness of psychological interventions (Keefe, Rumble, Scipio, Giordano, & Perri, 2004).

**Pain Self-efficacy (PSE)**

The concept of PSE is based on Bandura’s work on self-efficacy (Bandura, O’Leary, Taylor, Gauthier, & Gossard, 1987). It reflects the confidence individuals have in performing activities despite experiencing prolonged pain. It also relates to feelings of control an individual has over their pain symptoms and their ability to self-manage them (Asghari & Nicholas, 2001). In the laboratory, high levels of PSE have been shown to increase pain tolerance in cold-pressor tests (Dolce et al., 1986; Litt, 1988) and improve the effectiveness of opioid medication (Bandura et al., 1987). For persons experiencing chronic pain, studies have shown that when PSE is improved, both physical and psychological adjustments to pain also improve (Buckelew et al., 1995). In a study involving patients recovering from hip and knee replacement surgery, Moon and Backer (2000) found that high levels of PSE were correlated with greater post-operative recovery. Although PSE is a useful construct, it needs to be carefully considered within the context it is used (Bandura, 2006). For example, PSE for an individual in one domain, such as confidence in performing sporting activities, may not necessarily generalise to other contexts, such as, work or family commitments.

In his guide for constructing efficacy scales, Bandura (2006) emphasised the importance of phrasing questionnaire items in terms of perceived capability (i.e., I can do), rather than intention (i.e., I will do). He stated that self-efficacy is a judgment of capability, not intention, and it should be distinguished from judgments of self-worth (e.g., self-esteem) and outcome expectancy. Perceived efficacy influences goals and aspirations and influences whether people think strategically and optimistically, or whether they think pessimistically (Bandura, 2006). It influences how much effort they put into their endeavours, and how long they persist in the face of obstacles. High scores on a self-efficacy scale can predict how well an individual copes with taxing demands and how resilient they are to adversity. For this reason, it is a suitable measure for chronic pain studies seeking to increase self-efficacy in persons who face obstacles such as long standing pain.
Social and Cultural Factors

Social and cultural factors have also been shown to play a significant role in the experience of pain (Gatchel et al., 2007; Turk & Okifuji, 2002). In a study using thermal sensory analysers, Montoya, Larbig, Braun, Preissl, and Birbaumer (2004) found that for women with widespread unexplained pain, social support through the presence of a significant other moderated pain processing on both a behavioural level, and on biological level through reductions in thermal pain sensitivity. Differences in pain thresholds have also been found across different ethnic and cultural groups. Al-Harthy, Ohrbach, Michelotti and List (2016) found that Italians reported significantly lower pain threshold to mechanical and electrical stimuli than persons from Sweden. In a study examining chronic pain perception across different cultural groups, Bates, Edwards, and Anderson (1993) found that there were cultural differences in attitudes, beliefs and locus of control between ethnic groups, and these differences also influenced subjective notions of pain intensity.

Lifestyle and Social Factors

Lifestyle factors such as smoking, poor diet and lack of physical activity, as well as social factors such as low socio-economic status, low education and relationship stresses are risk factors for developing chronic pain conditions (Latthe, Mignini, et al., 2006; Lim et al., 2013). In a Danish population based health survey of males and females with chronic pain (excluding cancer patients) Eriksen, Jensen, Sjøgren, Ekholm, and Rasmussen (2003) interviewed 10,066 persons who also completed the SF-36 health survey (Ware et al., 2000). The authors found that divorced or separated persons had 1.5 times higher odds of chronic pain than those who were married, and the odds for chronic pain were 1.9 times higher for persons with less than 10 years of education compared to those with 13 years or higher. Consistent with sociodemographic characteristics in other developed countries, this study added to the weight of evidence that shows that persons of lower socioeconomic backgrounds and lower education levels present a heightened risk for developing chronic pain conditions.

Several studies have also shown a relationship between increased body mass index, smoking, and chronic pain (Palmer, Syddall, Cooper, & Coggon, 2003; Sá, Baptista, Matos, & Lessa, 2008). Having a pre-existing mental health condition such as depression, anxiety and psychosis also increases a person’s likelihood of experiencing
chronic pain (Jakobsson, 2010). In a systematic review of risk factors specific to women with CPP, Latthe, Mignini, et al. (2006) cited increased body mass index, smoking, drug and alcohol abuse and psychological comorbidity as being associated with an increased risk of non-cyclical pelvic pain relative to the general population. It is difficult to determine if these are specific risk factors for developing CPP, or just general associations that are typically found in studies assessing the risk factors of any chronic disease.

2.5 Cognitive Behavioural Approaches to Chronic Pain Management

Throughout the 1970’s Albert Ellis’s work on irrational thoughts, and Aaron Beck’s work on cognitive factors gained momentum as evidence for their efficacy in helping many psychological disorders grew (Beck, 1991). Drawing on this work, Turk and colleagues created a cognitive-behavioural model of pain which spawned much psychological research, and diverted treatment approaches for chronic pain away from biomedical approaches (Turk & Gatchel, 2002; Turk, Meichenbaum, & Genest, 1983). In the early 1980’s CBT began receiving empirical support and has remained the most frequently used psychological management approach for pain management (Ehde et al., 2014).

Since the evolution of CBT interventions for chronic pain, development of psychological approaches have continued into what some clinicians and researchers call “third wave therapies” (Arch & Craske, 2008). In these therapies, mindfulness and acceptance-based treatments are included in a more formal manner, incorporating their own evidence base (Dahl & Lundgren, 2006; Hayes, Luoma, Bond, Masuda, & Lillis, 2006; Vowles, Witkiewitz, Sowden, & Ashworth, 2014).

Cognitive Behavioural Therapy (CBT)

CBT for chronic pain focuses on pain related behaviours and cognitions, and incorporates a range of skills including pain education, mindfulness relaxation training, coping skills training, imagery techniques, goal setting, pacing, cognitive restructuring and motivation and relapse prevention (Bradley, 1996; Turk & Gatchel, 2002). CBT assumes that cognitions influence emotional and physiological arousal, and these in turn not only influence the experience of pain, but influence a person’s behaviour. CBT helps people become aware of how their thoughts, emotions and behaviours contribute
to their pain experience. It teaches them how they can replace automatic maladaptive thoughts with more helpful ones. The behavioural interventions in CBT are also designed to help undermine the pattern of fear and avoidance through gradual pacing (McCracken & Turk, 2002). A recent Cochrane review compared CBT for chronic pain with treatment-as-usual and concluded that CBT had statistically significant but small effects on pain and disability, and moderate effects on mood and catastrophising over treatment as usual (Williams, Eccleston, & Morley, 2012).

An abundance of research studies have shown CBT to be equally effective as pharmacological treatments for the management of some chronic pain conditions (Ehde et al., 2014; Gatchel et al., 2007). The complex comorbidities of mental health conditions that are present in persons who experience chronic pain further supports the use of CBT in chronic pain contexts (McWilliams et al., 2003). By targeting PSE and PC, CBT interventions teach individuals to see their pain as something that they can manage, rather than something that is overwhelming (Turk, 2002).

**Mindfulness**

In recent years, techniques such as mindfulness have often been included in pain management programs and have shown to be effective for a range of chronic pain and somatisation disorders (Fox, Flynn, & Allen, 2011; Hilton et al., 2016; Lakhlan & Schofield, 2013). Mindfulness therapies are based on ancient spiritual practices with a focus on completely experiencing a human phenomenon (e.g., thought, feeling, sound, emotion) in the present moment, without judgment or reference to the past or future (Kabat-Zinn, Lipworth, & Burney, 1985). Whereas cognitive restructuring might emphasise challenging unhelpful cognitions, mindfulness training involves monitoring the stream of unhelpful thoughts, and accepting that those cognitions are an ordinary part of the human experience. In this regard, mindfulness can be thought of as a metacognitive process (Bishop et al., 2004).

Cherkin et al. (2016) conducted one of the few randomised interviewer blind clinical trials that compared three pain treatment modalities within the same study (N = 342): mindfulness (without CBT), CBT, and usual care. The study found greater improvements for back pain in both the mindfulness and CBT groups above usual care. For both the mindfulness without CBT and the CBT groups, improvements in functional limitations were maintained after a 26-week follow up. This supports the suggestion that
the combination of pain education and mindfulness in CBT interventions is an effective intervention for chronic pain conditions (McCracken, Gauntlett-Gilbert, & Vowles, 2007). Most proponents of CBT for chronic pain believe that mindfulness is a necessary and integrative component of CBT interventions for chronic pain (Turk & Gatchel, 2002). The integration of mindfulness with CBT interventions for chronic pain will be discussed in more detail in Chapter 3.

**Acceptance and Commitment Therapy**

Acceptance and Commitment Therapy (ACT) is a formalised cognitive-therapy that incorporates mindfulness-based approaches (Hayes et al., 2006). Often referred to as “ACT”, and labelled a third wave CBT, this therapy is based on a language theory called Relational Frame Theory. Some proponents of ACT believe that it fundamentally differs from CBT as there is little emphasis on cognitive challenging, and a stronger focus on thought acceptance, and the activation of value-congruent observable behaviour (Hayes, Strosahl, & Wilson, 1999). Where CBT might rationalise unhelpful thinking patterns, ACT instead seeks to encourage psychological flexibility, thereby not changing the content of thoughts, but changing a person’s relationship to their thoughts (Dahl & Lundgren, 2006).

In the framework of ACT chronic pain is viewed as an experiential avoidance disorder (Hayes et al., 2006). The literature shows experiential avoidance is associated with higher pain intensity, pain related anxiety, depression and disability (Feldner et al., 2006; McCracken & Vowles, 2006). ACT based therapies for chronic pain have been shown to be effective in treating some chronic pain conditions (Veehof, Oskam, Schreurs, & Bohlmeijer, 2011) and the American Psychological Association (APA) has named ACT as an empirically supported treatment for chronic pain (McCracken & Vowles, 2006). In an RCT comparing ACT and CBT for chronic non-malignant pain in 114 participants, Wetherell et al. (2011) demonstrated improvements on pain interference, depression and pain related anxiety, in both treatment groups relative to controls.

**2.6 Multi-disciplinary Approaches**

Multi-disciplinary treatment approaches are based on the biopsychosocial model of chronic pain which emphasises that chronic pain consists of a complex interaction
between physiological, psychological and social factors that all work together to worsen or mitigate a pain experience, and the individual’s functioning (Gatchel, Lou, & Kishino, 2005). Although the approaches of each member of a multi-disciplinary team will vary depending on the needs of the patient, multi-disciplinary approaches generally comprise three main components: (1) medication management, (2) graded physical exercise, and (3) cognitive and behavioural techniques (Thomsen, Sørensen, Sjøgren, & Eriksen, 2001).

The efficacy, cost effectiveness, and sustained benefit of multi-disciplinary interventions for chronic pain are well supported in the literature (Bonica et al., 2010). In a systematic review of the cost-effectiveness of multi-disciplinary interventions for chronic pain, Turk (2002) measured cost effectiveness by calculating cost of treatment as a percentage of those who achieved a clinical outcome. He found that multi-disciplinary care was 15 times more cost effective than conservative care and 6.29 times more cost effective than surgery. Multi-disciplinary approaches to pain management are now considered to be the gold standard treatment for chronic pain (Flor et al., 1992; Furlan et al., 2005; Scascighini, Toma, Dober Spielmann, & Sprott, 2008).

2.7 Conclusion

This chapter provided an overview of the literature on chronic pain. It started with a definition of chronic pain and highlighted the complexities involved in obtaining a definitive prevalence rate due to the variations in the classification of chronic pain across studies (e.g., three months’ versus six months’ duration) and the subjective self-report nature of measuring chronic pain in individuals. Chronic pain reviews are unlike reviews for medical diseases which receive a definitive diagnosis through the presence of a disease or pathogen. Therefore, pooling data and making comparisons across different chronic pain studies is likely to remain a challenge for researchers.

The chapter then reviewed the literature around the theories and perspectives on chronic pain. Although many of these theories are still widely debated, they have informed a range of therapies and treatment approaches and have generated important research interest in the area. For example, the research interest in brain plasticity has given rise to a large volume of brain imaging studies specifically investigating brain plasticity within chronic pain conditions. These studies have also informed some effective CBT-based interventions and have helped maintain an emphasis towards a
biopsychosocial approach to chronic pain which adequately considers the complexities of the disorder.

Risk and moderating factors for chronic pain and some of the behavioural approaches to treatment were then reviewed. Despite the large volume of studies, specific predictive risk factors for chronic pain have not been identified. Furthermore, the risk factors for chronic pain do not seem to differ from those found in general chronic diseases such as heart disease and diabetes. Nevertheless, the associations and relationships found between psychological and social contributions further emphasise a biopsychosocial approach is necessary when considering chronic pain conditions. Biopsychosocial perspectives have given rise to a significant number of studies assessing the effectiveness of cognitive-behavioural interventions, such as CBT, mindfulness and ACT. Studies utilising CBT for chronic pain are growing and show promising results, although the literature reveals that the gold standard for chronic pain treatments is CBT within a multi-disciplinary setting.

This chapter highlighted the importance of a biopsychosocial approach to the management of chronic pain. The psychological and behavioural factors that mediate the experience of pain, and the complexities involved in the aetiology and maintenance of chronic pain lend themselves well to interventions such as CBT and mindfulness. The next chapter will address one particular type of chronic pain, namely chronic pelvic pain in women, which is one of the most common reasons for referral to women’s health services.
Chapter 3.
Chronic Pelvic Pain in Women

Chronic pelvic pain (CPP) is considered by many clinicians and researchers to be one of the most complex and difficult chronic pain conditions to treat (Engeler et al., 2013; Zondervan & Barlow, 2000). Although it affects both men and women, this review will focus on CPP in women. The chapter starts with a definition of CPP and examines some of the most common physiological causes of pelvic pain in women. It then reviews the literature on the predisposing factors and moderators of CPP and considers factors that may contribute to the inconsistencies between medical pathology, pain distress and chronicity of pain. The latter part of the chapter then provides a critical review of the treatment approaches use to help minimise symptoms and distress and gives a detailed account of how CBT can be used to manage CPP in women.

3.1 Definition and Prevalence

Chronic Pelvic Pain

CPP is defined as intermittent or constant pain in the pelvic region that lasts at least six months (Rhodin, 2013). The Royal College of Obstetricians and Gynaecologists provided a more precise definition as “intermittent or constant pain in the lower abdomen or pelvis of at least 6 months’ duration, not occurring exclusively with menstruation or intercourse and not associated with pregnancy” (Kennedy & Moore, 2005, p. 10). The IASP have a more specific diagnostic category, namely Chronic Pelvic Pain Without Obvious Pathology which they define as “chronic or recurring pelvic pain that apparently has a gynaecological origin but for which no definitive lesion or cause is found” (Merskey & Bogduk, 1994, p. 170). Like most forms of chronic pain, CPP has a profound impact on many aspects of a person’s life and functioning, including sensory, emotional, cognitive and interpersonal factors (Steege, Stout, & Somkuti, 1993). CPP in particular affects a woman’s identity, ability to be intimate and can affect the capacity to reproduce and care for children (Zadinsky & Boyle, 1996).

Prevalence

CPP in women is the most common reason for referral to women’s health services (Engeler et al., 2013). It is considered by many clinicians and researchers to be the most
difficult chronic pain condition to treat because of its clinical complexity, symptomatic inconsistency, and pervasiveness across many aspects of a person’s life (Grace, 2000; Zondervan & Barlow, 2000). A systematic review commissioned by the World Health Organisation reported the prevalence of CPP in women to be between 14% and 24% (Latthe, Latthe, et al., 2006). Lack of consensus amongst researchers and clinicians on the definition of CPP and the lack of population-based studies are cited as the main reasons for the wide variations in this reported figure (Ahangari, 2014). In an Australian study of pelvic pain in women using self-report measures, Pitts et al. (2008) found that 21.5% of women experienced CPP and those women were also likely to report other health conditions such as anxiety and depression.

3.2 Conditions Associated with Pelvic Pain in Women

The distinct underlying cause of pelvic pain in women can be difficult to detect (Moore & Kennedy, 2000). One of the most common surgical techniques used in the diagnosis of pelvic conditions in women is laparoscopy, which allows gynaecologists to visualise organs in the pelvic region. Although frequently used in clinical practice, studies show that laparoscopy fails to identify causal pathology in up to 35% (range 3% – 92%) of cases of pelvic complaints (Howard, 2003). Therefore, when trying to assess the causes of pelvic pain in women, taking a detailed history is encouraged, while at the same time refraining from making assumptions about what the physiological cause might be (McGowan et al., 2007). In a qualitative study involving in-depth interviews with women experiencing medically unexplained disorders, Werner and Malterud (2003) illustrated the struggle women with CPP face in maintaining credibility with treating practitioners. In a later qualitative study, Werner et al. (2004) examined the feelings of shame and disempowerment women often feel as they search for a satisfactory diagnosis. Some of the common medical causes of pelvic pain in women will now be examined.

Endometriosis

Endometriosis is defined as “the presence of endometrial-like tissue outside the uterus, which includes a chronic, inflammatory reaction” (Kennedy et al., 2005, p. 12). It is one of the most common causes of CPP and is diagnosed in approximately one-third of cases (Zondervan & Barlow, 2000). Endometriosis is also a common incidental finding in asymptomatic women, and therefore the severity of organic clinical
presentations often correlate poorly with symptom severity (Chapron et al., 2003). For symptomatic women, anti-inflammatory and hormone medications can be successful in slowing down the growth rate of the endometriotic tissue, but they are often accompanied by distressing side effects, such as nausea, low mood and weight gain, and symptoms often return after treatment ceases (Olive & Pritts, 2001).

Although surgical interventions can be successful in some cases of endometriosis, they are generally thought to be a last resort, particularly given the precise cause of CPP can be unclear (Olive & Pritts, 2001). For women with advanced stage endometriosis, some of these surgeries pose significant risks to other organs and can cause further chronic pain issues due to scarring (Kennedy et al., 2005). Procedures such as hysterectomy can be successful in some cases, but if endometriosis is not the primary cause of pain, the pain often returns, and in some cases, is exacerbated (Brandsborg et al., 2008). More than one third of women who have successful surgery for endometriosis require further surgery within five years (Abbott, Hawe, Clayton, & Garry, 2003).

**Adenomyosis**

Adenomyosis is another major cause of CPP in women and is implicated in the aetiology of around 40% of cases, although this prevalence rate varies widely across different studies (Moore & Kennedy, 2000). It occurs when the inner lining of the uterus (endometrium) breaks through the muscle wall of the uterus (the myometrium). In cases where the endometrium cells are widely distributed, surgical interventions are generally not possible. Adenomyosis is considered by some to cause menorrhagia (heavy prolonged periods), metrorrhagia (abnormal bleeding in the uterus), dysmenorrhea (recurrent menstrual cramps) as well as infertility (Kunz et al., 2005). Unfortunately, as with endometriosis, drug therapies that are successful in treating this condition are sometimes accompanied by intolerable side-effects, such as nausea, low mood and in some cases weight gain (Breivik et al., 2006).

**Adhesions, Congestion and Inflammation**

Adhesions are fibrous bands of scar tissue that form between organs and tissues, joining them together in an abnormal way. They have been implicated to be a cause of CPP in some cases, but like many other gynaecological anomalies, they are also present
in women who are asymptomatic (Moore & Kennedy, 2000). In one of the few studies of surgical procedures that remove adhesions in the pelvic region, no reduction in pain was found for women experiencing CPP (Swank et al., 2003), yet these surgeries are still performed. Furthermore, other conditions such as congestion and inflammation in the pelvic region can also create pain sensitisation and aggravate the pain. Although some surgical procedures for adhesions, congestion and inflammation can improve fertility, they do not appear to have a consistent positive effect on alleviating pain. Furthermore, these conditions are also found in asymptomatic women. In one study of women with unexplained CPP, dilated pelvic veins were found in 30% of women, but they were also found in 10% in the general population (Bora, Avcu, Arslan, Adali, & Bulut, 2012).

**Gastrointestinal, Musculoskeletal and Neurological Factors**

Long standing problems in the gastrointestinal tract, such as chronic constipation and irritable bowel syndrome, can also cause pain sensitisation in the pelvic region for women (Howard, 2003). When these problems are associated with pain-related fear, the pain can become chronic (Slade & Cordle, 2005). This is also the case with urological factors such as interstitial cystitis (painful bladder syndrome) and urethral syndrome (frequent painful urination and abdominal pain). In a similar way, musculoskeletal factors such as fibromyalgia (widespread pain and tenderness in the muscles and bones), hernia, joint pain and pelvic floor abnormalities can also be primary or secondary causes of CPP (Moore & Kennedy, 2000). These conditions all need to be investigated thoroughly before assuming the pain has no organic cause. This is also the case for neurological factors where nerve damage may occur due to entrapment, trauma or related surgery (Bonica et al., 2010).

**Dyspareunia and Vaginismus**

Pain just before, during or after sexual intercourse is termed dyspareunia. After an episode of painful intercourse, fear of further pain can start a cycle of muscle tension associated with sex, which in turn creates more fear and then more tension further reinforcing the cycle (Brauer, ter Kuile, Janssen, & Laan, 2007). Painful intercourse can also produce involuntary spasms, contractions and reflexes of the muscles surrounding the vagina, a condition known as vaginismus. The psychological impact of dyspareunia and vaginismus on a woman and her partner can be highly distressing and debilitating in
some cases (Reissing, Binik, Khalifé, Cohen, & Amsel, 2004). Psychological treatment that helps the woman feel in control, and graded exposure undermines the negative conditioned response cycle can be helpful, even in cases where the condition may be physiological in origin (Rhodin, 2013; ter Kuile et al., 2013).

In 2013 the terms dyspareunia and vaginismus were replaced with genito-pelvic pain/penetration disorder in the publication of DSM-5 (APA, 2013). Proponents for the change argue that this new classification provides a much-needed multidimensional diagnosis of sexual pain disorders and is more in line with current research in the area (Binik, 2005a). However, not all researchers agree and the classification is still widely debated (Reissing et al., 2014).

**Pelvic Pain with no Satisfactory Explanation**

The aetiology of CPP conditions is generally complex and multi-faceted, and diagnosis often involves multiple medical investigations. Women who do not receive a medical explanation for their symptoms often end up in a frustrating cycle of reinvestmentigation and referral (Ghaly & Chien, 2000; Howard, 1996). It is common for women who are in the process of seeking a diagnosis to have experienced a series of unsuccessful, inappropriate and sometimes damaging investigations or treatments (Toye, Seers, & Barker, 2014; Werner et al., 2004). Unfortunately, studies that seek to develop new diagnostic tools for CPP generally do not investigate how these tools should be used within this complex population. For some women, these new advancements may hinder their recovery by providing false hopes and potential false positive diagnoses (Howard, 1996). These problems may be exacerbated if medical advancements fail to adopt a biopsychosocial approach in their methods of inquiry (Gatchel et al., 2007).

For women with CPP, even in cases where lesions, scarring, or inflammation are found, treatment is difficult as these pathologies are also commonly present in individuals who are asymptomatic (Chapron et al., 2003). Several authors have cautioned against a dichotomous diagnostic mindset i.e., one that assumes an organic genesis when there is tissue damage present, or assumes the cause is psychological when there is no tissue damage present (Grace, 1998, 2000; Reiter, 1998). Some authors have suggested that an over-simplistic attempt to find a definitive cause for CPP, which
is prompted by both individuals and clinicians, is one of the major causes of poor doctor-patient relationships in the case of women with CPP (Twiddy et al., 2017).

Souza et al. (2011) argue that studies involving CPP in women need to be informed by qualitative research so that the advancements do not exacerbate the problems inherent in CPP. Furthermore, they argue that qualitative research is necessary to help uncover mechanisms for recovery, where present, as these need to be clearly understood if the findings are to be replicated appropriately in clinical practice.

### 3.3 Common Interventions

**Pharmacological Interventions**

Pharmacological treatments tend to be most common initial choice for most chronic pain conditions, including CPP, and usually involve either non-steroid inflammatory drugs, hormonal treatments, anti-depressants or analgesics (Fall et al., 2010). In a recent Cochrane review, the steroid hormone progestogen, which is commonly used to assist pregnancy, was found to provide a 50% reduction in pain scores after treatment (Allen, Hopewell, Prentice, & Gregory, 2009). It is considered a reasonable option for women not concerned with its side effects (e.g., weight gain and bloating). Drugs that target anxiety and depression are also commonly used as a means of reducing the distress associated with CPP. The evidence base for their efficacy in reducing pain is still lacking (Engel, Walker, Engel, Bullis, & Armstrong, 1998; Leo & Dewani, 2013).

Other medical treatments that are effective in reducing symptoms include ketamine and opioid agents, although most doctors are cautious to use these drugs because they are considered to be a short-term solution and are highly addictive (Højsted & Sjøgren, 2007). Unfortunately, the literature around the use of pharmacological interventions for chronic pain is not consistent. Some studies report that pain relief drugs are over-prescribed (Dunn et al., 2010; Johnson, 1998) while others caution against the ideals of “drug free’ pain programs (Dowell, Haegerich, & Chou, 2016; Woodcock, 2009). For some researchers and practitioners, pharmacological interventions for chronic pain is an emotive and in some cases political issue which may in some cases impede objectivity; the use of cannabis in chronic pain being one such controversial and emotive example (Martín-Sánchez et al., 2009). Adding to the difficulty, some medications such as
antidepressants or hormone treatments create unpleasant side effects before they provide any benefit, making treatment adherence and administration difficult (Howard, 2003).

**Interventions Involving Nerves and Spinal Cord**

Peripheral Nerve Stimulation and Spinal Cord Stimulation involve implanting electrodes directly on a nerve or parts of the spine and sending signals to those areas with the intention of interrupting the pain signals sent to the brain. Although the exact mechanism of the pain relief is not clear, these interventions can provide some relief for patients with intractable chronic pelvic pain (Siegel, Paszkiewicz, Kirkpatrick, Hinkel, & Oleson, 2001). Nerve blocks involving the injection of local anaesthetic into a peripheral nerve is another similar technique used to directly treat nerves associated with pain. Although nerve blocks are designed to be used for diagnostic purposes, they do provide some welcome short-term relief for some persons (Wechsler, Maurer, Halpern, & Frank, 1995).

**Physical Therapy**

Physiotherapeutic approaches that involve stretching and physical exercises have been shown to be effective for some subgroups of individuals experiencing CPP (FitzGerald et al., 2009). In these interventions, individuals are educated on which movements and strength exercises are helpful, and which will cause damage. These approaches are important as they help women with CPP manage their expectation about what they can and cannot do, they help them work within their limitations, while at the same time progressively increasing the range of movement and activities (Rhodin, 2013). The role of the physiotherapist in these settings is, therefore, to assess physical and functional capacity. For CPP that is perpetuated by tension in the pelvic region, the physiotherapist can also apply manual pressure to the affected area and this has also shown to provide some relief for CPP that seem to be exacerbated by excess tension (Weiss, 2001)

### 3.4 Risk and Moderating Factors

While several physical factors might initially cause CPP for some women, the previous section showed that the extent of physical pathology does not always correlate with the amount of pain, distress and disability experienced. In some cases, even moderate clinical pathology can lead to disabling long standing pain. In other cases,
women may be diagnosed with conditions ordinarily associated with CPP and remain asymptomatic (Dalpiaz et al., 2008; Weijenborg et al., 2007). Furthermore, there also appears to be variations in the way different women with similar CPP conditions respond to clinical interventions.

The previous chapter discussed how cognitive factors such as anxiety, pain-fear and PC as well as cultural, social and lifestyle factors, such as body mass index and low socio-economic background all appear to moderate and maintain the experience of a range of chronic pain conditions (Lim et al., 2013). Studies have shown that some of these factors are also relevant for women experiencing CPP (Latthe, Mignini, et al., 2006; Leeuw et al., 2007). This section builds on the review in the previous chapter and discusses how far studies have come in understanding the risk and moderating factors of CPP in women. It reviews studies which have sought to explain why responses to pain vary so much between women with seemingly similar gynaecological diagnoses.

**Abuse, Trauma and PTSD**

Studies examining the relationship between chronic pain and childhood abuse show an association between the two, although causal factors and mechanisms remain unclear. A meta-analytic review of the association of chronic pain symptoms with retrospective reports of neglect, sexual or physical abuse experienced during childhood was conducted by Davis (2005). It included 16 studies (sample size 357 females) and showed that individuals who reported abusive or neglected childhood experiences were significantly more likely to report pain symptoms than those who were not abused or neglected. Similarly, patients with chronic pain were more likely to report abuse and neglect in childhood than healthy controls. In a later study that included over 700 women who attended a pelvic pain clinic, almost 50% reported having been sexually or physically abused, and 31.3% screened positively for PTSD (Meltzer-Brody et al., 2007). Despite these associations, these studies did little to explain the mechanisms linking childhood abuse and pain syndromes in adulthood.

In order to obtain a better understanding of the relationship between childhood abuse and adult chronic pain, Walsh, Jamieson, MacMillan, and Boyle (2007) conducted a large community based study of 4,285 women aged between 15 to 65 from a wide variety of socioeconomic backgrounds, including homeless persons and people in institutions. This study sought to overcome the limitations of previous studies which
only involved clinical samples, and generally only targeted people who had already developed chronic pain. The results from Walsh, Jamieson, MacMillan, and Boyle (2007) suggested that physical abuse was significantly correlated with chronic pain, but sexual abuse was not. The study also failed to explain why some female children exposed to physical abuse went on to experience chronic pain conditions, while others did not. These results were inconsistent with an earlier longitudinal study by Raphael, Widom, and Lange (2001), which compared 676 abused children and 520 matched controls who were all followed into adulthood. The study found that children who suffered abuse were no more likely to have unexplained medical symptoms than those in general population.

Despite the inconclusive link between abuse and chronic pain in the literature, there are some CPP studies that show alterations in stress system functioning similar to those found in PTSD (Gupta, 2013; Heim et al., 1998). Furthermore, causal links and mechanisms between childhood abuse and PTSD are clearer in the literature (Wolfe, Gentile, & Wolfe, 1989). Therefore, future CPP research that builds on the theories around PTSD may provide some useful insights into the mechanisms. For example, it is already established that the experience of abuse is associated with poor health behaviours, deficiencies in the ability to regulate emotions, and heightened stress reactivity, all of which are factors that increase the risk of developing chronic pain disorders (Davis, 2005; Gupta et al., 2014). Nevertheless, at the present time, only associations have been established between childhood abuse and the development of CPP, and predictive links and causal mechanisms between CPP and childhood abuse remain unclear.

**Psychological Morbidity**

In a recent study examining the association between mental health conditions and patients with CPP, Brünahl et al. (2017) found that 95% of their sample of 178 CPP patients (60% female) met DSM-5 criteria for at least one psychological disorder. The most prevalent psychological disorders were somatoform disorders (91.7%), followed by mood disorders (50.6%) and anxiety disorders (32%). Although comorbid mental health conditions have long been associated in women who experience CPP (Grace, 2000; Savidge & Slade, 1997; Twiddy, Bradshaw, Chawla, Johnson, & Lane, 2017) a causal link is still not clearly established. Emotional disturbance appears to be a
consequence rather than a cause of chronic pain (Gamsa, 1991). Nevertheless, the psychological disorders that accompany mental health issues do alter the experience of pain, and do make a person more prone to helplessness and disability – all of which contribute to the distress and disability and make recovery more difficult (Frischenschlager & Pucher, 2002; Jensen & Turk, 2014). Collectively, these studies suggest that although causal links have not been established. Addressing psychological issues, where present, is still important in helping a person reduce distress experienced from pain (Bryant, Kleinstäuber, & Judd, 2014; Slade & Cordle, 2005).

**Personality Disorders and Types**

For women with long-standing pain, it is difficult to determine if certain personality types predispose them towards developing CPP, or if their experience of CPP, and the often-challenging medical journey that often accompanies the condition affects the way in which they manage their moods, thoughts and behaviours. Although causal links are difficult to establish conclusively, CPP is associated with abuse and trauma (Meltzer-Brody et al., 2007); which in turn is associated with increased risk of developing a personality disorder (Herman, Perry, & Van der Kolk, 1989). Therefore, in a sample of women with CPP, personality disorders are likely to be present. Supporting this idea, Fishbain, Goldberg, Meagher, Steele, and Rosomoff (1986) found that 58.4% of 283 male and female patients with CPP met the diagnostic criteria for a DSM-III axis II personality disorder. Although this study provides strong evidence for the presence of personality disorders in women with CPP, the results need to be interpreted with caution as the DSM-III personality disorders have come under scrutiny for their lack of clear boundaries demarcating diagnosis from the general population (Frances, 1980).

Some studies have also examined the relationships between CPP and personality traits. In one of the few studies examining links between the Big-5 personality traits (McCrae & Costa, 2004) and CPP in males, participants high in trait Neuroticism had significantly poorer treatment responses than those low on Neuroticism (Koh et al., 2014). Bonica et al. (2010) suggest that some women with CPP who are driven to work beyond their physical limits (e.g., perfectionists) may also be more prone to delayed recovery if their personal determination causes them to overexert or cause further injury to themselves. Other studies looking at less formalised traits in relations to chronic pain in general have found that enduring response patterns such as learned helplessness and
passive coping styles, are associated with higher perceived pain levels and disability in persons with chronic pain (Samwel, Evers, Crul, & Kraaimaat, 2006; Steege et al., 1993). The search for personality traits that might predispose individuals to develop chronic pain conditions has proven to be largely inconclusive, however, collectively the research suggests that some personality factors, specifically high perfectionism and neuroticism may have an impact on the experience and maintenance of CPP.

### 3.5 Utilising CBT as a treatment for Chronic Pelvic Pain in Women

The review of the literature thus far has highlighted the significant role that psychological factors play in the experience and maintenance of chronic pain conditions. CBT interventions that target psychological factors such as pain-fear, PC and PSE have been widely used in the management of many chronic pain conditions, including CPP (Ferreira et al., 2013; LoFrisco, 2011; Martin et al., 2000; Morley, 2011; Ehde et al., 2014; Gatchel et al., 2007). This section will review the literature that has evaluated the effectiveness of CBT as an intervention for women with CPP.

#### Defining CBT for Chronic Pain

The evidence base for CBT can be difficult to navigate due to the varying conceptualisations of what CBT for chronic pain encompasses. Most typically, CBT for chronic pain focuses on pain-related behaviours and cognitions, and incorporates a range of skills including pain education, mindfulness, relaxation training, coping skills training, imagery techniques, goal setting, pacing, cognitive restructuring, motivation and relapse prevention (Turk & Gatchel, 2002). Figure 3.1 illustrates a typical CBT intervention for chronic pain and highlights the range of topics covered. When reviewing the evidence base for CBT, it is important to be cognisant of the wide variations in what some studies define as CBT treatments for chronic pain. For example, some studies may compare mindfulness-based CBT, ACT and CBT in one study and consider them as separate therapies, while other studies may consider each of those therapies to be its own form of CBT (Arch & Craske, 2008; Hofmann & Asmundson, 2008). These variations in the conceptualisation of CBT make studies difficult to compare, and can make the data difficult to pool together in a meta-analysis. In light of the vast variations in what is considered to be CBT for chronic pain, this review will take the evidence on face value. For example, studies looking at ACT or mindfulness
based CBT will not be included in this review, and where they are included, they will be specifically noted.

**The Evidence Base**

The International Association for the Study of Pain (IASP) and the guidelines from the British Pain Society consider CBT to be the most appropriate first line of treatment for chronic pain conditions, including CPP (Morley, Williams, & Hussain, 2008; Niv & Devor, 2007). However, CBT studies that trial interventions specifically targeting CPP in women are lacking. Stones, Cheong and Howard (2005) in a Cochrane review examined a range of behavioural and medical treatments for treating CPP in women. The authors noted that although psychological therapies are shown to be effective for CPP in women, in practice, treatment recommendations generally come from single studies, and the authors make an urgent call for more research. Nevertheless, CBT interventions have been shown to be effective in reducing pain, managing distress, improving sexual function and reducing disability for a range of gynaecological conditions that are associated with CPP (Bergeron et al., 2001; Brown, Wan, Bachmann, & Rosen, 2009; Masheb, Kerns, Lozano, Minkin, & Richman, 2009). These will be considered in this section.

LoFrisco (2011) conducted a critical analysis of research studies examining CBT interventions for sexual pain disorders. The study evaluated each CBT intervention in detail and reported that for the most part, the studies found CBT to be effective (Appendix I). The review concluded that about three quarters of women had improved sexual functioning and reduced pain after receiving CBT treatments, with about one fifth able to resume intercourse. The gains achieved through CBT were maintained in the long term in some studies, but not all. For example, self-administered bibliotherapy was helpful in the short run, but the benefits did not last. LoFrisco (2011) reported that although other treatment types such as surgery and medication were more effective overall, CBT was preferable because of its non-invasive nature. The author concluded that more research was required because many of the studies had small sample sizes, and the modalities of CBT (e.g., group, with or without physical therapy) were not consistent across the studies reviewed.

Other single studies have shown that CBT can be effective in conditions associated with CPP in women. In an RCT comparing a 10-week CBT intervention with supportive
psychotherapy on 50 women with vulvodynia, participants in the CBT group showed statistically significant decreases in pain severity and greater improvement in sexual functioning relative to supportive psychotherapy (Masheb et al., 2009). This study also included one-year follow-up examinations by gynaecologists and showed that 42% of the overall sample maintained their clinically meaningful improvements in pain severity, sexual function and emotional function. Importantly, participants who received CBT reported satisfaction with the intervention and felt that CBT was a credible treatment for their condition. Although the study provided CBT in a clinical environment, the participants in this study were students of a school of medicine and a control group was not used.


Group-based CBT interventions have also been shown to be effective for treating gynaecological complaints in women (Bergeron et al., 2016; Bergeron et al., 2008;
Bergeron et al., 2001; ter Kuile et al., 2007). In a CBT trial of women experiencing dyspareunia, group-based CBT was associated with statistically significant reductions in pain at post-treatment and 6-month follow-up compared to biofeedback and surgery (Bergeron et al., 2001). In this study, no participants dropped out of the CBT group, while two of the 22 women in the surgery group reported experiencing a worsening of their symptoms after surgery. In a more recent randomised CBT trial of women experiencing dyspareunia, group-based CBT was compared with treatment involving a topical steroid (Bergeron et al., 2016). The findings showed statistically significant reductions in pain at post-treatment and 6-month follow-up compared to the topical steroid. Although these results are encouraging, neither of these studies used a control group, so it is difficult to determine if the participants would have improved on their own.

In a later study, van Lankveld et al. (2006) compared group CBT with cognitive-behavioural bibliotherapy against waiting list controls. Intention to treat analysis at 12-month follow-up showed that 21% of the group therapy participants, and 15% of the bibliotherapy participants reported successful intercourse compared with 0% in the control group. ter Kuile et al. (2007) conducted a follow-up to this study with 117 women experiencing with life-long vaginismus. One-third achieved full vaginal-penile penetration, reduced fear of coitus and higher sexual behaviour scores. As with the van Lankvel et al. (2006) study, this study utilised a wait list control group.

Couple-based CBT therapies have also proven to be effective for some conditions associated with CPP. Kabacki and Batur (2003) conducted a couple-based CBT intervention for women with vaginismus in a hospital setting with 16 couples. The CBT intervention included sexual education and graded desensitisation. All women had improved sexual functioning even after 4-week follow up, however, there was no control group for this study, nor follow up beyond 4-weeks.

As with most chronic pain conditions, multi-disciplinary programs that incorporate CBT and combine it with a range of physical and medical interventions provide the most effective long-term treatment approach for CPP (Kames et al., 1990; Okifuji, 2003; Peters et al., 1991). In an RCT comparing CBT with medication for 43 women with vulvodynia, Brown et al. (2009) found significant reductions in pain for the CBT group compared to medication alone. Although the study did not have a control group,
was not sufficiently powered to provide statistically significant results, and did not include a follow-up, the study showed that CBT with some physical therapy was effective in producing clinically significant outcomes.

Studies are also beginning to show that cortical pathways can change in response to programs that utilise CBT with physical therapy for some people with chronic pain conditions (De Lange et al., 2008; Seminowicz et al., 2013). In their review on cortical reorganisation in chronic pain patients, Moseley and Flor (2012) highlighted that CBT, combined with sensory and motor strategies, provide a means of reorganising the brain into more adaptive ways for people who experience chronic pain. Furthermore, as noted in the previous chapter, treatments that focus on the extinction of pain behaviours and acquisition of healthy behaviours can alter brain processes in persons experiencing chronic pain (Shpaner et al., 2014). More research is needed to ensure these findings generalise to women experiencing CPP.

Collectively, these studies provide evidence that CBT can be an appropriate and effective intervention for women experiencing several gynaecological complaints that are often associated with CPP. The previous chapter argued that many psychological factors moderate the experience of pain, including anxiety, fear, pain catastrophising and fear avoidance beliefs. These psychological complexities are present in women experiencing CPP (Grace, 2000; Savidge & Slade, 1997) suggesting this client group may be well suited to CBT. For example, the cognitive components of CBT might seek to target fear, anxiety and pain catastrophising, through cognitive restructuring and education, while the behavioural aspects may seek to challenge fear-avoidance beliefs and increase pain self-efficacy though relaxation skills, pacing and relapse prevention strategies. The next section will review each component of CBT for chronic pain with particular emphasis on how it can help women with CPP.

**CBT for Chronic Pain**

As stated earlier, there appear to be many variations in what is considered to be CBT for chronic pain. The components selected for this review are based on a CBT intervention for chronic pain developed by Turk & Gatchel (2002). This intervention has been utilised in several pain studies where CBT interventions are delivered.
Assessment and Formulation

The first phase of any CBT intervention involves clinical assessment. This phase typically begins by collecting information from a range of sources (e.g., clinical interview, self-report scales, structured interviews, family data, letters and reports from other medical practitioners) in order to obtain a formulation and to assist in collaborative treatment planning (Persons, 2012). In the case of CPP which is often comorbid with other psychological disorders it is important to obtain a clear diagnosis and understanding of any comorbid psychological conditions, and try to ascertain how that impact on the experience and maintenance of CPP (Grace, 2000). A formulation is also important to understand the extent of the symptoms, when they started, any mechanisms that might be causing or maintaining the problem.

Pain Education

It is counter-intuitive to believe that pain can exist or linger without tissue or nerve damage. Therefore, psycho-education (i.e., education about pain: its triggers, causes and maintaining factors) is an important element of a pain rehabilitation program (Lotze & Moseley, 2015; Moseley, 2004). Understanding how the pain system can become sensitised, and learning strategies for down-regulation, can also help demystify the condition and give hope for recovery. It is also helpful for persons with chronic pain to understand the role that fear, mood, tension and other environmental stressors play in their pain experience (Morley, Eccleston, & Williams, 1999; Vlaeyen & Morley, 2005).

The literature shows that when individuals learn a clear understanding of what elements of their condition they can and cannot control, it is empowering for them and can improve their self-efficacy (Buckelew et al., 1995; McCracken, 1998). Sleep disturbance has also been shown to be implicated in the experience of chronic pain (Smith & Haythornthwaite, 2004). Pain education around the importance of sleep and learning strategies for good sleep hygiene are an important part of CBT interventions for chronic pain.

Relaxation Training

Relaxation and stress management skills are the first skills taught in most CBT interventions for chronic pain (Bradley, 1996; Buenaver, McGuire, & Haythornthwaite, 2006; Turk et al., 1983). These often include breathing exercises, systematic body scans,
distraction methods, and progressive muscle relaxation. These skills are designed to teach individuals how to regulate their emotions and stress responses which chronic pain places on the mind and body. Techniques such as body scan and progressive muscle relaxation build awareness within the body, so individuals can notice when they are creating tension in their body (Hilton et al., 2016). This awareness helps individuals identify habitual triggers and reactions of which they may not otherwise be aware, and learn how to manage them more constructively (i.e., by releasing them through breathing).

With commitment and practice, these skills can help individuals move their attention away from their pain experience, towards the task of relaxation. The efficacy of relaxation exercises for chronic pain are well supported in the literature, particularly as a means of augmenting other therapies (Orlando, Manfredini, Salvetti, & Bosco, 2007). For chronic headache and back pain, some treatment effects of relaxation exercises are comparable to pharmacological treatments (Andrasik, 2007; Holroyd & Drew, 2006).

**Cognitive Restructuring**

The process of cognitive restructuring begins by helping individuals cultivate thought awareness in their everyday life. Individuals are taught how to identify unhelpful thinking patterns (e.g., catastrophising, all or nothing thinking, emotional reasoning, etc..) and are encouraged to notice them in their own everyday life, particularly in instances where they notice a change in their mood (Jensen & Turk, 2014). Thinking styles, and in particular pain catastrophising, have been found to not only influence the experience of pain but they also have a direct influence on the pain related fear and disability (Keefe, Brown, Wallston, & Caldwell, 1989; Sullivan et al., 2001). Table 3.1 shows examples of both negative and positive thoughts associated with pain. For an individual experiencing pain, thoughts in the left column are likely to result in greater levels of perceived pain than thoughts in the right column (Campbell & Edwards, 2009). Once individuals understand their own thinking patterns, and how these thinking patterns influence their beliefs, emotions and behaviours around their pain, they can then learn how to challenge these thoughts, and eventually replace them with more helpful thoughts.
Table 3.1.

**CBT Thinking Styles (Turk & Gatchel, 2002)**

<table>
<thead>
<tr>
<th>Negative Thinking</th>
<th>Realistic Thinking</th>
</tr>
</thead>
<tbody>
<tr>
<td>My pain is terrible!</td>
<td>The extreme pain is back again, but I know that it is only temporary.</td>
</tr>
<tr>
<td>I can't bear it! How long must this go on?</td>
<td>By relaxing my muscles, I can make my pain more bearable.</td>
</tr>
<tr>
<td>I shouldn't have so much pain. I don't deserve this.</td>
<td>I can keep my breathing as deep and even as possible and this will reduce my experience of pain.</td>
</tr>
<tr>
<td>I simply have to find some relief now!</td>
<td>Bad days are to be expected, we all have them.</td>
</tr>
<tr>
<td>Why can't they make my pain go away?</td>
<td></td>
</tr>
<tr>
<td>I'm going crazy! Where will this all end?</td>
<td></td>
</tr>
</tbody>
</table>

**Graded Exposure and Pacing**

The fear-avoidance model shows that some persons who experience chronic pain anticipate that certain activities will increase their pain or create further injury and this can result in fear-related disability (Vlaeyen & Linton, 2012). Failure to engage in activities or movement prevents the person from obtaining any feedback that challenges this belief, which further reinforces the negative associations of movement with activity, pain and injury (Crombez et al., 1999). Furthermore, lack of movement increases tension in the body and heightens the pain sensation (Vlaeyen et al., 1999). Therefore, graded exposure and pacing are important aspects of CBT interventions. Movement and activities need to be encouraged to break the fear-avoidance cycle.

It is also common for persons with chronic pain to experience alternating cycles of over-exertion when their pain is manageable, and under-activity when their pain is severe (Bonica, 2010). Due to the overwhelming nature of chronic pain, it is often difficult for individuals to identify when they are over or under exerting themselves. Body awareness and the ability to remain mindful and maintain graded activity despite pain are important skills in ensuring activity levels are kept consistent, thus increasing a person’s confidence in their body’s ability to function (Turk & Gatchel, 2002).

**Mindfulness and Self-Compassion**

Mindfulness interventions have also shown to be effective for some women experiencing CPP (Fox et al., 2011) and have been used as a psychological intervention for women coping with endometriosis (Kold, Hansen, Vedsted-Hansen, & Forman,
Mindfulness exercises teach a client how to observe the stream of thinking, and become a partial observer of their pain, rather than a reactive participant (Hilton et al., 2016; Kabat-Zinn et al., 1985).

Self-compassion is another critical component of CBT interventions that utilises mindfulness (Kuyken et al., 2010). In turn, mindfulness is one of the three essential elements of self-compassion (Neff, 2003). Studies show that self-compassion is a skill which can be learned and can improve mental health functioning and reduce symptom severity in a range of disorders including PTSD (Neff, Kirkpatrick, & Rude, 2007; Thompson & Waltz, 2008). In persons experiencing chronic pain, self-compassion has shown to be successful in helping patients overcome experiential avoidance and pain related disability (Costa & Pinto-Gouveia, 2013). In a study of experiential avoidance and persistent musculoskeletal pain, Wren et al. (2012) showed that self-compassion exercises can be effective in restoring psychological functioning and can help patients with their adjustment to pain.

Motivation and Relapse Prevention

Psychological treatment is challenging and requires commitment, and some individuals drop out (Davis & Addis, 1999; D. Turk, Turk, & Rudy, 1990). This can be particularly challenging in pain interventions as it is not unusual for symptoms to get worse before they get better (Turk & Rudy, 1991). Therefore, treatment adherence and relapse prevention strategies are important aspects of CBT. Furthermore, goals need to be realistic and attainable, and made in collaboration with individuals (Barazzone, Cavanagh, & Richards, 2012). Individuals who were initially willing to engage in CBT may need to be reminded of why they first sought help. Relapse triggers and prevention strategies are also necessary to ensure continued dedication. The message that relapse is a natural part of progression may be helpful in this instance. Challenging unhelpful cognitions around relapse and reframing them in terms of “paths to progression” are also important (Ehde et al., 2014).

3.6 Challenges in Delivering CBT to Women with Chronic Pelvic Pain

Utilising CBT approaches for CPP comes with many challenges both for women receiving treatment and for health care professionals administering them. Despite a strong evidence base, most medical professionals do not integrate behavioural
approaches into their practices (Turk et al., 2008). Some of the reasons include a lack of familiarity with behavioural interventions, and difficulty identifying appropriate clinicians trained and qualified to deliver them (Giordano & Schatman, 2008; Turk et al., 2008). For the individual receiving CBT, barriers include cost of these services, mobility and travel difficulties, as well as stigma associated with utilising psychological interventions (Corrigan, Watson, & Barr, 2006; Turk, Swanson, & Tunks, 2008). Furthermore, unlike medicine and surgery, it may not be obvious to an individual how behavioural interventions might help them manage their pain condition (Bonica et al., 2010). This concluding section will outline some of the challenges involved in delivering CBT to women with CPP, and present a review of the literature responding to those challenges.

**Mobility, Convenience and Cost**

Persons who have problems with mobility, live in regional areas where a therapist is not available, or those who cannot afford treatment may not be able to access CBT interventions for CPP (Rini, Williams, Broderick, & Keefe, 2012). Women who run a household report that it can be difficult to regularly attend medical appointments (Zadinsky & Boyle, 1996). Child care costs, travel costs as well as the extra cost of chronic pain services that are often not subsidised or covered provide further obstacles for women to receive treatment or commit to CBT pain management program (Ahangari, 2014).

**Availability of Clinicians and Resources**

The demand for pain clinics that utilise behavioural interventions outstrips supply. The median waiting time from referral to initial clinical assessment for publicly funded pain management service in Australia is 150 days, and multi-disciplinary clinics are almost non-existent in some regional areas (Hogg, Gibson, Helou, DeGabriele, & Farrell, 2012). Furthermore, in the case of CPP, it is not uncommon for a person to go through rehabilitation programs multiple times which further compounds waiting times (Jensen, Bergström, Ljungquist, & Bodin, 2005). In addition, there are insufficient clinicians who have experience administering CBT to women with CPP outside of multi-disciplinary pain clinics (Dalpiaz et al., 2008; McGowan et al., 2007).
Stigma

For many people there is a level of stigma attached to visiting a psychologist (Corrigan et al., 2006). Some people view it as a sign of personal failure or weakness, and although the views are often not explicit, there is still an underlying social and professional prejudice associated with persons who are thought to have mental health issues (Lannin, Guyll, Vogel, & Madon, 2013). There is an implication that people who require psychotherapy are weak, helplessness, and cannot cope on their own. For women with CPP, seeking help from a psychologist can come with an additional implication that the pain is psychological and not real (McGowan et al., 2007).

Suitability and Perceived Locus of Control

Although the literature suggests CBT can be beneficial for persons experiencing chronic pain, it may not be suitable for all individuals (Vlaeyen & Morley, 2005). Individuals who endorse the view that clinical outcomes are controlled by factors external to them (i.e., external locus of control) are less likely to see the value in utilising a CBT intervention (Crisson & Keefe, 1988). It is important to remember that a client’s orientation of their locus of control is not fixed. Coughlin, Badura, Fleischer, and Guck (2000) showed that patient’s perceptions of personal control over their pain increased after receiving treatment in a multi-disciplinary pain clinic. The authors noted that increasing the client’s self-efficacy in their control over their pain, and decreasing external attributions of control are essential to the success of a pain management program. Although studies examining locus of control in relation to CPP and engagement with therapy have not been conducted it may be likely that these relationships also hold true for women experiencing CPP.

Readiness to Change

Adopting a psychological approach to chronic pain requires significant lifestyle changes, as well as changes to long standing thinking patterns and beliefs around pain (Buenaver et al., 2006). How ready a woman with CPP is to make these necessary and somewhat counter-intuitive adjustments varies from client to client (Souza et al., 2011). A person whose primary motivation for seeking treatment is to eliminate rather than manage their pain, may not be as receptive to trying CBT as someone who has already exhausted all their medical options (Turk & Rudy, 1991).
The Transtheoretical Stages of Change (SOC) model outlines five stages of change from pre-contemplation through to maintenance and shows a strong correlation between a person’s readiness to change, and their ability to be successful in changing their behaviour (Kerns, Rosenberg, Jamison, Caudill, & Haythornthwaite, 1997). The SOC model has been adapted for chronic pain interventions and provides a useful framework for clinicians to measure how ready a client is to change, and to help them move through those stages (Kerns & Rosenberg, 2000). Although the SOC model has not been specifically adapted for CPP, its use in chronic pain studies suggests it may be applicable and relevant for women experiencing CPP.

**Importance of Therapeutic Relationship**

When women present to pain clinics it is usually because conventional treatments have failed, or in some cases have made the pain worse (Twiddy et al., 2017). Women in these situations sometimes direct their anger and frustration towards medical practitioners who have tried to help them but have failed (Slade & Cordle, 2005). Re-establishing broken trust, agreeing on new goals for treatment such as pain management rather than pain cure, and giving individuals the encouragement to try behavioural approaches is challenging (Rhodin, 2013). The literature suggests that individuals are more likely to engage and persevere with a treatment plan for their pain if they feel a therapeutic relationship is present between themselves and the treating clinician (Engeler et al., 2013). Therefore, establishing a therapeutic relationship is important when delivering CBT interventions to women experiencing CPP.

The therapeutic relationship has been explored extensively in the literature (Ferreira et al., 2013; Lopez, 2015; Martin et al., 2000). Sometimes called therapeutic alliance, it refers to the sense of collaboration, trust, mutual respect and support between client and therapist, and is a key concept in clinical psychology (Bordin, 1994). It is commonly broken down into three main components: (1) agreement between client and therapist on goals of therapy; (2) the client’s agreement that the therapy will address the problems of treatment; and (3) the quality of the interpersonal bond between the client and therapist (Bordin, 1994; Martin et al., 2000). The quality of therapeutic alliance between patient and therapist strongly predicts positive outcomes in both psychological and chronic pain interventions (Ferreira et al., 2013; Martin et al., 2000).
3.7 Conclusion

This chapter discussed some of the common causes of pelvic pain in women. It highlighted the complexities involved in diagnosing and treating gynaecological complaints and discussed the risk factors that may contribute to the chronicity of pelvic pain in women. The chapter began with a review of the common pharmacological and medical interventions used in the treatment of CPP and mirrored the findings in the previous chapter which stressed the importance of a biopsychosocial approach to chronic pain management. Although the evidence suggests that medical and pharmacological interventions can be effective in treating CPP, it also suggested that in some cases, some gynaecological interventions can prolong CPP in women who are solely investing in medical solutions. The medical literature around CPP could not explain why levels of distress and disability varied so much between seemingly similar diagnoses and provided little insight into how new medical advancements and diagnostic procedures benefit women experiencing CPP.

The review then moved onto risk and moderating factors for CPP developing in women. Most of the risk factors uncovered in the review did not conclusively identify specific causal factors and appeared to paint a similar picture to studies examining chronic diseases in general, such as heart disease and diabetes. Nevertheless, some important associations were revealed. For example, cognitive factors such as fear of pain, PC and PSE are associated with levels of pain distress and disability in women with CPP. These findings again mirror the conclusion in the literature on chronic pain by stressing the importance of a multi-faceted biopsychosocial approach to diagnosis and treatment, and the importance of utilising psychological interventions such as CBT. The consensus is that more research is required. CPP in women is a complex condition. Even interventions that are effective need to be informed by qualitative research so the mechanisms that led to any improvement can be replicated in clinical settings.

The chapter then moved onto CBT and its specific application to women with CPP. The evidence revealed that CBT has good clinical efficacy for a range of CPP conditions and lacks many of the side effects and risks associated with medical treatments. However, one factor that makes assessing, comparing and pooling CBT studies difficult is the wide variation in what defines and constitutes a CBT intervention. Some CBT studies incorporate mindfulness components within their intervention, while
other studies might label such interventions as mindfulness-based CBT. Furthermore, this chapter also highlighted some of the barriers to receiving CBT treatments such as lack of resources, cost, stigma and mobility. Considering these limitations, alternative ways in which CBT can be effectively delivered to women with CPP will be reviewed in the next chapter.
Chapter 4.
Self-Administered CBT for Chronic Pelvic Pain: Challenges and Co-Design Methodologies

The previous chapter highlighted the challenges involved in delivering CBT to women experiencing CPP. Technology-based interventions can help overcome some of those challenges, particularly those that are related to face-to-face contexts. This chapter reviews the literature on technology-based interventions and emphasises the importance of considering levels of clinician involvement when evaluating these novel approaches. The chapter then presents some of the challenges involved in utilising technology-based interventions and discusses how co-design can help overcome these challenges. It concludes by detailing methods that may be helpful in creating technology-based CBT interventions that are suitable and effective for women experiencing CPP, and how co-design methodologies may be used to help facilitate a therapeutic relationship.

4.1 Delivering CBT outside Face-to-Face Contexts

Non-face-to-face CBT interventions are gaining increasing acceptance across many chronic pain conditions, with treatment satisfaction ratings showing similar levels to face-to-face therapies (Buhrman, Nilsson-Ihrlfelt, Jannert, Ström, & Andersson, 2011; Carpenter et al., 2012; Dear et al., 2015). Sometimes referred to as Low Intensity CBT (Richardson, Stallard, & Velleman, 2010), delivering CBT outside face-to-face formats comes in many different forms, with varying levels of clinician input (Christensen, 2010; Newman, Szkodny, Llera, & Przeworski, 2011).

The level of clinician involvement is important to consider when reviewing the efficacy of non-face-to-face interventions, such as mobile phone apps, as it can influence clinical outcomes (Lindner, Ivanova, Ly, Andersson, & Carlbring, 2013). It is imperative that the level of clinician involvement intended in clinical practice matches the level presented in the evidence evaluating it (Donker et al., 2013). For example, the efficacy of apps that have been tested with clinician involvement may be compromised if a user only engages with the app on their own.

To review the clinical efficacy of non-face-to-face interventions, an adapted version of a classification system developed by Newman et al. (2011) will be utilised. This
system categorises technology-mediated interventions by three differing levels of clinician input: predominately therapist-driven; predominately client-driven; and purely self-administered treatments.

**Category 1: Predominately Therapist-Driven interventions**

In situations where mobility and proximity are barriers for receiving care, interventions utilising telehealth and video-conferencing have been used to assist in the management of chronic pain, with promising results (Chakrabarti, 2015; Kroenke et al., 2014; McGeary, McGeary, & Gatchel, 2012). In these interventions, a therapist is not physically present, but rather engages with the patient in real time using telephone, Internet or video calls. Communication tools are used to recreate the therapy room environment in a more accessible and convenient way, avoiding the need for travel. In these modalities, individuals can communicate back and forth with the therapist in a similar manner to face-to-face therapy (Rees & Haythornthwaite, 2004).

Backhaus et al. (2012) conducted a review of 65 papers from a sample of 821 journals reporting on videoconferencing psychotherapy. The range of disorders in the study included PTSD, mood disorders and eating disorders. The authors concluded that psychotherapy delivered via videoconferencing produces similar clinical outcomes to face-to-face therapies, and even the quality of the therapeutic relationship is comparable to face-to-face interventions. This review also included CBT interventions for what the authors described as pain or psychosocial issues. They found that video conferencing was as effective as face-to-face treatments. However, the study did not specify the specific types of pain conditions addressed.

At present there are no empirical studies outlining the efficacy of telehealth and video conferencing for women experiencing CPP. Nevertheless, Rees and Haythornthwaite (2004) have created a useful generic set of guidelines for psychologists to use when designing these therapies, which can be applied to interventions for women experiencing CPP. Key suggestions include maintaining consistent pace of sessions and allowing time and space to accommodate technical proficiency.

Although predominately therapist-driven therapies address some issues associated with disability and access for women experiencing CPP, they do not adequately address the cost, resource or stigma problem, since a therapist is still required to be involved at
the same time the therapy is being delivered. Furthermore, this method is not always convenient as therapy can only be delivered at a time when both therapist and patient are both available.

Category 2: Predominately Client-Driven interventions

The categories of minimal-contact therapy and predominately self-help interventions were described by Newman et al. (2011) as those therapies where a therapist is only involved in initial assessments, periodic check-ups, and in instances where support is required. In this review, these two categories will be merged and named *predominately client driven* since it is only the number of clinician hours spent during an intervention that distinguishes them. CBT therapies of this kind include bibliotherapy (the use of books as therapy in the treatment of psychological disorders; Buwalda & Bouman, 2009); computerised CBT (Fitria, 2017; Richardson, Stallard, & Velleman, 2010); and mobile phone apps with clinician support (Sundararaman, Edwards, Ross, & Jamison, 2017).

As the availability of the Internet and smartphones has grown, the development and use of these as treatment delivery methods has expanded considerably with promising results (Carpenter et al., 2012; Ehde et al., 2014). Although Internet-based interventions have shown to be effective in delivering CBT across different chronic pain populations (Bender et al., 2011; Palermo et al., 2016; Rini et al., 2015) no study has yet tested these interventions with women experiencing CPP. Furthermore, predominately client-driven interventions do not fully address the cost or resource problem as a therapist is still required to either support or supervise treatment. They also do not address issues associated with stigma as some official involvement with the medical profession is necessary for treatment to be accessed.

Category 3: Self-Administered interventions

Self-administered CBT for chronic pain generally involves the use of self-help books, websites or smartphone apps; although only websites and smartphone apps have been tested empirically in studies involving no clinician guidance. In an evaluation of a self-administered online CBT intervention involving 305 male and female participants with varying types of chronic pain, Ruehlman, Karoly and Enders (2011) found that utilisation of the pain intervention was associated with significant decreases in pain
severity, perceived disability, catastrophising, and pain-induced fear. The intervention also led to significant declines in depression, anxiety, and stress, as well as increased knowledge about the principles of chronic pain. In another pilot study evaluating an online self-help intervention for chronic lower back pain with 141 women and men, Carpenter et al. (2012) found positive effects on several pain-related outcomes, including reductions in pain catastrophising and disability, and increases in pain self-efficacy. Although these results are encouraging, no study has tested self-administered interventions for women experiencing CPP.

**Studies Comparing Different Degrees of Therapist Involvement**

The evidence suggests that interventions involving some form of clinician guidance are generally more effective than purely self-guided interventions (Donker et al., 2013; Lindner et al., 2013). In a meta-analysis examining clinician involvement on Internet interventions for mental disorders, Baumeister, Reichler, Munzinger and Lin (2014) found that clinician guidance helps patients stay engaged with the intervention. Attrition is often cited as a reason why there are fewer studies supporting the efficacy of self-administered therapies where no clinician is present (Rini et al., 2012). Therefore, it is difficult to determine if the greater levels of clinical efficacy found in technology-based studies with clinician guidance is due to factors associated with clinician involvement, or if it is because these studies have lower attrition rates, and are therefore greater in number.

To address this question, Dear et al. (2015) conducted a study comparing an Internet-delivered pain management program, *The Pain Course*, with differing levels of clinician support. Their results replicated an earlier Cochrane review which showed that clinician involvement is less important in non-face-to-face therapies if the intervention contains high quality content, is credible and engaging, and if the study involves some level of screening of participants for suitability (Dear et al. 2015; Eccleston et al., 2014). This suggests that interventions that are well-designed and well-matched to their patient group may be as effective as interventions involving clinician guidance, a notion well supported in the literature (Clemensen, Larsen, Kyng, & Kirkevold, 2007; Doherty et al., 2010; Poole, 2013).

There are still some research gaps in this area. More studies are needed to identify the characteristics of people who are best suited to self-administered interventions (Dear
et al. 2015; Eccleston et al., 2014). Furthermore, the idea that treatment adherence equates to better clinical outcomes has been challenged in studies involving some technology-based interventions (Smith, Ploderer, Wadley, Webber, & Borland, 2017). Attrition will be covered in more detail later in this chapter.

### 4.2 Utilising Mobile Phone Technology for the Management of Pain

Although self-administered CBT interventions for chronic pain are still being developed for use through websites, in recent times the trend for researchers and developers of self-administered therapies is to utilise smartphone technologies (Lalloo et al., 2015; Portelli & Eldred, 2016). This section will outline the advantages of using mobile phone apps for treating chronic pain. It will review the evidence base for CBT-based mobile phone apps targeting chronic pain.

#### Advantages

Well-designed and well-suited CBT-based smartphone interventions for chronic pain can be helpful in reducing the psychological distress associated with chronic pain and some of its comorbid symptoms, even without clinician guidance (Cuijpers et al., 2011; Lindner et al., 2013). Utilising mobile phone apps in a self-guided manner has significant advantages: they are cost-effective; can reach a large proportion of the population; and can be utilised at any time, day or location (Rini et al., 2012). Furthermore, mobile phone apps present treatments in a consistent manner, and can overcome some of the problems associated with face-to-face therapies such as stigma and dependence. Some of these advantages will be discussed in more detail in this section.

#### Accessibility and community cost.

The almost ubiquitous adoption of portable electronic devices offers new opportunities for delivering health care to a broader cross-section of the population including those living in rural and remote regions. It is estimated that by 2020, 90% of the world’s population will own a mobile phone (Ericsson, 2015). For governments and institutions looking to reduce the economic burden of chronic pain, developing self-guided interventions delivered via mobile phone apps can provide significant cost savings for the community (Heber et al., 2013; Lin et al., 2015; Macea, Gajos, Calil, & Fregni 2010).
Heber et al. (2013) used economic modelling to estimate the cost of lost productivity, sick days and other indirect economic costs associated with stress. They concluded that even with modest effect sizes, unguided interventions can produce greater cost savings to the community than face-to-face interventions as they are accessible to greater proportion of the population at lower cost. In a meta-analysis reviewing 11 RCTs (pooled sample $N = 2,953$) assessing the efficacy of web-based CBT interventions for a range of chronic pain conditions, Macea et al. (2010) reported that participants showed a greater capacity for work, fewer physician visits and reported reductions in medication use. Although the authors reported small effect sizes in these outcome variables, they argue that the potential to deliver treatments across a wider range of chronic pain patients can result in greater cost savings to the community.

**Convenience.**

Smartphone based therapies allow patients to utilise therapy programs wherever and whenever is convenient, and at their own pace (Rini et al., 2012). For women with CPP, this overcomes problems associated with mobility and disability, and provides flexibility around busy schedules and work and family commitments. Furthermore, access to these services can be provided quickly without the need to synchronise appointments or reschedule. This is also particularly helpful for women who are already on long waiting lists to receive other forms of treatment. For these women, low-cost CBT can be administered through a mobile phone app as soon as they are ready to receive treatment.

Smartphone interventions can be useful tools for women experiencing CPP as they can be accessed in instances of acute pain flare-ups or emergencies (Sundararaman et al., 2017). Since smartphones are typically “always-with-you, always-on” (Marcus & Chen, 2002 p. 39) women can instantly access treatments when they need them. If the app has proven to be helpful for them, then this portability may provide women with some reassurance, autonomy and a greater sense of control in their day-to-day lives.

**Stigma and other challenges.**

Self-administered therapies also provide opportunities for women with CPP to receive psychological therapy discreetly without friends, family members or work colleagues knowing (Waller & Gilbody, 2009). Furthermore, women with CPP often
have concerns relating to sex, intimacy and body image (Zadinsky & Boyle, 1996), while many have been exposed to sexually-related trauma and feel reluctant to disclose this information to another person (Meltzer-Brody et al., 2007). The discreet nature of receiving therapy via a mobile phone may help overcome these problems and may provide opportunities to engage with psychological treatment without obligation or pressure to continue (Coyle, Doherty, Matthews, & Sharry, 2007). Apps allow health consumers to “test the water” (Webb, Wadley & Sanci, 2017 p. 13): If women find self-administered CBT helpful, the benefits might encourage them to overcome their fear of stigma and try face-to-face therapy sometime in the future (Prior, 2012).

Evidence Base

In 2015 there were over 165,000 health-related apps available on the market (Aitken & Lyle, 2015). Studies that review the efficacy of health-related apps tend to converge towards the same conclusions (Bakker, Kazantzis, Rickwood, & Rickard, 2016; Donker et al., 2013; Laloo et al., 2015; Reynoldson et al., 2014; Rosser & Eccleston, 2011). First, most apps do not incorporate evidence-based practices. Second, health care providers are rarely involved in the development of these apps. Third, unlike many pharmaceutical interventions and medical devices, there is a lack of peer-reviewed studies of these apps (Cuijpers et al., 2009; de Graaf et al., 2009).

In a review specifically considering smartphone apps for pain management, Rosser and Eccleston (2011) reviewed 111 smartphone apps and found only one that incorporated evidence-based practices. The authors also found that 86% of the apps reported no health care involvement in their development, and that no app reported an RCT of its efficacy. Consistent with this review, Portelli and Eldred (2016) reviewed 360 smartphone applications that utilised CBT for the management of chronic pain. They reported that no smartphone app was supported by an adequate RCT, only six apps in their list included specific psychological components, and the professional background of the app developer was usually unclear. The authors concluded that health professionals need to exercise caution when administering pain apps to patients as the interventions may not only be unhelpful, but may do more harm than good.

Although there have been no adequate trials conducted on mobile phone apps for chronic pain without clinician guidance (Bender et al., 2011; Macea et al., 2010; Rini et al., 2012), some recent trials of CBT mobile phone apps for psychological disorders that
do not involve clinician guidance have been conducted and show some promise. Birney, Gunn, Russell, and Ary (2016) developed a CBT app called *MoodHacker* for the self-management of mild-to-moderate depressive symptoms. In an RCT involving 300 adults exhibiting mild-to-moderate depression, *MoodHacker* users experienced fewer depressive symptoms, increased behavioural activation, and better functioning in the workplace relative to controls. In a study utilising a third wave CBT intervention for social anxiety delivered by smartphone, Ivanova et al. (2016) compared the efficacy of varying levels of therapist support. Their results indicated that the intervention was successful in reducing social anxiety symptoms and that there were no differences between a group that was guided by a therapist and an unguided group.

Collectively, the evidence shows some promise for the efficacy of mobile phone apps for chronic pain; however, more research is needed. In terms of smartphone apps specifically designed for CPP, there have been no trials - with or without clinician guidance - and there are currently no mobile phone apps on the market that deliver evidence-based CBT to women with CPP.

### 4.3 Considerations and Challenges

Self-administered CBT interventions, such as those delivered through smartphones, have their own set of challenges and limitations which not only undermine their clinical efficacy, but can make them unsafe to use (Banks, Newman, & Saleem, 2015). This section will cover some of the common challenges associated with delivering therapies through a smartphone.

**Attrition**

Treatment attrition is a challenge in all forms of therapy involving behaviour change (Ritterband, Thorndike, Cox, Kovatchev, & Gonder-Frederick, 2009). Up to 70% of individuals who initiate any form of psychological therapy discontinue treatment prior to the suggested treatment course length (Gearing, Townsend, Elkins, El-Bassel, & Osterberg, 2014). Attrition has been cited as one of the most difficult challenges to overcome in smartphone interventions not guided by clinicians (Eccleston, 2011; Rini et al., 2012). Furthermore, high drop-out rates are also cited as one of the reasons why there are few published studies supporting their efficacy (Geraghty et al., 2010).
Attrition can be predicted by factors such as readiness to change (Beutler et al., 1991; Biller, Arnstein, Caudill, Federman, & Guberman, 2000); perception of illness (Davis & Addis, 1999); outcome expectancy and locus of control (Geraghty et al., 2010; Turk et al., 1990). Geraghty et al. (2010) showed that an internal locus of control (i.e., the belief that a person is in control of their treatment) predicts greater levels of treatment adherence. Other studies have shown that a person’s readiness to change, based on Kerns et al.’s (1997) Transtheoretical Model for Change, provides a more reliable predictor for treatment adherence (Derisley & Reynolds, 2000). The consensus is, however, that more research in the area is required for interventions delivered outside of face-to-face contexts (Cuijpers et al., 2012; Davis & Addis, 1999; Dobkin, Sita, & Sewitch, 2006).

Premature termination from an intervention may not necessarily suggest treatment failure. In a review of Internet-delivered CBT for anxiety and depressive disorders, Hilvert-Bruce, Rossouw, Wong, Sunderland and Andrews (2012) found that some participants withdraw early from treatment because they felt better and no longer required help. Furthermore, the idea that stronger user engagement results in more effective outcomes has been challenged recently in a study on smoking cessation which showed that early disengagement with an on-line intervention was sometimes associated with successful behavioural change (Smith et al., 2017).

Safety

Developers of apps targeting chronic pain rarely consult with clinicians and users in the design process (Lalloo et al., 2015). This can not only compromise an app’s usability and effectiveness, but can make it unsafe, particularly for users with a trauma background. For example, whilst mindfulness exercises are an important part of CBT interventions for CPP, they can evoke disassociation in persons with PTSD (Banks et al., 2015). Given the likelihood of trauma history in some women who experience CPP (Heim et al., 1998), precautions may be necessary when administering mindfulness exercises, particularly to those who experience PTSD symptoms (Lustyk, Chawla, Nolan, & Marlatt, 2009). Furthermore, information delivered to patients in non-face-to-face contexts needs to be unambiguous and precise to avoid distress caused by misunderstandings. Since there are no opportunities for questions and clarification from users, there is little margin for error, particularly for women with CPP who might
already be sensitive about the information they have received from medical personnel (Price et al., 2006; Souza et al., 2011).

**Literacy**

Self-administered therapies such as mobile phone apps require a certain level of technical literacy. A user needs to be able to download an app, install it, set it up, and then navigate through it. Women who are experiencing CPP and are open to utilising psychological interventions are likely to have tried several previous treatments with limited success (Toye, Seers, & Barker, 2014). An unsuccessful attempt at utilising a self-administered CBT therapy due to lack of technical experience may not only provide disappointment in the short run, but it may reinforce negative beliefs about treatments for CPP.

**Collaborative Goals and Therapeutic Relationship**

One of the advantages of delivering self-administered therapies through a mobile phone is that the intervention can be distributed to many people at a low cost, minimising the strain on resources. This advantage, however, may come at the expense of personalising the therapy to the person receiving it. One of the important processes in CBT interventions for chronic pain involves assessment and formulation, during which a clinician determines which treatment course is most appropriate for a particular client and collaboratively determines the appropriate goals for therapy (Turk & Gatchel, 2002).

Collaborative goals are also an important element of the therapeutic relationship between patient and clinician (Bordin, 1994). Sometimes referred to as therapeutic alliance or working alliance, it has been shown to predict therapy effectiveness (Ferreira et al., 2013; Martin et al., 2000). The level of therapeutic alliance perceived can be influenced by several different factors, such as whether a patient feels their feelings are validated, or whether they feel understood by their therapist (Martin et al., 2000). Some studies suggest that individuals are more likely to engage and persevere with a treatment plan if they are collaboratively involved in the development of that plan (Engeler et al., 2013; Singh et al., 2014).

Developing this form of relationship in a therapy where no clinician is present is a considerable challenge for developers of these interventions. Some researchers have
examined therapeutic alliance in computerised interventions without clinician involvement and shown levels of perceived empathy and warmth comparable with face-to-face therapies (Anderson et al., 2012; Barazzzone et al., 2012; Martin et al., 2000). If some aspects of therapeutic alliance are possible within self-administered therapies, then involving end users in the design of those interventions may produce features that can help facilitate that alliance.

4.4 Co-design of Technology-Based Interventions

The previous section outlined some of the challenges involved in designing self-administered CBT interventions for women with CPP. There is increasing use of technology to improve access, engagement and effectiveness of therapy interventions and overcome some of these limitations (Mohr et al., 2013). However, the challenges of attrition, safety, lack of empirical and theoretical basis mean that the success of technology-based interventions have been limited (Donker et al., 2013; Laloo et al., 2015; Rosser & Eccleston, 2011).

In response, co-design methodologies have been proposed, because these methods are believed to lead to designs that better suit particular user cohorts (Clemensen et al., 2007; Doherty & Coyle, 2010; Poole, 2013). Originally called co-operative design (and more recently participatory design) co-design involves all stakeholders, including end users and clinicians, in the design process (Muller, 2003). As a design and evaluative approach, it has been utilised in a wide range of technology based psychological interventions (Poole, 2013). For a comprehensive history of co-design within health sciences, see Clemensen et al. (2007).

Guidelines and Procedures

Utilising co-design for technology-based psychological interventions involves a unique set of concerns. First, the expanding knowledge in the area makes it difficult to determine what information is most useful and what principles need to be applied (Doherty et al., 2010). Second, it is also important to facilitate successful collaboration with balanced input from each party. This includes considerations regarding group sizes, and considerations about how much weight to give contributions from competing sources (Muller & Kuhn, 1993). Third, considerations also need to be made about
evaluating the intervention, such as how to determine which methods are most appropriate at different stages of development (Muller, 2003).

To address these concerns, Doherty et al. (2010) derived a set of co-design guidelines that draw on experience gained from development projects in mental health settings. Although yet to be utilised on technologies for women experiencing CPP, the guidelines are designed to be adaptable to psychological interventions seeking to elicit behaviour change within an evidence-based framework (Doherty et al. 2010). Applying these guidelines to a project designing a self-administered CBT intervention for women with CPP would involve the following steps:

1. A data gathering phase involving focus groups and interviews with patients and clinicians who work with them.
2. Creating a set of design specification on the basis of the data gathered and in light of appropriate theoretical models
3. Developing the technology on the basis of the design specifications
4. Evaluating the technology and its methods of investigation in a pilot-study using qualitative and quantitative data
5. Modifying the technology and its methods of evaluation on the basis of the pilot-data
6. Evaluating the modified technology in an RCT

The guidelines from Doherty et al. (2010) also recommend that appropriate ethical guidelines are followed, and that relevant theory or therapy models form the basis of the intervention.

**Methods Utilised in Co-design**

**Focus groups and structured interviews.**

Conducting focus groups with stakeholders is a critical component of co-design (McCurdie et al., 2012; Muller & Kuhn, 1993). The group dynamics and social interaction generated by the focus group can yield deeper insights and richer data than those obtained in one-to-one interviews (Thomas, MacMillan, McColl, Hale, & Bond, 1995). Focus groups can also generate large amounts of data in a short space of time.
(Krueger & Casey, 2014). They not only provide a wide range of ideas and feelings, they can also illuminate important differences between individuals within a particular cohort. In healthcare settings, conducting focus groups with end users has been shown to increase clinical efficacy and result in interventions that are more acceptable to users (Clemensen et al., 2007; Dabbs et al., 2009; Wadley, Lederman, Gleeson, & Alvarez-Jimenez, 2013).

One of the major criticisms of technology-based psychological interventions is that end users are rarely involved in the design process (Portelli & Eldred, 2016). For women with CPP, who often feel they are not listened to or understood, this factor is particularly pertinent (Souza et al., 2011). Using focus groups to understand the experience of women with CPP within the context of their everyday lives and creating a shared level of empathy between designers and end users may be a vital factor in creating an intervention that is useful and engaging for them.

Conducting multiple focus group sessions provides the opportunity for iterative design, whereby a series of prototypes can be evaluated leading to improvement over time (Nielsen, 1993). Topics and ideas generated in early focus groups can be refined and re-presented in later ones to refine and verify ideas.

Focus groups that are conducted with clinicians can also be useful. They can help the designer build a picture of the therapeutic approaches and materials used and help understand the challenges clinicians face in clinical practice (Doherty et al., 2010). These interviews can also be used to identify existing therapists use of technology, their own attitudes towards technology, and their perceived attitudes of technology from their client group. Interviewing clinicians and involving them in the design process seeks to ensure intervention approaches are relevant and adequately meet the desired goals for their target clinical group (Doherty et al., 2010; Dabbs et al., 2009; Hagen et al., 2012).

Furthermore, in a seminal paper on co-design, Muller (2003) recommended that interviews be conducted within the users’ workplaces, so the environment and materials used can also be referenced within the design. Doherty et al. (2010) applied this logic to the design of mental health technology by recommending that focus groups be conducted at a clinic.
Qualitative analysis is an important tool in the co-design process from both design and evaluative perspectives. It provides information from the perspective of the people studied and is considered a more personalised method of analysis (Onwuegbuzie & Leech, 2005). This suits psychological interventions involving women with CPP, a clinically sensitive and often misunderstood population (Pope & Campbell, 2001; Souza et al., 2011). For self-administered interventions without clinician guidance, qualitative research provides important information on how interventions can be designed and delivered to maximise usability and clinical efficacy and minimise risk of distress or injury (Werner & Malterud, 2003). This is particularly important if the intervention is intended to be utilised in a large trial involving many participants.

Co-design can involve the analysis of data from many different sources. One commonly cited method for accommodating diverse data sources is a hybrid-method devised by Fereday and Muir-Cochrane (2006). This method is based on Schultz’s theory of social phenomenology (Shultz, 1967). The theory posits that the experience of the world is constructed from raw, observable ‘taken for granted’ data. Behind this notion is the idea that two persons may be exposed to the same raw data but construct very different experiences from it. In the same way, women diagnosed with the same gynaecological pathology may experience a very different set of symptoms resulting in very different levels of distress. This by no means implies that women are consciously or unconsciously the cause of their distress; however, the methodology of data inquiry employed is well suited to uncover the mechanisms for why some women with gynaecological pathology experience CPP, while others remain asymptomatic. Furthermore, by revealing differences in these meaning-making processes between individuals, the constructivist approach can provide a useful framework of psychological inquiry and data gathering that may assist in understanding how those processes can be reconstructed with psychologically more adaptive ones.

The hybrid method proposed by Fereday and Muir-Cochrane (2006) can provide a rich and detailed set of themes accommodating a range of structured interviews and open-ended discussions. Qualitative data analysis is a tool commonly used for evaluating complex and novel health interventions (Campbell et al., 2000; Lewin, Glenton, & Oxman, 2009). It has been utilised in a range of studies involving pelvic
conditions in women (Ballard, Lowton, & Wright, 2006; Jones, Jenkinson, & Kennedy, 2004; Price et al., 2006). Although labour intensive, there are many advantages to collecting and analysing qualitative data: it can help validate psychometric measures, help understand mechanisms of and barriers to change, investigate reasons for attrition, elicit information regarding attitudes towards treatment, determine reasons for effective engagement, and help in obtaining suggestions for improvements in both the intervention and in its evaluation methods (Bryman, 2015; Hammersley & Atkinson, 2007; Onwuegbuzie & Leech, 2005).

**Pilot-Testing.**

Pilot studies, sometimes referred to as feasibility studies, are considered by researchers and designers to be a crucial aspect of developing effective and acceptable technology-based interventions (Doherty et al., 2010; Lancaster, Dodd, & Williamson, 2004). Wittes and Brittain (1990) argue that pilot studies are wise investments in the acquisition of knowledge and consider them to be important in determining appropriate controls and sample sizes for larger RCTs. In a widely-cited paper, Lancaster et al. (2004) argue that well-conducted pilot studies provide clear aims and objectives ensuring a study is scientifically valid, leading to higher quality RCTs. For more complex and novel interventions, pilot studies are also crucial in identifying the active clinical components and mechanisms of an intervention (Hagen et al., 2012).

In their guidelines on evaluation, Doherty et al. (2010) recommend the use of pilot studies to improve designs and build confidence in therapeutic validity. Since RCTs generally require substantial time and resource commitments, pilot studies provide useful preliminary answers regarding the fit of the technology, and can identify critical issues early (Campbell et al., 2000).

Pilot studies with smaller samples can also help minimise risk of harm. This is any important consideration for women with CPP who are a complex population with comorbid psychological symptoms and varying clinical presentations including trauma and PTSD (Heim et al., 1998; Meltzer-Brody et al., 2007; McGowan et al., 1998). The smaller scale of pilot studies, along with qualitative methods, makes any adverse effects easier to manage and provides opportunities for learning how to avoid them in larger trials (Campbell et al., 2000; Price et al., 2006; Souza et al., 2011).
Co-design and Therapeutic Alliance

The therapeutic relationship between patient and clinician, sometimes referred to as *therapeutic alliance* or *working alliance*, is an important factor that has been shown to predict therapy effectiveness (Ferreira et al., 2013; Martin et al., 2000). Developing therapeutic alliance outside face-to-face contexts has been considered for some time in self-administered therapies, such as bibliotherapy (Lopez, 2015); computerised CBT interventions (Barazzone et al., 2012); and other technology-mediated therapies (Anderson et al., 2012; Martin et al., 2000). It is commonly broken down into three main components: (1) agreement between client and therapist on goals of therapy; (2) clients’ agreement that the therapy will address the problems of treatment; and (3) the quality of the interpersonal bond between the client and therapist (Bordin, 1994). Each of these elements will be addressed in more detail with suggestions on how co-design may help facilitate the therapeutic relationship perceived between end-users and technology-mediated therapy.

Bordin (1994) states that the first component of therapeutic alliance is an agreement on goals of therapy. Co-design provides a useful framework for facilitating this component in mediated therapy. If a representative patient sample is collaboratively involved in the process of designing and establishing goals for a targeted therapy, then it this collective agreement on therapy design may generalise to the patient group being represented. How well the representative sample generalises to a patient group might be the subject of an empirical investigation.

The second component of therapeutic alliance is agreement that the therapy will address the problems of treatment (Bordin, 1994). In their guidelines on co-design, Doherty et al. (2010) stressed the importance of ensuring that interventions are derived from evidence-based therapies which are appropriate for the client group. To satisfy this component, these evidence-based therapies could be presented to representative patient groups in focus group workshops. Participants could be asked to provide feedback on the treatment proposed and provide suggestions for how this credibility and reassurance of their efficacy can be passed onto their representative patient group.

The third requirement for therapeutic alliance is a quality interpersonal bond between the client and therapist (Bordin, 1994). Barazzone et al. (2012) explored these elements in a qualitative study examining self-administered computerised CBT
interventions for depression. They found that features of therapeutic alliance, such as empathy and warmth, were present at levels comparable to face-to-face therapies. The study also revealed additional relational factors such as empowerment and guidance which were unique to self-administered co-designed therapies may also help to address this by directly asking user groups about prior and existing relationships with technology. Users could discuss the elements they think are necessary to facilitate empathy, engagement, validation and mutual understanding in technological contexts.

For all these elements of therapeutic alliance, the evaluative aspects of co-design (e.g., pilot studies with qualitative interviews) could measure the quality of the therapeutic relationship established and provide suggestions for how it could be improved.

4.5 Conclusion

This chapter reviewed the different ways in which CBT can be delivered outside face-to-face contexts. It also showed how varying levels of clinician guidance can influence clinical outcomes and attrition rates. It illustrated the importance of matching clinician involvement in evaluation studies with the levels intended in clinical practice and showed how evidence for some interventions can be misleading to users who intend to utilise self-administered therapies in their own time and without clinician guidance.

This review also highlighted that clinician involvement is less important in studies that are credible, engaging and well suited to their treatment group, emphasising the importance of good design for non-face-to-face interventions. The review also noted that studies involving self-administered therapies without clinician guidance are fewer in number, and this may account for their weaker empirical basis.

The literature reviewed in this chapter demonstrated the advantages of utilising self-administered smartphone interventions and how they can make CBT therapies more effective and available to those who need them. It also showed how mobile phone apps, by their ubiquitous nature, can provide modest but effective gains across a wider segment the population, providing greater savings to the community than possible with face-to-face interventions. One notable feature of the studies assessing the clinical efficacy of technology-based interventions was how so few involved rigorous RCTs. The review also noted how few apps developed involved end users and health
professionals in the design process, and how few had a foundation of evidence-based therapies.

The chapter concluded by discussing some of the challenges involved in utilising smartphone technologies in clinical populations, and how these might be overcome by utilising co-design. It also emphasised the importance of utilising focus groups and qualitative analysis when designing and evaluating the usability, safety and efficacy of interventions. It argued that co-design suits women with CPP who are a clinically sensitive and often misunderstood population. It outlined how co-design methodologies may be used to provide features that can help facilitate therapeutic alliance.

Based on the literature review presented, Chapter 5 will outline the rationale and aims of the project, and present the research questions that were addressed.
Chapter 5.  
Aim, Rationale and Research Questions

The overall aim of this research was to design and pilot-test a self-administered CBT intervention for women experiencing CPP utilising a co-design approach. It sought to explore the acceptability of a non-face-to-face CBT intervention for CPP, design and develop that intervention, and then pilot-test it along with its evaluation measures. To meet this aim, three phases were required: an investigative phase, a design and development phase, and a pilot study. This chapter provides a brief outline of the rationale and overall aim of the project and presents the research questions associated with the three phases of the study. It is anticipated that the results of this research program will be used to inform a larger RCT in future.

5.1 Rationale

CPP in women is a complex, costly and distressing condition that affects many aspects of life (Ahangari, 2014). It is often comorbid with other psychological conditions, such as anxiety and depression (Ghaly & Chien, 2000; Savidge & Slade, 1997) and in some cases, is associated with trauma and abuse (Heim et al., 1998; McGowan et al., 1998). Its causes are complex and physical pathology does not always clearly correlate with the amount of pain and distress experienced (Dalpiaz et al., 2008; Ghaly & Chien, 2000; Weijenborg et al., 2007). A review of the literature around CPP in women shows that psychological and social factors are often implicated in the experience and maintenance of the condition (Dalpiaz et al., 2008; Weijenborg et al., 2007).

Psychological interventions, such as CBT, can be effective in the management of many chronic pain conditions (Morley et al., 2008; Niv & Devor, 2007) including those associated with pelvic pain in women (Ferreira et al., 2013; LoFrisco, 2011; Martin et al., 2000). These interventions are particularly effective when provided in the context of multi-disciplinary settings involving social workers, pain doctors and physical therapists (Peters et al., 1991; Turk & Gatchel, 2002). Unfortunately, demand for these services outstrips supply. Furthermore, CBT interventions are not always utilised even when they are available with stigma, cost, lack of time and physical disability being the greatest obstacles to uptake and engagement (Carpenter et al., 2012; Turk et al., 2008).
To overcome some of these barriers in treating chronic pain, self-administered CBT interventions have been developed and in some cases, have demonstrated effect sizes similar to those of face-to-face therapies (Fitria, 2017; Richardson, Stallard, & Velleman, 2010). Furthermore, recent technological advances, such as the widespread use of smartphones, have provided new opportunities to deliver CBT interventions outside face-to-face contexts, with growing evidence for their effectiveness in many clinical areas (Bender et al., 2011; Grist & Cavanagh, 2013; Rosser & Eccleston, 2011). Self-administered interventions have several advantages: patients can use programs at their own pace and engage in therapy in their own home, overcoming immobility and stigma barriers; they are also generally more affordable to users and can be distributed to several patients simultaneously, overcoming the resource problem and while at the same time reaching a greater proportion of the clinical population (Bakker, Kazantzis, Rickwood, & Rickard, 2016; Rosser & Eccleston, 2011).

Although effective in a range of mental health and chronic pain settings, self-administered CBT therapies have their challenges and limitations. Few apps embody evidence-based practices and few have been tested for their safety and efficacy in RCTs (Donker et al., 2013; Lalloo et al., 2015; Rosser & Eccleston, 2011). Those studies that have tested their efficacy cite attrition being the biggest obstacle, particularly for self-administered therapies not involving clinician guidance (Rini et al., 2012). Also, despite the vast number of technology-based interventions for chronic pain, few developers involve end users and clinicians in the design process (Lalloo et al., 2015). A review of intervention studies and available therapies for CPP also show there are no web or smartphone-based CBT interventions that are specifically designed for women experiencing CPP.

This research sought to overcome these challenges by involving end users and specialist clinicians in the co-design of a technology-based intervention for CPP (Dabbs et al., 2009). Researchers have advocated the use of co-design (Hagen et al., 2012) and some have published guidelines for applying it to technology based psychological interventions (Doherty 2010). By utilising co-design, this project sought a greater understanding of the difficulties and experiences of women with CPP. It also sought to check the acceptability of CBT for this client group, and to see whether technology could play a role in delivering CBT to them outside the face-to-face context.
Co-design, which empowers end-users of technology by allowing them to contribute to design (Hagen et al., 2012), provides a good fit for women with CPP who have traditionally felt their voice is not heard when negotiating treatment with medical staff (Werner & Malterud, 2003). It can also help facilitate a therapeutic relationship between end users and the technology-mediated therapies they utilise. Therefore, co-design principles and methodologies were utilised in this project to develop a technology-based CBT intervention for women with CPP. The intervention delivered a course of pain education, cognitive restructuring and mindfulness skills which women engaged with over 28 days.

The usability and efficacy of the intervention, along with the methods of investigation and instruments for measurement were evaluated through a pilot study. Qualitative investigations were also utilised to help validate the findings and understand mechanisms or barriers for change (Price et al., 2006; Souza et al., 2011) and to provide suggestions for future design improvements.

The scope of this project ended with a pilot study which yielded suggestions for refinement of the intervention. Implementing these refinements and testing the app in a large scale RCT is beyond the scope of this current project. Recommendations for refinements and RCT will be addressed in the section on future research in the concluding chapter.

5.2 Outline of the Study

The first phase of this project involved conducting focus groups with women experiencing CPP, and health professionals who help them manage their pain. If an intervention is to be created for women with CPP, then, as with all interventions, it is important to understand the condition being targeted and the people who have it (Orlowski et al., 2015). The focus group workshops provided an opportunity to ask women what treatments have or have not helped them, to check to see if they were open to utilising CBT, and if so, to obtain some insight as to what they thought would be the most effective way of delivering CBT in a non-face-to-face context. Exploring these issues with clinicians experienced in treating women with CPP in the context of their clinical practice was also an important part of the investigative process.
The purpose of Phase 1 was to answer key questions regarding the acceptability of utilising a non-face-to-face CBT therapy for managing CPP. These research questions included:

P1.Q1. Are women with CPP open to utilising CBT for their pain condition?

P1.Q2. Are women with CPP open to utilising CBT outside of a face-to-face context?

P1.Q3. If women with CPP are open to receiving CBT outside of face-to-face contexts, what is their preferred mode of receiving that therapy?

P1.Q4. If women with CPP are open to receiving CBT outside of face-to-face contexts, what design features should be considered?

The second phase involved designing and developing the intervention. The design specifications were based on the findings from Phase 1 and on evidence-based treatments described in the literature for chronic pelvic pain. This phase involved building the intervention, testing its functionality, and setting up modes of data collection within the technology in preparation for the pilot study. Given the nature of this phase of the study, there were no research questions associated in this design phase.

The final phase required to address the aim of the research program was to pilot-test the technology, to assess its feasibility, acceptability and effectiveness in helping women manage CPP. This phase also involved evaluating the data collection instruments and methods used, as this information would inform a future RCT. To meet this aim, women participated in a pilot study where they were asked to utilise a self-administered CBT intervention on their mobile phone for 28 days. Usage and survey data were collected while they used the intervention. Participants also filled in a series of psychometric measures before and after the intervention and participated in structured interviews before, during and after the intervention. The research questions for this phase include:

P3.Q1. Was the app engaging to use?

P3.Q2. Was the information within the intervention relevant and helpful for women managing CPP?
P3.Q3. Does the information gathered from the app adequately inform designers about which aspects of the app were most helpful for women managing CPP?

P3.Q4. Was a therapeutic relationship present between the user and the app?

P3.Q5. Does the information gathered from the app adequately inform designers about what aspects of the app contributed to the therapeutic relationship?

The first five related to usability, usefulness and therapeutic relationship. The next four questions relate to the primary outcome measures:

P3.Q6. Does utilising a non-face-to-face intervention for CPP help reduce pain catastrophising, and what are the self-reported mechanisms for these changes?

P3.Q7. Does utilising a non-face-to-face intervention for CPP increase pain self-efficacy and what are the self-reported mechanisms for these changes?

The final question related to the secondary measures:

P3.Q8. Do psychometric measures such as the Depression Anxiety and Stress Scale (DASS), Pain Stages of Change Questionnaire (PSOCQ), Multidimensional LOC Scale, Treatment Credibility measure, and 12-Item Short Form Health Survey (SF-12) provide useful information about what factors may have influenced PC and PSE scores, and can these measures serve as tools for screening participant suitability?

5.3 Reflexivity Statement

Reflexivity refers to the sensitivity of the ways in which the researcher and the research methods devised may shape and influence the data collected (Finlay, 2002; Shaw, 2010). It assists researchers by helping them become aware of how prior assumptions and biographical information such as cultural background, political ideology, ethnicity, age, gender and socio-economic status can influence the data collection and analysis. The process of reflexivity is an attempt to identify, acknowledge and accommodate these limitations. It is particularly pertinent in research involving qualitative data collection and analysis.

Qualitative data collection and analysis features heavily in this research project and the allocation of resources to that task makes this project vulnerable to some biases. As
the student researcher, I was the first contact for recruitment; the facilitator of the focus group workshops; the facilitator of all interviews with clinicians and pilot study participants; was responsible for transcribing and analysing the qualitative and quantitative data; and created a new set of design modifications in preparation for an RCT. My gender and professional background would have inevitably played a role in influencing the data collection and analysis process.

As a male researcher designing and evaluating an intervention for women, there were sensitivities of which I needed to be aware. My ability to understand women’s issues is hampered somewhat by my gender, and this limits my ability to fully empathise with their condition. I have done my best to listen and empathise with them, I have read relevant literature, and I am a trained practicing clinician. In time, I hope my continual clinical work will make me better able to understand women with CPP, and this project has certainly helped progress in that regard.

My previous work background was another potential source of bias of which I needed to remain aware. Before studying psychology, I worked as an IT professional developing technology to help people manage safety in their workplace. This included creating websites and smartphone apps. This project was initiated from a senior gynaecologist at the RWH who was seeking ways to provide a self-administered intervention for women experiencing CPP. The intention was for the intervention to be utilised as a preventative measure for women experiencing CPP, and an intervention that women could utilise while on a waiting list for treatment. I did my best to remain open about what format that intervention should take (e.g., mobile phone app, audio book, bibliotherapy) and offered those option to participants in the focus groups. However, my expertise in creating web-based and smartphone-based interventions was a potential bias I did my best to remain aware of during the investigations in this project.
Chapter 6.

Phase 1: Investigating Self-administered CBT for Women Experiencing Chronic Pelvic Pain

The main aim of this phase of the project was to gather data and design preferences from women who experience CPP and clinicians. This process was conducted in two stages (Table 6.1). The first involved a series of focus groups with out-patients from a women’s pelvic pain clinic. The second involved a series of focus groups and one-on-one interviews with clinicians who treat women with CPP. Data gathered in each stage were analysed collectively. These data informed a set of design principles and specifications for the purpose of developing an intervention that maximised useability and clinical efficacy for women experiencing CPP.

Table 6.1

Sequence of Data Collection for Phase 1 Including Stage 1 and Stage 2

<table>
<thead>
<tr>
<th>Members</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stage 1</strong></td>
<td></td>
</tr>
<tr>
<td>Focus Group 1</td>
<td>Women with CPP (N = 4)</td>
</tr>
<tr>
<td>Focus Group 2</td>
<td>Women with CPP (N = 4)</td>
</tr>
<tr>
<td>Focus Group 3</td>
<td>Women with CPP (N = 2)</td>
</tr>
<tr>
<td><strong>Stage 2</strong></td>
<td></td>
</tr>
<tr>
<td>Clinician Focus Group</td>
<td>Pain Specialist &amp; Social Worker</td>
</tr>
<tr>
<td>Clinician Interview 1</td>
<td>Physiotherapist</td>
</tr>
<tr>
<td>Clinician Interview 2</td>
<td>Pain Psychologist</td>
</tr>
</tbody>
</table>

6.1 Method: Stage 1 Focus Groups with Patients

Sample

This phase of the study took place in the CPP Clinic of the Royal Women’s Hospital (RWH), a public hospital for women in Melbourne, Australia. Ten out-patients were recruited. To be eligible to join, women were aged between 18 and 65 years, and had experienced persistent or recurring pain in the pelvic region for more than six
months. Understanding conversational English was also a requirement and was assumed if a patient could understand the plain language statement, and converse easily over the telephone. All women who participated in the focus groups were offered a $20 gift voucher and were reimbursed for travel or parking costs.

**Recruitment**

Women attending an appointment at the CPP Clinic were invited to participate in the study via an information flyer (Appendix A1) located in the waiting room. The flyer contained an email address which patients used to request a plain language statement and consent form (Appendix A2 & A3). After signing and returning the consent form, patients attended a scheduled focus group meeting. All participants were informed that a senior psychologist and supervising researcher would be present in the meeting. Eight participants were scheduled to attend each focus group (Krueger & Casey, 2014).

**Procedure for Data Collection**

Three two-hour focus groups were conducted using a focus group protocol (Krueger & Casey, 2014; Appendix B). At the start of each focus group, patients were asked about their experience of CPP, any treatments they had tried, and whether they felt that psychology could play a role in helping them manage their condition. They were then taken through some mindfulness and CBT exercises and asked to provide feedback on their experiences and feelings about the suitability of those exercises for managing CPP. The focus group discussions then turned to technology use. Patients were asked about their use of smartphones and other consumer technology and were presented with some initial design ideas for an online app-based CBT intervention targeting CPP. Based on feedback from the first focus group, design prototypes were created and presented for discussion and refinement in subsequent focus groups. This process was repeated until the focus groups yielded no new design ideas. In total, three focus groups were required to exhaust this iterative design process.

**Instruments Stage 1: Focus Groups with Patients**

Focus groups were selected over individual interviews as a means of collecting data from patients and clinicians (Krueger & Casey, 2014; Thomas et al., 1995). Focus groups provide several advantages: They provide a more efficient means of gathering data from multiple persons within a short space of time; they provide a rich data source
through group dynamics and social interaction; and they can illuminate differences in perspectives between individuals through group discussion. Krueger and Casey (2014) suggest that approximately two hours is optimal for a focus group session. Although the optimal number of participants may vary, they suggest between six to eight participants provides a good balance between manageability and variety of perspectives.

Multiple focus groups were planned so responses from earlier focus groups could inform later ones. For example, preferences for design ideas from early focus groups were presented for discussion in later ones. This iterative process was repeated until no new design ideas were generated. This iterative process was also utilised to refine mindfulness and relaxation exercises which were presented in earlier sessions, and then modified and presented in later sessions.

For each of the three focus groups a research protocol was followed (Appendix B). The discussion questions in the protocol were grouped into three sections: 1) experience of CPP; 2) views about psychological factors; and 3) views about technology. The questions presented to participants are described here and presented as sub-headings.

**Experience of pain.**

*Does anyone want to discuss their pain experience and the impact CPP has had on their life?*

This broad question was used to start a discussion about women’s pain experiences, how the pain impacted their lives, and the effective and non-effective treatments they have tried in the past. It was important to get a clear picture of their day-to-day experiences of living with pain within the context of their social, intimate, and family lives.

**Views on psychological factors.**

*Do you think psychology can play a role in helping women with CPP?*

Some people who experience chronic pain may react negatively when it is suggested there might be a psychological component to their condition. It was important to know if women with CPP thought psychology was appropriate and could play a role in helping them manage their pain condition - and whether they had any experience with psychological treatments in the past.
Can you think of any times when your thoughts influenced your pain experience?

To test the suitability of CBT, it was important to know if women with CPP were able to understand how thoughts might influence their experience of pain and how it might contribute to pain related disability. In this part of the sessions, CBT examples were presented, and reactions were carefully noted and discussed in detail. It was important to know if the women felt that changing unhelpful thoughts was something that might be within their control.

Could anxiety, stress and tension influence a pain experience?

Educational material that is used in chronic pain clinics was presented to the group. Given the overwhelming amount of clinical information available around chronic pain, it was important to identify what elements were going to be most informative, relevant, and helpful for women experiencing CPP. It was also very important to determine what information might be unhelpful or potentially alienating.

Please describe your experience of the mindfulness exercise and rate its usefulness.

After each mindfulness exercise, patients were asked to provide detailed accounts of their experience. It was not only important to determine if the exercises were helpful, it was important to check that no adverse effects resulted from the exercises. The women were also asked if they had any adverse experiences with mindfulness relaxation exercises in the past.

Views about technology.

Do you use digital technology, or any health-related apps or websites?

Patients were then asked about general technology use and if they had used technology to help them manage their pain or any other health issues. They were also asked if they were open to receiving psychological therapy outside face-to-face contexts.

If you were to receive therapy outside of a face-to-face context, how would you prefer to receive it?
This question followed on from the previous discussion question. Ideas on how psychological therapy could be delivered most effectively outside face-to-face contexts, and how using technology might fit into their daily routine was discussed. Patients were asked to consider whether they preferred receiving therapy via CDs, DVDs, websites, books or mobile phone apps.

*Do you have any suggestions on how this therapy could look, how it would work, and what features it should have?*

Depending on responses to the previous question, patients were then asked to clarify exactly what a non-face-to-face CBT intervention might look like and what features it would ideally include. Some website and app interface designs were also presented, and users were invited to rate their preferences for each. Finally, patients were presented with pens and paper and invited to draw some designs and present ideas on a whiteboard.

**Data Analysis Stage 1**

This phase of the study employed thematic analysis as a means of analysing the focus group and interview data (Braun & Clarke, 2006; Bryman, 2015). Thematic patterns were identified using an inductive (‘bottom up’) approach rather than a deductive (‘top down’) approach. This inductive approach suits focus group discussions and open-ended interview questions as themes are strongly derived from the data themselves, rather than from a theory or hypothesis (Patton, 1990). Furthermore, this process can facilitate the generation of innovative design ideas as the analysis does not try to fit into a pre-existing framework and is independent of the researcher’s analytic preconceptions (Braun & Clarke, 2006).

To analyse the data, focus groups and interviews were audio-recorded and transcribed verbatim. Instances where information was repeated by the same individual, or information provided was not relevant to the study were removed, leaving only key responses. Key responses were then coded, and similar codes were grouped together to create themes (Bryman, 2015). In instances where multiple ideas were generated through discourse between individuals, each specific idea was coded, and similar codes grouped together to form additional themes.
Although it was anticipated that some themes may conform to the questions proposed, the focus-group protocol questions (Appendix B) were ignored during the coding to facilitate maximum independence from any pre-existing ideas. After the analysis was complete, the protocol questions were then used to categorise themes, but only in instances where the themes conformed to the questions. There was no attempt to categorise responses according to any theory.

Instances where coded responses or discourse were met with general consensus (or disagreement) were specifically noted. Suggestions that seem to generate consensus (or disagreement) across all three focus groups were given the greatest weight. Also, coded responses to design ideas from previous sessions that were presented and validated in subsequent sessions through the iterative process were also given the greatest weighting.

The transcriptions of the focus group responses, and the coded data did not identify any specific individuals, but rather considered responses collectively within a particular focus group (i.e., FG1, FG2 and FG3). As suggested by Krueger and Casey (2014) data were reported using lay terminology supported by quotations from participants. Information from individuals such as age, number of years since pain started or clinical diagnosis were not collected from participants.

A two-step data verification process was instituted for the focus group data. In the first step, a short excerpt of the raw transcript from the focus groups was randomly selected by the student researcher. The audio recording corresponding to that transcript was selected and replayed by the student researcher to check the transcript corresponded correctly to the recording. This process was repeated three times. In the second step, the analysed data of all the focus groups were then presented to the senior psychologist and supervising researcher, who were both present in each focus group. In each session, there were always two researchers, one being a psychologist. This ensured pertinent discussion points and responses were not overlooked.

6.2 Results: Stage 1 Focus group with Patients

Three focus group sessions were conducted, and ten women participated in total. Although it was intended that each group contain between six and eight participants, recruitment proved challenging. Eight participants were scheduled to attend the first two sessions, and four were scheduled to attend the third session, however, only half the
participants attended each of the three sessions. Focus groups were scheduled at 6pm to accommodate work commitments, but pain, inability to find a babysitter, and feelings of anxiety were cited as the principal reasons for not attending. Two women attended in wheelchairs, and more than half were accompanied by their partner or family member. Most participants appeared either visibly distressed or had restricted movement due to their pain although they did not verbalise this distress at any stage during the focus groups.

Participants were open, friendly and respectful to each other. They were enthusiastic about presenting design ideas, and there were very few differences in opinion and perspectives within the group. The focus groups started with questions about the experience of pain, then moved on to views about psychological factors, and then discussed technology.

In the following section, each focus group protocol question will be presented as a section heading with a summary of the key responses. In most instances, themes were derived from the questions asked, however, in some instances new themes emerged from open ended discussions. In instances where new themes emerged, the section under which those responses support that theme will be prefixed with the term “Emerging”.

**Experience of Pain**

*Does anyone want to discuss their pain experience and the impact CPP has had on their life?*

Most women reported that they felt few doctors, partners, family members and friends really understood the extent of their pain and how much it impacted on their life:

*It took a long time for my husband to accept that I am not crazy.* – FG1

*Not even my mother understands, even though she has taken me to emergency so many times.* – FG3

Others felt as though their life was “on hold” while they were waiting for a solution. This was typified by this quote which prompted acknowledging nods from the rest of the group:
Everything is about waiting. Waiting for the next operation and hoping it will help. Waiting to feel better before dating. Waiting for pain medication to work. Waiting for my next appointment. – FG2

**Emerging: Experience with medical professionals.**

Almost all patients had at least one occurrence where they were taken to the emergency department after experiencing an episode of intense pain. One patient reported that doctors in emergency dismissed her pain as period pain. Others in the group reported that they had the same experience:

*There was a tearing sensation up the front and down the back that made me double over and pass out... “no idiots, it’s not period pain!”* – FG3

Many patients complained about the way they were treated by certain doctors and medical staff:

*You have to keep nagging your doctors. Some are just sick of their job and have been in it too long.* – FG1

*Doctors are very dismissive and miss critical pieces of information.* – FG1

*Don’t tell me it’s all in my mind. That scares me even more. How can my mind create something this bad?* – FG2

**Emerging: Chronic pelvic pain and intimacy.**

Some women reported that they were afraid of losing their partners, some avoided relationships altogether, while others in relationships avoided any form of affection in fear that contact might inevitably lead to painful penetrative sex. One participant typified these concerns:

*What is going to happen when I am old? Who will love me? I don’t want to live another 20 years alone like this.* – FG1

When asked if they had discussed their feelings and fears around intimacy and body image with their therapist, most said they had not, citing embarrassment and stigma as typical reasons. One participant stated that communicating with intimate partners and reassuring them was her biggest challenge:

*I had a partner who thought for a long time that he was the cause of my [pelvic] pain.* – FG2
Participants suggested that an app could offer education on how to navigate difficult conversations about sex, and some provided suggestions for useful ways to initiate the topic of intimacy with partners and health professionals. These suggestions were presented to women in later focus groups, who also acknowledged them as important inclusion in an intervention for CPP.

**Views about Psychological Factors**

*Do you think psychology can play a role in helping women with CPP?*

When asked if there was a role for a psychologist to help with pain management, most patients felt that psychological therapy can play significant role in helping them manage CPP. One participant stated:

*Psychologists help you realise whatever you were going to realise anyway, but much sooner. – FG2*

For those who had positive experiences with psychologists, the most helpful aspects included: learning to use metaphors for pain; doing relaxation exercises; having an empathetic ear to talk to; being reassured they were not ‘crazy’; and linking pain experience to psychological states. One participant reported that a psychologist was an important part of her pain management:

*Things changed for me when my psychologist helped me realise that I have a real illness, and the symptoms get worse depending on my mental state. – FG2*

Negative stigma and the implication that pain was ‘all in the mind’ were the biggest factors for one participant who did not want to visit a psychologist:

*I do not want to be labelled. And I do not want other people to think I am crazy. I get that enough. – FG2*

This person was, however, open to the idea of engaging in psychological therapy with an electronic device. Another participant suggested that she was reluctant to be completely open when speaking with her psychologists, in fear that she may be diagnosed with a disorder which might limit her professional options.

*Can you think of any times when your thoughts influenced your pain experience?*
One woman reported that cultivating an attitude of acceptance towards her pain was a big step forward for her, however, she reported that this realisation only occurred through collaborative reflection with a therapist she trusted:

*I trusted the [pain management] method because of the way the person delivered it. The way she explained it helped me get on board.* – FG3

**Could anxiety, stress and tension influence a pain experience?**

When presented with a cognitive restructuring exercise that illustrated how thoughts can alter a pain experience, all the women in the group understood how those mechanisms worked:

*Sometimes it’s good to admit I am the cause of my own suffering.* – FG2

*This [CBT] is good, but you need energy to fight off negative thoughts.* – FG2

When patients were presented with general psycho-education around pain and its triggers and avoidance behaviours, most agreed that the information presented reflected their own personal experiences. They welcomed good, reliable information. One participant stated:

*On the Internet, you read 100 unhelpful posts before you come across one good one.* – FG2

However, when they were asked if hearing testimonials from other women with CPP could be helpful, most patients thought it was not a good idea. This response typified the feeling in the group:

*They [testimonials] can be demoralising and make things seem worse than they are.* – FG2

**Please describe your experience of the mindfulness exercise and rate its usefulness.**

Some women were initially doubtful that they could do the mindfulness exercise during the focus groups with one participant reporting she had an anxious reaction to a hypnosis exercise in the past. Nevertheless, all participants reported that they felt relaxed after the exercise, apart from one who had to open her eyes as she began to feel uncomfortable. In later focus groups, pre-recorded mindfulness exercises with sound
effects were presented to patients. Most women reported that the exercises were effective as a relaxation tool. They commented that the tone of voice in the recording was relaxing and the exercise was delivered in a calming manner.

Following the positive response to the mindfulness relaxation exercises, a pain visualisation exercise was conducted. Patients were initially asked to focus on their out-breath, release any tension in their body, and then focus directly on the pain sensation in their body and describe it in detail while remaining relaxed. When asked for feedback on this session, some women reported they felt relaxed and noted a mild shift in their pain, however others were distracted by the way the exercise was delivered:

- *I didn’t want you to suggest what my pain looked like! Make the ideas more open ended.* – FG1

- *Ask, don’t dictate. Let me come to the conclusion myself.* – FG1

- *Telling me to release the tension is better than telling me to relax. It is better for me to do something, rather than wait for something to happen.*
  – FG1

Some women in the first focus group also suggested that the pace of the exercise was too fast, and that they would have preferred fewer suggestions and a more open-ended approach. These suggestions, along with some of the suggestions presented in the quotes were incorporated into subsequent focus groups with better results. In focus groups two and three, most women noticed a reduction in their pain during the exercise.

**Views about Technology**

*Do you use technology, or any health-related apps or websites?*

All patients aside from one reported owning a mobile phone and using apps such as *Period Tracker, Toilet Finder, One Giant Mind* and *Headspace* to help them manage aspects of their CPP condition. Patients reported using websites for clinical information, such as *Chronic Illness Cat* (through Facebook), *WebMD* and *Google* search (to source information about diseases and remedies.) One woman used affectionate language when describing her favourite apps and sites, and this was met with agreeable remarks from some other members of the group:

- *Toilet Finder app is a god-send. I can’t live without it.* – FG1
If you were to receive therapy outside of a face-to-face context, how would you prefer to receive it?

Most patients felt that technology-mediated therapies would be more convenient than visiting a psychologist. One participant stated:

*I do not like the idea of taking a day off work to see a psychologist…I would rather sort it out myself with an app.* – FG2

All women confirmed that they were unaware of any existing app or online therapy that targeted CPP specifically, and that they were mostly interested in using a mobile phone app for CPP. When asked how using that app would fit into their daily routine, patients suggested that 15 minutes a day every day was a reasonable amount of time to expect. However, one participant stated this could be a challenge:

*You need to create space in your life, but women do not give themselves the permission to have that sort of space.* – FG1

In response to this statement, patients reported that if the therapy was on a mobile phone then it was more likely that they would find the time and appropriate place to do the exercises. Also, some patients liked the idea of having a treatment ‘on hand’ in case they needed to use it unexpectedly.

Do you have any suggestions for how this therapy could look, how it would work, and what features it should have?

Given the openness of the patients to utilise a non-face-to-face CBT intervention for CPP, patients were then asked to clarify exactly what that non-face-to-face therapy would look like. CDs, DVDs, websites, books and phone apps were presented as options. It became immediately clear that the preferred mode of delivery was a mobile phone app. Therefore, screen shots of existing pain and relaxation apps, as well as relaxation themed photographs and web designs were presented for discussion and critique (Figure 6.1). Although there was no preference for a colour scheme, one woman made a comment about the colour pink. This was met with unanimous agreement from the rest of the group, and was also endorsed in subsequent focus groups:
Whatever you do, do not make it pink. Why does everything that has to do with women always have to be pink? It’s degrading. – FG1

The iterative nature of the focus groups also provided opportunities for patients to create their own designs, with some ideas presented for comment in subsequent groups. Overall the consensus was that the technology needed to be simple, calming and relaxing. Preference was for relaxing sounds (no high-pitched noises) and for a simple user interface. Suggestions included the following:

Typing things into an app is really annoying [all agreed]. – FG1

It better not be complicated or you will lose me. – FG1

It needs to be a pleasant place to go [all agreed] – FG2

The idea of receiving therapeutic content through sound-only (i.e., no visuals, no text, no typing) was most appealing to all users. Patients also unanimously agreed that videos were annoying and inappropriate and provide too many opportunities for distraction from the message (e.g., hair styles, clothes, inauthentic facial expressions). Therefore, the preference was that the app deliver content through audio-only. One user noted that voice-only was a far more engaging mode of delivery than video. There was no special preference for a male or female voice, however, there were suggestions that the voice needed to sound soothing:

A baritone register is really calming. - FG1
In subsequent focus groups, patients were presented with pre-recorded mindfulness exercises using a male voice and sound effects. The audio scripts were well received, and most patients found them relaxing and preferred to listen to the audio sessions with eyes closed. When asked what other features the app could include, some suggested that an app should offer education on how to navigate difficult conversations about sex and provide suggestions for useful ways to open up the topic with intimate partners and health professionals.

**Emerging: Format of daily therapy sessions.**

In the first patient focus group, participants reported that the app needed to feel calming when they first open it up. In response to this suggestion, it was proposed that each 15-minute daily session could start with three minutes of relaxation, followed by five minutes of education, and end with seven minutes of skill building exercises. In focus groups two and three, women agreed that this format would provide them with “a nice place to go” followed by informative education, and then the development of skills they need to manage their pain.

At the end of each focus group, patients were thanked and given a $20 gift voucher. Most reported that they enjoyed the sessions and talking with other women. They felt comforted to know that they were not alone in their journey, and were happy to be able to contribute to what they thought was a relevant and necessary piece of research. No patients reported any adverse reactions from participating in the sessions.

### 6.3 Methods of Investigation Stage 2: Clinicians

**Sample**

This sample comprised four clinicians: a pain specialist (anaesthetist who manages pain medicine, monitors potential organic causes of pain and provides pain education); a physiotherapist (who specialises in women’s health); a social worker (who addresses psychological, behavioural, and cognitive aspects of CPP); and a senior health psychologist who had 20 years’ experience working with people who have experienced chronic pain and trauma. No rewards or incentives were given to clinicians for participation.

**Recruitment**
Three of the four clinicians who were invited to join the study worked at the CPP Clinic of the RWH in Melbourne, Australia. These three clinicians were approached at the clinic where they signed a consent form and agreed to take part in a scheduled focus group meeting. The fourth clinician was an experienced chronic pain psychologist who was recommended by the other three participants. She was recruited via telephone and interviewed in her private clinic.

**Procedure for Data Collection**

As suggested by Muller (2003) each of the focus groups was scheduled to take place in the clinics where the clinicians worked. Although one focus group with three clinicians was scheduled, one clinician could no longer attend at the scheduled time and was interviewed one-on-one at the clinic later. Another interview with a pain specialist was not initially scheduled, however, it was recommended based on the discussions in the first focus group meeting. All focus groups and interviews were audio recorded then later transcribed.

**Instruments Stage 2: Focus Groups and Interviews with Clinicians**

As with the focus groups involving patients, focus groups with clinicians were selected over individual interviews as a means of collecting data from patients and clinicians (Krueger & Casey, 2014; Thomas et al., 1995).

Interviews with pain clinicians provided an opportunity to obtain clinical expertise on treatment approaches and discuss any positive or negative clinical experiences around treating women experiencing CPP. It also provided an opportunity to obtain opinions on the design suggestions put forward in the focus groups with patients and discuss clinical issues that might arise from delivering psychological therapy to this patient group outside usual face-to-face contexts. The questions presented to participants are described here and presented as sub-headings with an explanation outlining the rationale for asking it.

*How does working with women with CPP differ from patients presenting with other chronic pain conditions and do you think CBT is appropriate for this client group?*

The literature on chronic pain is vast and covers many different chronic pain conditions. Yet, specific information about CBT treatments for women with CPP is
limited, and targeted calls have been made for more research (Souza et al., 2011; Stones et al., 2005). Therefore, it was important to understand from experienced clinicians how women with CPP differed from patients experiencing other chronic pain conditions, and how the complexities of the condition were handled in practice. Learning about any ineffective treatments or negative experiences was also important to avoid any common pitfalls.

There are few chronic pain clinics that specialise in the treatment of women with CPP. Therefore, these interviews provided a unique opportunity to ask treating clinicians who have experience working with women with CPP if they thought CBT was an appropriate intervention. If it was deemed appropriate, then obtaining a clinical perspective on how CBT could be administered to this patient group was valuable to learn.

**How do you maintain rapport with women with CPP?**

A common complaint from women with CPP is the difficulty they have in communicating their needs to doctors and medical staff (Twiddy et al., 2017). They often report feeling dismissed and uncared for (Toye et al., 2014). It was important to discuss these common complaints with treating clinicians and obtain their perspective on why they thought women with CPP might feel this way. Learning how clinicians maintained good rapport with their patients was also necessary so those principles could be applied within the intervention design.

**How do you approach the topic of intimacy with women experiencing CPP?**

Given the topic of intimacy was raised in the focus groups with patients, clinicians were asked how they approached topics of intimacy and sex with women experiencing CPP.

**Do any of your patients use apps, websites or other technology for their pain?**

This question was designed to determine how open this patient group was to using technology to manage their pain, and if the clinicians had any experience administering technology-based therapy with this client group.
Do you think the mobile phone app we are looking to design will be engaging for patients and clinicians in your clinic, and do you have any suggestions for how we could make it more engaging?

It was important to obtain a clinical perspective on the design specifications proposed for the app and if they thought it was appropriate for women experiencing CPP. These questions also provided an opportunity to elicit ideas about which features clinicians thought would make the app more engaging to use.

Do you think that CBT, mindfulness breathing and skill-building exercises we are proposing for the app are relevant for women with CPP?

The therapy proposed in the intervention required users to learn a range of mindfulness breathing exercises and apply them in the context of their pain. It was important to get a clinical opinion about the appropriateness of these exercises, particularly the two-breath, five-breath and ten-breath exercises which were proposed as a learning outcome of the intervention.

Data Analysis

The focus groups and interviews with clinicians were audio recorded and later transcribed. As with the focus group sessions with patients, thematic analysis was used to analyse the clinician data using an inductive (‘bottom up’) approach (Braun & Clarke, 2006; Bryman, 2015; Patton, 1990). For each question presented in both the focus groups and interviews, individual responses were coded, and similar codes were grouped together to create themes (Bryman, 2015). For questions pertaining to design ideas, an integrative approach was then used to analyse the data whereby the clinician responses were collected and categorised within the themes already created from the patient data in stage one. This allowed a more formalised way of integrating the clinical perspective within the existing patient data. Instances where coded responses from clinicians differed from patient responses were specifically noted. Unlike the patient data, individual clinician responses were identified by profession (i.e., pain specialist, physiotherapist, social worker). The data were reported using lay terminology supported by quotations (Krueger & Casey, 2014).

6.4 Results Stage 2: Focus Groups and Interviews with Clinicians
The information gathered in the series of focus groups from clinicians is presented here within section headings that represent the questions asked. Specific responses from clinicians that related exclusively to medical interventions (e.g., injections and dry needling) were not included in the analysis. Only responses that provided insights into how women with CPP manage their condition, the issues they face in treatment, and general responses that can be applied to psychological treatment and pain education were included.

**How does working with women with CPP differ from patients presenting with other chronic pain conditions and do you think CBT is appropriate for this client group?**

Consistent with the existing literature, clinicians all agreed that women with CPP are among the most complex and difficult group of pain patients to treat. One clinician stated:

_They are highly somatic focused, more so than normal. They are more complex psycho-socially and there is generally more trauma involved. Certainly, more than in the general community._ – Pain Specialist

When asked about how the complexities of CPP were handled, one clinician stated that helping women understand the pain-fear cycle was particularly important:

_It is important to recognise how the fear creates the expectation of pain, which in turn creates more pain._ - Physiotherapist

Clinicians also reported that patients with CPP often present with comorbid conditions such as anxiety and PTSD. One clinician stated that for patients with comorbid conditions, providing them with a correct medical diagnosis can sometimes make all the difference:

_When a person is in pain, their world is contracted. In this state it is difficult for patients to focus on anything. But when they get diagnosed as having stage 3 or 4 Endometriosis, you see their lives suddenly open up._ – Pain Specialist

When asked to present a perspective on the psychological management of pain, and the use of CBT, all clinicians agreed that the psychologist’s role was amongst one of the most important roles in the multi-disciplinary team:
Psychology is most important. You can’t run a pain clinic without a psychologist. – Pain Specialist

How do you maintain rapport with women with CPP?

One clinician stated that maintaining rapport is not a general principle and is something that is specific to each patient:

It depends on the patient. Some are low functioning and can’t bath or walk so rapport is difficult. Others are brighter and more motivated and it’s easier. – Social Worker

Another clinician cited communication as the most important factor in maintaining rapport:

I think the language you use is the most important thing. – Social Worker

How do you approach the topic of intimacy with women experiencing CPP?

Although all clinicians understood the importance of having discussions around intimacy, only one had such a conversation with a CPP patient in the past. The clinicians cited embarrassment, stigma and lack of time as the main reasons for not engaging in conversations around intimacy. Each felt, however, that a mobile phone app could overcome these barriers. One clinician stated:

In our clinic, sex is the lowest priority, but the idea of increasing their ability to communicate about sex through the app is a really good idea. – Pain Specialist

Do any of your patients use apps, websites or technology for their pain?

All clinicians stated that their patients use Google, Facebook and WebMD (a website which provides medical information) to obtain information about their condition, although the information is generally about medical diagnosis and not pain management:

Most of my patients are using apps for period and ovulation tracking. They also use forums and Facebook groups. - Physiotherapist

Do you think the mobile phone app we are looking to design will be engaging for patients and clinicians in your clinic, and do you have any suggestions for how we could make it more engaging?
One clinician stated that it was important to reassure users that the app would not make them feel worse, and that it is designed to help them. Another clinician was more sceptical in her response, suggesting that the benefits may in fact need to be understated:

*Remember there are secondary benefits to the pain. If they think it will work, they may not want to use it.* – Pain Specialist

However, she also added that an app could be helpful in augmenting their existing treatments:

*I think an app would be really good for these women so they can use it all the time. Some women we only see us once a month and in-between those sessions they could be doing work with the app. That would be very helpful.* – Pain Specialist

**Do you think CBT, mindfulness breathing and skill-building exercises we are proposing for the app are relevant for women with CPP?**

All clinicians unanimously endorsed the two-breath, five-breath and ten-breath breathing skills and suggested CBT was an appropriate intervention for women with CPP. When asked about the pain visualisation exercises involving the breath, some clinicians were concerned, particularly given the likely trauma background of women with CPP. One comment summed up this overall feeling:

*There is a risk of patients experiencing disassociation and flashbacks. I think it would be good to talk to a PTSD expert about mindfulness and what exercises might trigger adverse reactions.* – Pain Specialist

In response to these suggestions, an experienced psychologist who worked in the area of trauma-related chronic pain was interviewed. She reported that in her practice she first establishes a psychological safe space with her client before engaging in mindfulness or pain visualisation exercises, particularly in instances where the client may have suffered trauma in the past. This safe space includes pleasant imagery and reassurance so if an adverse reaction occurs, the user can be led back to her safe space.

### 6.5 Discussion

This discussion is built around the research questions proposed in Chapter 5 for this phase of the project.

**Research Questions**
P1.Q1. Are women with CPP open to utilising CBT for their pain condition?

Women with CPP responded positively to the CBT and mindfulness exercises and appeared open to utilising psychological strategies to address their pain. Some reported helpful experiences with psychologists in the past, and some were already aware of how their mental states affected their experience of pain. This is consistent with the literature which shows CBT can be helpful for a range of gynaecological complaints in women (Ferreira et al., 2013; LoFrisco, 2011; Martin et al., 2000) and has strong clinical efficacy for many chronic pain conditions (Vlaeyen & Morley, 2005).

Consistent with the literature, some women reported that they were reluctant to engage in psychotherapy, citing stigma, cost, and lack of time as reasons (Rini et al., 2012). Others were concerned about being labelled with an unhelpful psychological condition that may limit medical treatments, while others feared the distress of being told that their pain was “all in their mind” (Souza et al., 2011; Twiddy et al., 2017; Werner & Malterud, 2003). Despite these responses from patients, clinicians emphasised the importance of psychotherapy in their multi-disciplinary clinic. They suggested that although administering CBT to women with CPP may be challenging, it was an appropriate and valuable intervention for this client group.

P1.Q2. Are women with CPP open to utilising CBT outside of a face-to-face context?

The focus group and interview data suggest that some women with CPP are open to utilising CBT as part of their pain management strategy; and willing to try it in a non-face-to-face context with some citing that as a preference. This is consistent with some studies that have shown there are patient groups who, if given the choice, would prefer to receive psychology therapy outside face-to-face contexts rather than in person (Cuijpers et al., 2009). One clinician stated that utilising an app could be helpful in augmenting existing treatments. She reported that the app could provide avenues for consistent engagement that is not otherwise possible in a clinic where clients are seen monthly.

P1.Q3. If women are open to receiving CBT outside of face-to-face contexts, what is their preferred mode of receiving that therapy?
The data suggested that women with CPP preferred to use their own mobile phone, rather than use CDs, DVDs, or computers. They did not want to carry around another device and appreciated the convenience of having a therapy on a device that they already carry with them. Those who had used health related apps before indicated that they were not aware of technology that specifically targeted CPP. The women also emphasised that any app that was created for them would need to be easy to use and suggested “audio-only” as a preferred mode of delivery. The participants unanimously agreed that they did not like watching videos or typing information into a small screen.

The iterative nature of the focus groups provided opportunities to create some prototypes and present them in subsequent sessions. These prototypes were met favourably. Data from clinicians suggested that women like to use their mobile phone for managing other aspects of their health (e.g., period and ovulation tracking) and are therefore likely to be open to utilising a pain intervention on their mobile phone.

**P1.Q4. If women are open to receiving CBT outside of face-to-face contexts, what design features should be considered?**

In this phase of the study, both patients and clinicians provided useful design suggestions for the intervention. The general consensus was the app had to be simple; easy to use; it needed to be a relaxing and calming experience for the user; and it needed to avoid any use of the colour pink. Given the experiences of this user group, it was important for the information in the therapy to be delivered in a non-judgmental and emotionally validating manner, using a carefully considered choice of language. Although most users felt that the expectation to use the app daily for 15 minutes was reasonable, some women anticipated that they would grow tired of using the app if they did not feel they were making progress in some way.

Although clinicians suggested that an audio-based self-administered CBT intervention for CPP would be an acceptable and appropriate intervention for women experiencing CPP, there were some safety concerns. For women with longstanding CPP, experiences of trauma and PTSD symptoms are more likely to be present relative to the general population (Meltzer-Brody et al., 2007). Moreover, some mindfulness exercises may evoke unpleasant reactions for persons with these backgrounds (Banks et al., 2015). An experienced pain psychologist provided some useful tools and
suggestions which were incorporated into the technology and pilot study in response to these safety concerns.

**Ethical Considerations**

Many people who experience persistent pain search for a cure, as their primary goal is to escape from pain (Ghaly & Chien, 2000; Kennedy & Moore, 2005). Therefore, it was critical to communicate clearly that the purpose of the focus groups was to obtain information from women experiencing CPP, and that group therapy or counselling was not being offered. As it is common for women with CPP to feel that doctors do not take their condition seriously (Price et al., 2006) it was also important to be sensitive to the possibility that asking patients to contribute to discussions around psychological therapy for CPP may lead to the perception that the researcher believed that CPP is a psychological problem with no medical basis. Furthermore, the focus group offers a platform where different participants can present differing opinions, and so disagreements among participants needed to be resolved respectfully. Differences in the degree of personal disclosure made by different participants also needed to be managed respectfully.

Some women who experience CPP find sitting for long periods of time uncomfortable (Engler et al., 2013). Therefore, checking in regularly with how patients were feeling, and encouraging movement and stretching, were important considerations in the administration of the focus groups. Pain-related disability was also a factor. Some of the most enthusiastic patients could not attend a session because of their pain, while one attended in a wheelchair.

CPP is often associated with trauma (Meltzer-Brody et al., 2007). Therefore, discussing past experiences or asking patients to calm their mind and focus on their breath has the potential to trigger unpleasant memories and adverse reactions (Banks et al., 2015). At recruitment, patients were advised that a senior clinical psychologist would be present at each of the focus groups. Also, to minimise the possibility of distress occurring, each mindfulness breathing exercise was followed up with a brief discussion before longer and deeper forms of relaxation were presented. At completion of each focus group, participants were invited to stay behind and converse with the psychologist if they felt it was needed. One week after each focus group, patients were
contacted again to check how they were feeling. Ethics approval was granted by the hospital for this phase of the project (RWH ethics project number 15/06; Appendix A4).

**Strengths and Limitations**

A strength of this phase was the student researcher (first author) who conducted the focus groups and interviews, was a provisional psychologist with experience working in multi-disciplinary pain clinics. The clinical knowledge, along with counselling skills, helped facilitate in-depth discussions thought the use of open ended questions and reflective listening. The clinical knowledge also provided opportunities for informative discussion around the use of CBT in managing the complexities of CPP in women. Furthermore, gaining insights from women with CPP first-hand evoked a level of empathy and provided a level of understanding for this client group that would not otherwise be possible by reading the literature on CPP. Given the researcher is also responsible for the design and development of the intervention, this level of empathy may prove to be valuable in the development phase of the project. The student researcher’s experience working with other clinicians in multi-disciplinary teams, his clinical knowledge, and the use of clinical language was also helpful in adding depth to the focus groups and interviews with clinicians. This strength also raised some considerations regarding reflexivity which were detailed in the previous chapter.

Focus group size may be considered a limitation of the study. The first two groups contained four participants, and the final only two. Krueger and Casey (2014) suggest that the optimal number of focus group participants may vary and suggest six to eight provides a good balance between manageability and variety of perspectives. For women experiencing CPP, it is difficult to ascertain if large group numbers would yield richer information. The nature of the material discussed in the sessions was highly personal and at times graphic and explicit. Although it is difficult to determine, it is possible that the smaller groups may have facilitated a necessary level of intimacy for this patient group. Another limitation of this phase of the study was that further focus groups were not conducted after the intervention was created. This would have provided informative feedback and suggestions how the technology created could be further improved. Although the data in this phase confirms that the intervention needs to be simple and engaging and deliver treatment in a manner that is empathetic and emotionally
validating, how well these objectives were met was not known until after the pilot study was complete.

**Conclusion**

The data from this phase of the study affirms that CPP is a difficult condition to treat, it is distressing to the individual, is associated with disability, and is comorbid with other psychological conditions. Further insights were obtained in this study that were not explicitly stated in the literature but provided useful information for the design and evaluation of the intervention. Some women with CPP can feel a perpetual sense of ‘waiting’ that can be debilitating: waiting to receive treatments; waiting to see if surgery works; waiting for menstrual cycles to pass; waiting for drugs to work. Some women feel time poor and prioritise their family over their own well-being. Some feel isolated and although they feel the need for affection in their intimate relationships, they avoid it in fear of the intimacy turning into painful sex. They avoid relationships altogether as they cannot meet the demands of physical intimacy. Some women reported that their partners sometimes feel responsible for the pain women experience. Although many qualitative interviews have been conducted, this is the first study to adopt focus groups.

The focus groups also showed that some women experiencing CPP are open to utilising non-face-to-face CBT intervention for their pain. They showed a preference for receiving the intervention on their phone rather than through a book, CD, video or laptop/computer. The participants indicated that the intervention needed to be easy to use and “audio-only” was the preferred mode of delivery. Typing information into a phone, watching videos or reading information on a small screen were all described as potential obstacles to engagement. The comments of the women in the focus groups suggested that if the CBT intervention was delivered through a mobile phone and incorporated 15 min of interaction a day, then the challenge for designers would be to make each encounter with the app pleasant to use and engaging for the user over the 28 sessions. The next chapter outlines some of the underlying principles that informed the design of the intervention and presents a detailed description of the development phase of the research project.
Chapter 7.
Phase 2: Intervention Design and Development

The aim of this phase of the co-design process was to utilise the data gathered in the previous phase and develop a technology-based CBT intervention for women with CPP. This chapter outlines the development of that intervention, and the theoretical principles that informed its design. It also presents the individual elements that made up the intervention and presents supporting evidence for each component. The intervention was then pilot-tested in Phase 3 of the research program with women experiencing CPP.

7.1 Design Principles and Therapy Goals

This section covers the underlying principles and goals considered to be most important in developing the self-administered intervention for women with CPP. These principles and goals were derived from the Phase 1 data and the literature on CBT interventions for chronic pain. They were used to guide the development of the app.

Clear Goals and Achievable Skills

The aim of the intervention was to build a simple, yet effective, toolkit of skills that users could learn. RCTs and pilot tests of technology-based psychological therapies generally run from four to eight weeks in duration (Heapy et al., 2015). One study similar to the current one was conducted by Kristjánsdóttir et al. (2013). In this study, they tested a 28-day CBT-based smartphone intervention seeking to reduce PC and increase PSE in women with chronic widespread pain. Therefore, to make meaningful comparisons with other studies, it was decided that the intervention in this study would be 28 days. This time duration affords enough time for women to learn the skills required, while minimising the risk of attrition through a more extensive program.

The skills learned over 28 days were designed to help women manage unhelpful pain-related thoughts and feelings, notice and release tension, manage acute pain flare ups, and build self-efficacy in their day to day lives. In the focus group sessions, participants responded well to mindfulness and cognitive restructuring exercises. During one breathing and visualisation exercise, more than half of the focus group participants experienced some level of relief from their distress. Collectively, this provided reassurance that learning breathing exercises, along with cognitive restructuring may be
useful for women experiencing CPP. Furthermore, learning these skills was an attainable goal. If taught in a systematic and progressive manner, they could provide encouraging gains for women who are may have experienced unsuccessful interventions in the past (Tunks, 2008).

**Cultivating Awareness**

It is helpful for users to learn how to build awareness around their pain-related thoughts, and to learn how to challenge them as they arise (Turk & Gatchel, 2002). Psychological factors such as anxiety, pain catastrophising and fear-avoidance beliefs are known to moderate the experience of pain and contribute to pain-related disability (Savidge & Slade, 1997). A self-administered CBT intervention can help with distress management, particularly if the thoughts and beliefs around the pain (e.g., pain catastrophising) can be identified as they arise (Quartana et al., 2009; Sullivan et al., 2001).

Learning how to notice when acute pain is beginning to arise and learning how to identify pain triggers and flare ups early is another important skill (Turk & Gatchel, 2002). It can help women develop a plan that allows them to continue to engage in activities despite their pain (Litt, 1988). Furthermore, understanding the subtle difference between pain and pain fear, and gradually learning how to identify and challenge those fears, along with their triggers, are important steps in building self-efficacy (Samwel et al., 2006).

**Careful Use of Language and Emotional Validation**

A consistent theme that emerged from the Phase 1 data, also supported by the literature, was that women with CPP feel that no-one understands them and that others, including some doctors and loved ones, think they are feigning (Dalpiaz et al., 2008; Souza et al., 2011). Since the intervention was self-administered without opportunities for clarification, the use of language needed to be considered carefully. Instructions needed to be framed in terms of invitations rather than commands. Pain related analogies were presented as “alternative ways of conceptualising pain” rather than categorical statements. Furthermore, in sessions that were likely to evoke emotions, users needed to be reassured that their feelings were valid and appropriate, and encouraged to experience them in a spirit of self-compassion (Wren et al., 2012).
Welcoming and Safe Environment

Patients in the focus group workshops indicated that the app needed to be “a pleasant place to go”. Therefore, a key design principle was to make the environment in which the therapy took place feel welcoming and reassuring, with a calming user interface and pleasant greeting sounds. Sessions needed to start and end with simple relaxation exercises giving users with a sense of comfort and relief. In more challenging sessions, such as those that might challenge a user’s perception of pain or challenge the limitations that pain might have on their life, users would need to be reminded of the safe space feature. This would provide some reassurance that engaging with the app on a particular day would not leave them feeling worse than they felt before they started.

Ease of Use

Participants in the patient workshops indicated that simplicity and ease of use were important requirements for any technology-based therapy. Given the diverse group of users who were likely to participate in the pilot study; smartphone literacy, age and socioeconomic background were all considered. Therefore, the Research-Based Web Design & Useability Guidelines developed by the U.S. Department of Human Services was a resource that was referred to in the design process (Leavitt & Shneiderman, 2006). Features such as consistency of screen design, easy to read text, understandable language and consistently structured sessions were all derived from the guidelines to facilitate and maximise ease of use.

Acceptance and Self-Compassion

The acknowledgment and awareness of unhelpful thinking patterns needed to be managed with care. Consistent with the literature, the focus groups revealed that women with CPP often engage in critical self-talk (McGowan et al., 2007; Twiddy et al., 2017). They criticise their physical limitations, their failing bodies, and their inability to socialise and interact with others in a cheerful manner. Therefore, teaching self-compassion was considered an important part of the intervention.

Participants were encouraged to accept that there will be times when they would be hard on themselves, and they will sometimes react in ways that are not helpful. Perceived shortcomings and failures needed to be reframed in terms of skill building, new-found awareness and self-compassion (Neff, 2003). Furthermore, the ability to
practice acceptance and self-compassion were not conceptualised as personal qualities inherent within an individual, they were considered skills that a user could learn with consistent practice.

**Application of Skills Learned**

An important principle of CBT skills training is the application of acquired skills within daily life (Dobkin et al., 2006). At the end of each session, users will be encouraged to apply the skills they have learned into their daily lives. Similarly, at the start of each session, users will be asked to reflect on moments when they may have applied the skills in practice.

The delivery of the intervention through a mobile phone also provides further opportunities for the application of skills learned. Users will be encouraged to leave SMS message and email notifications on during each session so that any notifications that occur can be incorporated into the session. i.e., they will be encouraged to remain focused on the audio exercises while receiving notifications and messages. Similarly, at the start of each session, users will be encouraged to use any noises or distractions they might hear outside the room as opportunities to stay focused on the session and practice their mindfulness and relaxation skills for full the duration.

### 7.2 Features of the Intervention

With the above principles and goals in mind, a set of key design specifications were created to provide a clear guide for app developers and session writers to follow when creating the mobile phone app.

**Three-Part Sessions**

Each daily session contained three separate parts (Figure 7.1). In keeping with the principle that the app needed to be a welcoming environment and needed to have clear and achievable goals, time was set aside at the start of each session for a simple relaxation exercise (Part 1: Relax). These exercises invited users to release tension, and in some cases, release unhelpful thoughts and feelings, by utilising skills learned in previous sessions. This provided an opportunity for users to obtain quick and easy gains early in the session. Since some users suggested that learning new skills was something they would look forward to, these initial relaxation exercises were followed by an
education session (Part 2: Educate), leaving the more difficult and challenging aspect of
the session for the final seven minutes (Part 3: Intervene).

Each session concluded with some thought-provoking quotes which serve to shift
the listener’s focus from their feelings to their cognitions. This follows the principles of
CBT practice which suggests it is not always good for a participant to leave a session
whilst in a heightened emotional state (Buenaver et al., 2006). The total playing time for
each session was 15 minutes (Figure 7.1).

![Figure 7.1. Graphical depiction of the format of each 15-minute session](image)

**Limiting Sessions to One per Day**

Focus group participants suggested they would stay engaged if they felt they were
acquiring new knowledge and skills. Therefore, particular attention was paid to how the
therapy was structured and delivered, and how skills were taught over the 28 days. To
avoid the pitfalls of other self-guided therapies which allow a user to skip ahead or work
longer on some days than others, users were limited so they could only engage with one
new therapy session a day (Rees & Haythornthwaite, 2004). Most mindfulness
approaches suggest that short but consistent daily practice achieves best results (Kabat-
Zinn et al., 1985); therefore, exercises at the beginning of the 28-day program started
simple to encourage small gains early. Although users could replay current or previous
sessions or mark them as “favourites” for future reference, they were not given the
option at any stage to skip forward.

**Audio-Only Delivered Therapy**

Patients in the focus group workshops stated that they preferred the intervention to
be audio-only. This created unique design challenges, but it also provided novel
opportunities for engagement and use of sound design for therapeutic effect. Sound associations are used in some chronic pain interventions, but they are cumbersome to manage in face-to-face form (Guetin et al., 2012; Newbold, Bianchi-Berthouze, Gold, Tajadura-Jiménez, & Williams, 2016). At the start of each session, users were encouraged to close their eyes while soundscapes of calming ocean effects introduced each session so that the user was conditioned to think of the app as a pleasant place to go. Sound associations were also used throughout the sessions at strategic times. For example, in some early sessions, calming sounds and melodies were associated with pleasurable exercises such as “savouring the out-breath”. In later sessions these same sounds were then presented to patients in critical moments when they were asked to focus on more difficult pain areas.

Sound was also used to establish a sense of familiarity, routine and continuity with the program. Different musical themes were used to differentiated different groups of topics across the 28 sessions. Also, within each daily session, musical motifs were used to differentiate the educational components from the relaxation instructions so that the user understood when they were moving from one section (e.g., Part 1 - Relax) to another (e.g., Part 2 - Educate). Recorded speech also provided an opportunity to present the information in a particular valenced tone. For example, information that required the attention of the listener was presented in a sharper tone, whereas information designed to have a calming effect was presented with a softer tone of voice and accompanied by soothing background sounds.

**Relief for Acute Pain Flares**

In the focus groups, a series of pain visualisation exercises were presented to patients. These exercises were designed to help reduce the distress associated with persistent pain by helping women acclimatise to the discomfort of pain and remain relaxed while focusing on painful areas in the body. Some women expressed a preference for pain visualisation, while others preferred guided imagery and methods of distraction. All these options were created and made available to users within a group of sessions titled ‘pain relief’.
Safe Space Option

Although most participants reacted positively to mindfulness scripts in the focus groups, there were some safety concerns. One participant had to open her eyes as she began to feel uncomfortable. Another reported having had an adverse reaction to hypnosis in the past. Consistent with the literature, clinicians also stated that relaxation exercises can trigger adverse effects for women with trauma backgrounds. Therefore, a safe space feature was implemented. In situations where a user felt uncomfortable or distressed, even with their eyes closed they could tap their screen three times, and a session of calm music and pleasant audio imagery would then replace the audio session currently playing. After the safe space session, the user was invited to keep listening to the music, switch off the app, or return to their current session.

Data Collection Capabilities

Data collection capabilities were also built into the app for obtaining feedback from users and logging the use of the safe space feature. Knowing which sessions were most helpful to users and how women felt while engaging in each session was important from a design, safety and clinical perspective. Obtaining this information in real time also provided an opportunity to determine how often users were playing each session, and what time they engaged with the app. Although the app was designed to be used every day over 28 days, it was important to determine how realistic that suggested level of engagement was, and usage data informed that assessment.

Post-Therapy Toolkit

Self-management of pain is an important goal in CBT based chronic pain programs (Turk & Gatchel, 2002). After guiding users through 28 days of pain education, cognitive restructuring and mindfulness training, the user interface of the app changed. The app no longer emulated a clinician giving guidance, but instead turned into a toolkit, with a set of advanced features that the user was now trained to use. The features included the favourites list, populated during training, and a link to the three short exercises which the users would have mastered over the 28 days. These exercises include a two-breath, a five-breath, and a ten-breath exercise which were designed to be used whenever the user felt limited or distressed by their pain. For example, the two minute ten-breath exercise might be appropriate to use in the privacy of a bathroom,
whereas the one minute five-breath exercises are more suitable to use on a train or at work desk. Clinicians interviewed in Phase 1 all endorsed these exercises as being useful and relevant in the context of helping women manage CPP.

7.3 Topics Covered

The topics covered in the intervention addressed key areas of concern expressed by patients and clinicians and was consistent with established CBT principles for chronic pain management (Bradley, 1996; Turk & Gatchel, 2002). Delivered within a 28-day program, the intervention incorporated mindfulness, cognitive restructuring and pain education. An overview of the program is presented in Table 7.1, with chapter headings for each session presented in Appendix C.

Relaxation and Mindfulness Training

The 28-day intervention started with simple mindfulness and relaxation training, setting up foundational skills for the rest of the program. In the first four sessions, users were encouraged to ‘savour the out-breath’. They were reminded of the body’s natural tendency to release tension with the out-breath and reminded that every breath provides an opportunity to savour that experience. In instances where thoughts, feelings or emotions might intrude on the exercises, users were encouraged to allow those thoughts, feelings and emotions to occur on the in-breath, but then give the out-breath their full attention each time it came around. This was a much simpler exercise than some mindfulness techniques which require focused breathing the whole time. The out-breath exercise was designed to provide quick gains early on so that users could experience a sense of achievement. This series of sessions was then followed by two sessions covering progressive muscle relaxation and body scan.

For the remainder of the program, each daily session started with a short relaxation exercise reiterating the skills learned in the initial sessions. Users were encouraged to notice where they were storing tension in the body and notice how that tension arose in their everyday life. Some sessions started by asking users to remember difficult situations or encounters, and then encouraged the use of the out-breath exercise to release any tension that arose from those recollections. This served to provide guided practice within the app and encouragement for applying the skills outside of the program.
Table 7.1: List of Daily Sessions in Order of Sequence

<table>
<thead>
<tr>
<th>Session</th>
<th>Topic</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>The Outbreath</td>
<td>A simple technique to help manage your nervous system.</td>
</tr>
<tr>
<td>02</td>
<td>Resting Thoughts</td>
<td>Using the out-breath to rest your thinking mind</td>
</tr>
<tr>
<td>03</td>
<td>Resting Feelings</td>
<td>Accommodating unpleasant feelings</td>
</tr>
<tr>
<td>04</td>
<td>Tension and Pain</td>
<td>Tension as a major part of the pain experience</td>
</tr>
<tr>
<td>05</td>
<td>Body Scan</td>
<td>Learning the body scan</td>
</tr>
<tr>
<td>06</td>
<td>PMR</td>
<td>Learning Progressive Muscle Relaxation</td>
</tr>
<tr>
<td>07</td>
<td>Self-Acceptance</td>
<td>Practicing acceptance and pragmatic self-kindness</td>
</tr>
<tr>
<td>08</td>
<td>Fear of Pain</td>
<td>Understand and experiencing the difference between pain and fear</td>
</tr>
<tr>
<td>09</td>
<td>Pain Visualisation</td>
<td>Observe your pain areas while releasing tension</td>
</tr>
<tr>
<td>10</td>
<td>Values and Identity</td>
<td>Identifying what is most important with who you are</td>
</tr>
<tr>
<td>11</td>
<td>Valued Choices</td>
<td>Making choices that move you toward your values</td>
</tr>
<tr>
<td>12</td>
<td>Valued Living Obstacles</td>
<td>Recognising obstacles to valued living</td>
</tr>
<tr>
<td>13</td>
<td>Thought Awareness</td>
<td>Learning more about how thoughts affect feelings</td>
</tr>
<tr>
<td>14</td>
<td>Unhelpful Thinking</td>
<td>Catastrophising, Black and White Thinking and Emotional Reasoning</td>
</tr>
<tr>
<td>15</td>
<td>Shoulds and Musts</td>
<td>Understanding how language and self-talk affects mood</td>
</tr>
<tr>
<td>16</td>
<td>Reframing &quot;Why?&quot;</td>
<td>Understanding the emotional quality of “Why” questions</td>
</tr>
<tr>
<td>17</td>
<td>Pain Education</td>
<td>5 Breath technique: Forehead, Sensations, Thoughts, Feelings, Full-body</td>
</tr>
<tr>
<td>18</td>
<td>Exploring Anger</td>
<td>Exploring and understanding the physiology of anger</td>
</tr>
<tr>
<td>19</td>
<td>Anger and Pain</td>
<td>Understanding and experiencing expressions of anger</td>
</tr>
<tr>
<td>20</td>
<td>Gratitude and Pain</td>
<td>Training in gratitude and evoking the feelings you really want</td>
</tr>
<tr>
<td>21</td>
<td>Enemies of Gratitude</td>
<td>Maintaining gratitude among noise and its many enemies</td>
</tr>
<tr>
<td>22</td>
<td>Communicating Intimacy</td>
<td>Communicating intimacy</td>
</tr>
<tr>
<td>23</td>
<td>Self-Compassion</td>
<td>The elements of self-compassion and its health benefits</td>
</tr>
<tr>
<td>24</td>
<td>Social Anxiety</td>
<td>Pain, nerves and the challenge of socialising</td>
</tr>
<tr>
<td>25</td>
<td>Sleep and Worry</td>
<td>The importance of good sleep hygiene and how you can optimise your sleep</td>
</tr>
<tr>
<td>26</td>
<td>Relapse and Progress</td>
<td>Progress is not always a straight line up</td>
</tr>
<tr>
<td>27</td>
<td>Pain Flare-ups</td>
<td>Planning for and coping with pain spikes</td>
</tr>
<tr>
<td>28</td>
<td>Graduation Day</td>
<td>Recap and moving forward</td>
</tr>
</tbody>
</table>
Pain Fear and Pain Visualisation

After the initial relaxation and mindfulness training, users were instructed on how they could use those skills to experience pain sensations in a more objective manner. The guided relaxation exercises in sessions eight and nine encouraged users to remain relaxed while thinking about instances where their pain had been particularly severe. By noticing the physiological changes that occurred in their body, users had the opportunity to learn how their body not only reacts to pain, but how it also reacts to the fear of pain (Crombez et al., 1999; Samwel et al., 2006). Users were taught that the experience of pain includes not only the nociceptive pain signal, but often comes with a set of automatic thoughts, feelings, and emotions (Ehde et al., 2014). Learning how to identify these aspects allowed users to learn which elements were within their control, and which ones were not. This pair of exercises was designed to give women more autonomy and a greater sense of power and self-efficacy when experiencing pain (Litt, 1988).

Motivation and Values

The program then moved on to values-based exercises in sessions ten, eleven and twelve. Users were encouraged to think about what aspects of their life were most important to them, and whether their current behaviours were moving them towards, or away from their values. These exercises are widely-used in third wave CBT interventions like ACT (Vowles et al., 2014). Throughout the program, when behaviour change was suggested, users were invited to consider behavioural options that moved them towards or away from their values, emphasising that this was a choice for them to make.

The key skill for users to learn in this series of sessions was awareness (Bradley, 1996). Users were reminded that maintaining an awareness of the choices they make can be empowering. What was emphasised as most important in these sessions was the ability to choose, more so than whether the choice itself was correct or incorrect. Users were encouraged to notice and reflect on the choices that were available and encouraged to feel the sense of empowerment that comes from making active rather than passive choices.
Cognitive Restructuring, Sleep and Worry

The program then moved on to address the cognitive aspects of CPP. The relaxation and mindfulness skills learned earlier were used in these sessions to help build awareness around unhelpful thinking patterns (Bradley, 1996). These sessions outlined common unhelpful thinking styles that are known to be present in persons experiencing chronic pain and anxiety (e.g., black and white thinking, ‘shoulds’ and ‘musts’, and emotional reasoning). Users were taught how the physiology of anxiety narrows thinking and why practicing breathing exercises in instances where they notice themselves engaging in unhelpful thinking styles was so important (Quartana et al., 2009). Users were also reminded that challenging unhelpful and catastrophic thoughts around pain is much easier to do when the nervous system is calm.

Throughout this series of sessions, users were encouraged to seek face-to-face therapy if they felt the exercises were relevant to them. They were advised that cognitive restructuring can be particularly effective when administered in person with a trained psychologist. Some additional cognitive restructuring sessions were also revisited later in the program in the sessions covering sleep hygiene, worry and social anxiety.

Accommodating Feelings and Emotions

The program then moved onto more advanced skill training involving feelings and emotions (sessions eighteen to twenty-two). Mindfulness relaxation and cognitive challenging were the foundational skills required here (Bradley, 1996). Users were encouraged to invite unpleasant feelings with the in-breath, and then focus entirely on savouring the out-breath. Users were then encouraged to try and notice when feelings arose and understand how those feelings could be triggered by pain sensations. These sessions built on earlier sessions that covered the different elements that collectively make up the pain experience (i.e., thoughts, feelings, emotions, tension). By learning how to acclimatise to rather than avoid feelings as they arise, users were taught that it is possible to maintain a calm nervous system, even while experiencing painful sensations and emotions.
Self-Compassion

Self-compassion training was included because it became clear from the focus group workshops that women with CPP can be particularly hard on themselves. Even though women may not feel they deserve to be compassionate to themselves, this part of the program was designed to encourage self-compassion by appealing to their sense of pragmatism. The literature suggests that self-compassion can lead to improvements in physical health and productivity and produce physiological effects such as decreases in stress and cortisol levels leading to greater feelings of well-being (Costa & Pinto-Gouveia, 2013; Neff et al., 2007). Users were encouraged to think about practicing self-compassion as a means of calming the nervous system and reducing pain-distress.

Although self-compassion may not come naturally for some women, they were reminded that it is a skill, like any other, which can get easier with practice (Neff, 2003). Furthermore, women were encouraged to ask for help from others in times of need, with the suggestion that in some instances, they may appreciate an opportunity to help someone close to them if they were in need.

Communicating Intimacy

In focus group sessions, many women stated that communicating feelings of sexual inadequacy was confronting for them. Drawing on the literature on graded exposure (Crombez et al., 1999) and mindfulness (Bishop et al., 2004), this session encouraged women to sit with the uncomfortable feelings that arose when they entered a space of intimate communication with their partner. Rather than discuss the important issues with their partner right away, women were encouraged to first cultivate a safe environment for communicating difficult topics. By sitting in that space with their partner, they could both gradually learn to acclimatise to the sense of vulnerability that comes with intimate communication.

Social Anxiety, Secondary Gains and Relapse Prevention

In some instances, pain can serve a useful purpose for someone seeking to avoid difficult situations. In the session covering social anxiety, users were encouraged to consider what aspect of their life, if any, may be more difficult if their pain was not a part of it. Acknowledging these aspects was important in recognising any obstacles that might be undermining their rehabilitation and progress (Cheong et al., 2014).
Recognising where pain–related thoughts maintain unhelpful behaviours were addressed carefully within a framework of self-compassion and understanding.

The program then concluded with a session on relapse prevention. Users were encouraged to understand that progress is not linear, and that relapsing into old habits and unhelpful ways of managing pain will inevitably occur (Turk et al., 1983). Even more so than consistent behaviour change, maintaining awareness and making conscious decisions was emphasised as being the most important measure of success.

**Supplementary Sessions**

In addition to the 28 sessions which users encountered one day at a time, a series of supplementary sessions were available which could be accessed at any time. The *Introduction* session on the opening screen introduced the program and outlined its goals. The opening screen also included a *Keep Motivated* session. If the user data showed a participant’s interest or engagement is waning, then they were alerted and encouraged to listen to that particular session. It also contained information encouraging users to stay with the program.

The pain relief sessions within the app were designed for users to utilise when they were experiencing acute pain flare ups. These sessions provided three different options: pain relief with breath, pain relief with visualisation, and pain relief with sound and rhythm. Users were encouraged to listen to each of these sessions early in the program so they could establish which of the three options was most suitable and effective for them. In instances where a pain flare-up occurred, users could play their preferred pain relief session.

### 7.4 Creating the App

**Creating Scripts for Narration**

Text files were created for each of the daily and supplementary sessions (Appendix D). The text was written in a conversational manner and drew on information from CBT textbooks on chronic pain, the literature on CPP, data from patients and clinicians in Phase 1, and from the narrator’s own clinical experience working as an intern in chronic pain clinics. The sessions also included some relevant quotes taken from various literary sources.
When creating the scripts, input was sought from the principal supervisor, who was a senior psychologist working in the CPP Clinic of the RWH. Sessions involving emotions, pain visualisation, intimacy and anger, as well as the appropriate use of language were among those instances where this input was required the most. In these instances, the scripts were reviewed, advice was given on their suitability, and suggestions and changes were made.

Narrating the Scripts

The text-files were then narrated and recorded in a professional recording studio. In the focus groups, the student researcher created some sample audio recordings for the participants to listen to and critique. The consensus was the voice was calming and pleasant to listen to. The student researcher also had experience working in pain clinics and facilitated the focus group sessions where he experienced testimonials from women with CPP first hand. Given his level of experience and empathy for this patient group, he was considered the most appropriate choice for narrating the scripts. To increase the quality of the recordings, a professional voice actor was hired to provide voice coaching during the narrations.

Choosing Appropriate Sounds and Music

Welcoming introductory chimes with calming sound effects were created to help ensure the app was a “pleasant place to go”, however, careful choices needed to be made. Sound effects that appeared too “new age” could discredit the clinical integrity behind the app. Conversely, if the program appeared too formal and clinical it may have undermined the warm, pleasant and welcoming appeal of the app. These decisions produced design challenges that were difficult to overcome. The subjective nature of this part of the project meant that there was no objective scientific means of solving this problem other than to obtain feedback from users during and after the pilot study in Phase 3.

Producing the Audio Sessions

After the scripts were narrated, and music composed and recorded for each session, the audio was engineered, mixed and mastered. Part of the audio production involved deciding on the length of the gaps between certain phrases. For example, a phrase like: “some people confuse pain with fear of pain, but they are not the same thing” is a
statement that might present a new insight for some women. Therefore, some reflective time after the statement was considered necessary (Rees & Haythornthwaite, 2004). Also, reflective music needed to be at a volume that was evocative, but not distracting.

Technical decisions also needed to be made around file sizes. Large sound files produce a higher quality result but take longer to download and use more mobile data. After testing a variety of file compression programs, one that kept the audio files in stereo whilst maintaining a minimal file size without noticeable degradation in sound quality was chosen.

**User Interface Considerations**

The goal of most app designs is to create an interface that is functional, engaging, yet transparent to the user. Women in the focus group workshops emphasised that using the app needed to be an enjoyable experience. In line with their aesthetic preferences in the design section of the focus group workshops, a pebble and water graphic design was chosen. The therapy and its accompanying features needed to occur in a natural and intuitive sequence, so users could use the app without any initial training or guidance. Since the app was going to deliver therapy in an audio only format, decisions needed to be made as to which sections of the app would be used with eyes open, and which with eyes closed. For example, volume alterations, safe space enabling and adding a session to favourites all needed to be enabled with eyes closed. Yet, collecting survey data from users after each session could be done with eyes open.

**The Administrator Panel**

An administrator website was also created to serve several functions. All session headings and explanations for each daily session that appear on the app for users are entered directly through this website by the administrator, not the app developer. Furthermore, the website allows the administrator to upload audio files into the app directly, allowing for great flexibility and autonomy during the trial without the need for the app developer to be involved in changing the intervention. The website also allowed the administrator to create new users, monitor progress and produce survey and usage data reports in a variety of exportable formats.
Collecting Usage and Survey Data from Users

Each participant was assigned a unique identification number at the start of the program. Each time they opened the app, played a session, saved that session as a favourite or evoked safe space, usage data were recorded and stored on a central server computer. In addition to usage data, after each session had been completed, the user was asked to rate how useful they felt the session was for them, which part of the session was most useful, and how they felt about their interaction with the narrator. Details of the questions asked are provided in the next chapter, in the section on data collection.

Budget Constraints

A grant had been awarded to the candidate’s principal supervisor from a philanthropic body (Collier Charitable Trust). Although the grant covered app development and hosting costs, it was not sufficient to cover costs for all the features proposed, including two relaxation and mindfulness games. Furthermore, the app could only be created on only one platform, necessitating a choice between Android and iPhone. Two leading technology analysts, Telsyte and Kantar World Panel, cited Android as having 55-60% of the market share, and given Android phones could be purchased under an unlimited data plan for under $100, Android was selected. Usage and reminder notifications also could not be built into the app due to the limited budget and so these were set up manually using external software.

appEase

The resulting non-face-to-face audio-only CBT intervention created for women experiencing CPP was given the name: appEase. When the user opens appEase, they are presented with a home screen (Figure 7.2.1). At this point, the user can press the arrow (play button) and go straight to their current daily session (Figure 7.2.2). They can listen to introductory material, motivational information, or select ‘pain relief’ to go to the pain relief page (Figure 7.2.5). If the user chooses to go to their current session (Figure 4.2) and then press play, the session will start and a new screen will appear (Figure 7.2.3).

At this point welcoming sounds are heard, and the user is encouraged to close their eyes and listen. If they wish to save that session to their favourites, they can tap their screen once. If they wish to evoke the safe space option, they tap their screen three
times. Otherwise the session plays for 15 minutes, after which the user is prompted to open their eyes and fill in the post-session survey.

After the user has completed a particular session, they are required to wait until the following day before the next session is available. There are 28 sessions in total, and each available session is presented in colour. The sessions that are not yet available are presented in greyscale, and their play buttons cannot be clicked (Figure 7.2.4).

Figure 7.2. Screenshots of the intervention
7.5 Technical Considerations

Collecting Usage and Survey Data from Users

The administrator website was created that allowed the administrator to create new users, monitor progress and produce survey data and usage reports. Each user was assigned a unique identification number at the start of the program. Each time they opened the app, played a session, saved that session as a favourite or evoked safe space, usage data were recorded and stored on a secure server at the supported university. In addition to usage data, after each session had been completed, the user was asked to rate how useful they felt the session was for them, which part of the session was most useful, and how they felt about their interaction with the narrator. Details of the questions asked are provided in the next chapter.

Trouble Shooting and Testing

Unlike iOS which generally runs on phones created by Apple, the Android operating system can run on several different phone models. Some of these Android operated phones can run operating systems that are up to 10 years old. After the first week of testing, it became apparent that the app was not stable on certain versions of the Android operating system. A decision was then made to only develop the app for phones that carried the Android version 4 operating system and above. This meant that users with phones more than 10 years old would be ineligible for the study.

7.6 Development Summary

This chapter described the development of the mobile phone intervention, appEase, which participants utilised in the pilot study phase of the project. Unfortunately, due to budget constraints not all designs put forward could be executed in the development. The app was Android only, it did not have notifications built into it, there were no games which users can play to provide feedback on skill building, and some compromises were made with the amount of money that was spent on graphic design work. Nevertheless, the app was more than sufficient for a pilot study. It was fully functional, looked professional and was free of technical glitches. It also incorporated some useful data-gathering elements and had a flexible administrator interface which exceeded the student researcher’s expectations.
If appEase proved to be engaging and helpful for women experiencing CPP, then its portable nature provided opportunities for use in several different contexts:

1. First, appEase could be administered as a standalone downloadable app for women who are open to utilising a self-administered CBT pain management program. In this context, women experiencing CPP can simply download the app and start the therapy in their own time.

2. Second, the app could be utilised within the context of a multi-disciplinary team, reducing costs and easing the resource burden. In this context, physiotherapists, occupational therapist or pain doctors in a multi-disciplinary pain clinic may administer the app to women who are already taking part in a chronic pain program. This not only frees up resources and reduces costs, but it provides much needed psychological expertise for a complex and highly distressed clinical population.

3. Third, appEase can be used to augment face-to-face psychotherapy by providing an engaging set of daily exercises women can utilise in between their weekly, monthly or fortnightly sessions.

The next chapter outlines the pilot phase of the project and presents an integrative analysis summary of both the qualitative and quantitative findings, as well as some important design modification that may be necessary for its evaluation in a RCT.
Chapter 8.
Phase 3: Pilot Study

The aim of this final phase of the project was to pilot-test the intervention created in the previous phase. Women experiencing CPP were invited to participate in a 28-day self-administered CBT intervention using their personal smartphone. To assess the clinical efficacy of the program, psychometric data were gathered before and after the intervention. To understand women’s experiences of using the intervention, a series of structured interviews were also conducted for each participant. In addition, usage and survey data were gathered while users engaged with the intervention. The data were analysed collectively and used to answer the research questions proposed for this phase of the study.

8.1 Method

Sample

Women aged between 18 and 65 years who had experienced persistent or recurring pain in the pelvic region for more than six months and understood conversational English were eligible to participate in the study. Those who were pregnant or due for pelvic surgery within the time span of the intervention were not eligible. The eligibility criteria for joining were explicitly stated in the advertising and recruiting material (Appendix E1, E2 & E3). Understanding conversational English was assumed if the participant could understand the recruitment material and converse easily in the screening interview. Participants who remained in the study to complete the post-intervention measures and interviews were given a $50 gift voucher.

Although the app was developed for Android only, women who used iPhones were offered an Android phone for the duration of the pilot study. The option to borrow an Android phone was explicitly stated in the advertising materials in the CPP clinic, however, given the limited number of Android phones available for loan, it was not stated in the social media advertisements. For those interested participants, the use of an Android phone was offered on a case-by-case basis when they were available.
Four separate methods of recruitment were used. Only methods one and two were initially planned. Methods three and four were added later to recruit a sufficient sample:

1. First, women who attended the focus groups (Phase 1) and expressed interest in taking part in the pilot study were contacted via email or telephone. At the time of the pilot study, nine of the ten women were interested in joining. Although they were all eligible to join, only two participants were recruited. The other seven either did not respond to the email, or were unable to attend the scheduled screening interview.

2. Second, women attending the CPP Clinic of the RWH were approached by clinic staff and treating clinicians and invited to take part in the study. Interested participants were given a flyer with recruitment details when they attended appointments. After six months, this method yielded two recruits.

3. After consultation with clinical staff of the hospital, another recruitment method was devised whereby hospital patient records of women who were on a waiting list for gynaecological treatment were searched. There were over 300 women on this list, and most were not scheduled to see a gynaecologist for at least 12 months. Patient files indicated that 60 of these women had experienced CPP for more than six months and were not scheduled for immediate surgery. These women were sent invitation letters; however, this labour-intensive method yielded no recruits.

4. Finally, a Facebook page with information advertising the study and inclusion criteria was set up. This page was emailed to pelvic pain and endometriosis social media groups, as well as specialist pain clinics across Australia and New Zealand. Meetings with endometriosis awareness organisations (e.g., EndoActive) and other pelvic pain organisations for women were also conducted to establish avenues for promoting the study on their websites and social media pages. To boost exposure, Facebook advertisements were also purchased monthly. Using this method, twenty women were recruited within a three-month period.

With the four methods of recruitment combined, the total sample comprised 24 women. The total recruitment time was 18 months and required three additional ethics
amendments. To make the recruitment process more convenient for interested participants, changes were also made to the recruitment protocol in the fourth and final recruitment method. Participants were no longer required to come into the hospital to take part in the screening interview, instead, this interview was conducted over the telephone.

**Ethical Considerations**

The pilot study was approved by both the university and hospital research ethics committees (RWH ethics project number 15/06; Appendix E5). Informed consent was obtained from participants via a consent form which they signed in person or completed online (Appendix E6). Participants who were patients of the hospital were reassured their care and treatment from the hospital would not change if they decided at any stage to withdraw from the study.

This study included four levels of safety. First, mindfulness sessions were trialled in the focus groups with a psychologist present and modified based on feedback from participants. The resulting exercises were then presented to clinicians for their input. Second, as outlined in the previous chapter, a safe space feature was then added within the app. Third, aspects of the program most likely to evoke unpleasant thoughts or feelings (e.g., topics around anger and pain visualisation) were closely considered and scrutinised by the principal supervisor, who was a pain psychologist, in the design and development phase. Fourth, a safety protocol was devised: if a participant became distressed while using the app and felt they could not continue, they were encouraged to discontinue the intervention and call the principal supervisor. These instructions were clearly outlined in the plain language statement and reiterated in the screening interviews.

Participants were recruited individually, and no participant was aware of the identity of another. Some women who chose to post their interest on Facebook may have been identifiable, but this was done at their own discretion. All data collected, including the app data, were de-identified, encrypted and stored on a secure server maintained by the university. Any data downloaded from the app was encrypted and remained on a university machine. Usage and survey data that was temporarily stored on the app developer’s servers was encrypted and secure to the satisfaction of the
hospital and university ethics review panels. No survey or usage data were stored on individual participants’ mobile phones.

**Procedure for Data Collection**

The data collection sequence is summarised in Table 8.1. Starting dates for each participant differed depending on when they were recruited. Those interested in joining the study would in the first instance undertake a 20-minute structured screening interview either in person (at the hospital) or over the telephone (Appendix G1). This interview was used to assess eligibility for recruitment and obtain general background and clinical information. Eligible participants were then sent a link to an online questionnaire (baseline measures; Appendix F) and then an installation link so they could download the app onto their phone.

Table 8.1

*Sequence of Data Collection for Each Participant*

<table>
<thead>
<tr>
<th>Data</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening Interview</td>
<td>Twenty-minute semi-structured interview</td>
</tr>
<tr>
<td>Baseline Measures</td>
<td>Participants complete questionnaire with primary and secondary measures. Following this, participants were sent a link for installing the app</td>
</tr>
<tr>
<td>Survey Data from App</td>
<td>Daily usefulness and level of care ratings were filled in after each session</td>
</tr>
<tr>
<td>Usage Data from App</td>
<td>Number of times app was used and sessions were played</td>
</tr>
<tr>
<td>Mid-intervention Interviews</td>
<td>Weekly Interview to gather first impressions and check well-being of participants</td>
</tr>
<tr>
<td>Post-intervention Measures</td>
<td>Qualtrics questionnaire with primary and secondary Measures</td>
</tr>
<tr>
<td>Post-intervention Interviews</td>
<td>30-minute structured interview conducted shortly after post-intervention questionnaire was administered</td>
</tr>
</tbody>
</table>

While each participant was using the app, usage and survey data were collected from their phone. After the first week of joining the study, participants were contacted
via telephone (mid-intervention interview; Appendix G2) to check how they were responding to the intervention, and to obtain their first impressions of the app.

When a participant completed the trial (or decided to discontinue) they were sent a link to a post-intervention questionnaire. Data for that participant (i.e., screening interview, mid-intervention interview, questionnaires, and app data) were analysed and discussed in a final post-intervention interview immediately after. Although thirty minutes was allocated for each interview, most participants were willing to converse for longer, so the average length of each interview was one hour. This post-intervention interview was recorded and later transcribed and analysed. This data collection method was planned for all 24 participants; however, only 18 completed the final interview.

The data collected throughout the pilot study can be summarised as:

1. Psychometric measures: these were collected before and after the intervention and comprised a series of measures consistent with other studies evaluating chronic pain interventions.

2. Data collected within the app: this included usage data as well as survey data collected from users after each session.

3. Qualitative data: three separate interviews were conducted with participants before, during and after the pilot study.

Note: the mid-intervention interviews conducted during the pilot study also served to check on participants to ensure they were not experiencing any distress from using the app.

**Instruments**

**Screening interview (20 minutes).**

Each of the 24 women who were interested in participating in the pilot study were interviewed (Appendix G1). The first four women who joined the study were interviewed in person at the hospital (RWH). For the remaining 20 participants, the interviews were conducted over the telephone. The interview started with questions about pain: when the pain started, treatments sought, experiences with doctors and the impact the pain had on their life. Participants were also queried about any psychological therapy they might have received for their pain, if they had received any psychological
diagnosis, and if they had seen a psychologist for matters not relating to their pain. This was followed by a series of questions about past and current use of mobile phone apps including any health-related apps, or any apps specifically for their pain (Appendix F1). These interview questions were designed to provide general background information and a clinical profile for each participant.

**Baseline and post-intervention questionnaires.**

A series of psychometric measures were presented together as one online questionnaire using Qualtrics© (Appendix F). This questionnaire was administered at baseline and at the completion of the pilot study to compare differences across time. Responses to these measures were also used as discussion prompts in the post-intervention interviews to try and ascertain what may have contributed to changes (or lack of changes) in the outcome measures.

**Pain catastrophising (PC) scale (Primary measure).**

The PC scale is a 13-item self-report measure that was developed to measure the mechanisms by which thinking styles can impact the experience of pain (Quartana et al., 2009; Appendix F2). It comprises questions like: ‘I worry whether pain will end’ and ‘I feel I can’t go on’. Respondents were asked to indicate on a four-point Likert-type scale of 0 (Not at all) to 4 (All the time) the degree to which they have those thoughts and feelings when experiencing pain. The scale measures three domains: rumination, magnification, and helplessness surrounding pain. The measure has good validity and reliability with Cronbach’s alpha calculated at .93 (Osman et al., 1997; Sullivan et al., 2001).

The PC scale is commonly used to assess the clinical efficacy of psychological interventions for chronic pain (Sullivan, Bishop, & Pivik, 1995; Sullivan et al., 2001). A decrease of approximately six points is considered to be a clinically significant change (Quartana et al., 2009). The literature supports the view that PC is a modifiable construct, and for persons experiencing chronic pain in the absence of any intervention, PC remains relatively stable over time (Sullivan et al., 1995). The skills building exercises, pain education, self-compassion and cognitive restructuring components of the intervention developed were designed to reduce PC in women experiencing CPP.
Pain self-efficacy (PSE) questionnaire (Primary measure).

The PSE questionnaire is a 10-item questionnaire developed to assess the confidence people with persistent pain have in performing activities while in pain (Nicholas, 2007). Participants were asked to rate how confident they were in doing things despite their pain on a seven-point Likert-type scale. Sample items include ‘I can enjoy things despite my pain’, ‘I can cope with my pain in most situations’ and ‘I can cope with my pain without medication’. The questionnaire is commonly used in pain studies and has good reliability and internal consistency with Cronbach’s alpha calculated at .93 (Asghari & Nicholas, 2001). A change in the score that shifts from below 40 to above 40, or any 10-point change over time is considered clinically significant (Maughan & Lewis, 2010; Nicholas, 2008). The skill building, values, sleep hygiene, and mindfulness breathing components of the intervention were designed to target PSE by giving users a set of tools that might encourage them to persist with their goals and activities despite the pain they might be experiencing.

Secondary Measures.

Several secondary measures were also collected to pilot their use in an RCT (Appendix F4-F9). Some of these measures were explored for use as potential validation instruments, and others as potential screening tools.

Measures such as DASS-21, SF-12 and BPI were used to validate the primary measures. It was expected that reductions in PC and increases in PSE would be associated with favourable outcomes in these secondary measures, as they are well-validated instruments for measuring levels of psychological and physical distress within individuals.

Secondary measures such as LOC scale, PSOCQ and treatment credibility were used to determine if they could serve as potential screening tools. Some researchers examining self-administered therapies have called for more research in understanding what factors may predict treatment adherence, and they emphasise the importance of screening individuals for suitability in these types of therapies (Dear et al. 2015; Eccleston et al., 2014).

The secondary measures collected were used as discussion points in the post-intervention interviews to try and ascertain what factors individuals believed influenced
their PC and PSE scores, and to see if the measures could be helpful in determining treatment suitability.

**Depression anxiety and stress scale (DASS-21 short form).**

The DASS-21 is a widely-used 21-item self-report instrument designed to measure emotional states within three domains: depression, anxiety and stress (Henry & Crawford, 2005; Lovibond & Lovibond, 1995; Appendix F3). The scale has good reliability and internal consistency with Cronbach’s alpha calculated at .88. Table 8.2 shows the range of scores that signify normal to extremely severe levels of depression, stress and anxiety as measured by the scale.

Table 8.2

*Score Ranges for DASS-21*

<table>
<thead>
<tr>
<th></th>
<th>Depression</th>
<th>Anxiety</th>
<th>Stress</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>0-4</td>
<td>0-3</td>
<td>0-7</td>
</tr>
<tr>
<td>Mild</td>
<td>5-6</td>
<td>4-5</td>
<td>8-9</td>
</tr>
<tr>
<td>Moderate</td>
<td>7-10</td>
<td>6-7</td>
<td>10-12</td>
</tr>
<tr>
<td>Severe</td>
<td>11-13</td>
<td>8-9</td>
<td>13-16</td>
</tr>
<tr>
<td>Extremely Severe</td>
<td>14+</td>
<td>10+</td>
<td>17+</td>
</tr>
</tbody>
</table>

**Multidimensional health locus of control (LOC) scale.**

Developed by Rock, Meyerowitz, Maisto, and Wallston (1987), the Multidimensional Health LOC scale, henceforth called the LOC scale (Appendix F5), consists of 18 items classified into three subscales: internal health locus of control (the extent that an individual believes personal behavioural factors are responsible for their health); chance locus (the belief that health is determined by luck or chance); and powerful others (the extent that an individual believes their health to be determined by powerful others, such as physicians). Each subscale contains six items rated on a six-point Likert-type scale ranging from 1(*strongly disagree*) to 6(*strongly agree*). It is a widely-used and well validated scale with good reliability and internal consistency, with Cronbach’s alpha calculated at approximately .70 (Wallston, 2005).
LOC that is attributed to external factors is related to poorer outcomes in pain management (Grotz, Hapke, Lampert, & Baumeister, 2011). This scale was used to explore the relationship between LOC and changes, if any, in the primary variables. LOC scores were also used in the qualitative interviews to ascertain if LOC can be a useful tool in highlighting factors that might influence PC and PSE scores. It was also piloted as a potential screening tool to assess user suitability.

*Pain stages of change questionnaire (PSOCQ).*

The PSOCQ is 30-item self-report scale that is used to assess patient readiness for a self-management approach to chronic pain (Jensen, Nielson, Romano, Hill, & Turner, 2000; Kerns & Rosenberg, 2000). It is based on the transtheoretical model of change which states that behaviour change is a multi-stage process; that is, it moves through the following stages: pre-contemplation, contemplation, action, and maintenance. Successful completion of pain programs has been associated with higher contemplation and lower pre-contemplation scores on this scale (Biller et al., 2000). Therefore, this measure was piloted as a potential screening tool for suitability. This was done to determine if changes in PC or PSE, or if treatment adherence was related to relative pre-contemplation scores. The scale has good validity and internal consistency, with Cronbach’s alpha greater than .70 across a range of pain conditions (Jensen et al., 2000). Its authors have recommended its use as an outcome measure for controlled pain studies (Kerns et al., 1997).

It was expected that participants who scored high on pre-contemplation would not be ready or willing to try a self-management approach to CPP (Biller et al., 2000). They would therefore be less likely to benefit from the intervention or willing to engage with the program. To minimise the length of the questionnaires participants were required to complete, this study used a modified version of the PSOCQ scale that only included the first two stages (pre-contemplation and contemplation; Appendix F4).

*12-Item short form health survey (SF-12).*

The SF-12 is a multipurpose short-form generic measure of health status (Ware, Kosinski, & Keller, 1996; Appendix F6). It measures eight aspects of health within two separate domains: physical health and mental health. Two subscales are derived from the SF-12. Firstly, the physical components summary (PCS) assesses physical
functioning, role limitations due to physical health problems, bodily pain, general health, vitality (energy/fatigue) and social functioning. Secondly, the mental component summary (MCS) measures role limitations due to emotional problems, psychological distress and psychological well-being. The measure has good reliability with Cronbach’s alpha calculated at .70 (Busija et al., 2011). This pilot study sought to examine if changes in PC and PSE were also related to changes in mental or physical well-being for women experiencing CPP.

**Single item measure taken from the Brief Pain Inventory (BPI).**

The BPI is a widely-used nine-item self-administered instrument used to evaluate the severity of a person’s pain, and the impact that pain has on their daily activities (Keller et al., 2004; Appendix F7). To minimise the length of the survey, one item was selected: ‘please rate your current level of pain (1–10)’. Since this intervention did not target pain reduction directly, the score was not expected to change between the two-time points; however, it was included to see if pain levels at baseline were related to any changes in PSE or PC.

**Treatment credibility and expectation rating.**

One item from the five-item measure of treatment credibility and expectancy (Borkovec & Nau, 1972; Appendix F9-F10) was included and administered only at baseline: ‘how confident are you that this program will be successful in helping you cope with chronic pain? (Rate from 1 to 10)’. This measure was also piloted as a potential screening tool for user suitability. At the end of the pilot study, participants were also asked to rate out of ten: ‘how confident are you in recommending this program to a person with chronic pain?’ High levels of treatment expectancy and credibility scores were expected to relate to better clinical outcomes and treatment adherence (Devilly & Borkovec, 2000). These scores were also used as discussion prompts in the post-intervention interviews.

**Data Collected Within the App.**

Administering the intervention on a personal smartphone provided opportunities to collect usage and survey data while users were engaging with the technology. The various forms of data collected from user’s smartphones are covered in this section.
Usage data.

Each time a participant opened the app, usage data were logged. This included the number of times each session was played, whether a particular session was added to the user’s ‘likes’ list, and the number of times supplementary sessions such as pain relief and safe space were evoked. The usage data were also used to calculate the rate of usage over time, and to determine when users needed prompting to continue using the app. Although participants were aware that usage data would be collected through the app, this data collection process was not explicitly visible to the user.

Survey data.

Data were also collected from users in the form of a three-item survey addressing session relevance and valence which participants completed after each session was played (Table 8.3). These data served three purposes. First, they provided a means of checking on the well-being of participants in instances where potentially harmful was selected as a response. Second, they provided another means of assessing how useful the intervention was to participants; and a means of determining if a therapeutic relationship was felt. Third, they provided useful design information for modifying individual sessions and maximising their effectiveness. For example, sessions marked as extremely useful were discussed in the post-intervention interviews so factors that contributed to that usefulness could be determined. Similarly, sessions marked as not useful at all could be discussed to determine why they were not useful and how they might be improved.

After listening to a session, participants were prompted to rate how useful they felt that particular session was, and then asked to specify which part of that session was most useful. Responses ranged from 1 (extremely useful) to 5 (potentially harmful). As each user was progressing through the intervention, these data were recorded and made available to the student researcher through a separate administration website. Although these responses were discussed in the post-intervention interviews, in instances where participants selected potentially harmful, those responses were discussed in the mid-intervention interviews to check on the well-being of participants.

Participants were then prompted to rate how they felt about their interaction with the narrator. For this question, selecting the option Like someone talking specifically to
me was considered to imply a stronger relationship was present than the option *Like talking to a group of patients*. One of the critical elements in a therapeutic relationship is the quality of the interpersonal bond between the client and therapist (Bordin, 1994; Martin et al., 2000). In this study, level of care felt from the narrator was operationalised as a measure of that particular element of therapeutic alliance.

Table 8.3

*App Survey Questions*

<table>
<thead>
<tr>
<th>Survey Question</th>
<th>Response Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>How useful/relevant was that session to you?</td>
<td>Extremely useful</td>
</tr>
<tr>
<td></td>
<td>Very useful</td>
</tr>
<tr>
<td></td>
<td>Mildly useful</td>
</tr>
<tr>
<td></td>
<td>Not useful at all</td>
</tr>
<tr>
<td></td>
<td>Potentially harmful</td>
</tr>
<tr>
<td>Which section was most relevant to you?</td>
<td>The education part</td>
</tr>
<tr>
<td></td>
<td>The reflective/skill building part</td>
</tr>
<tr>
<td></td>
<td>Both parts were relevant</td>
</tr>
<tr>
<td></td>
<td>Don’t know I fell asleep during it</td>
</tr>
<tr>
<td>How did the interaction with the narrator feel?</td>
<td>Like listening to a robot/computer</td>
</tr>
<tr>
<td></td>
<td>Like listening to a radio announcer</td>
</tr>
<tr>
<td></td>
<td>Like someone talking to a group of patients</td>
</tr>
<tr>
<td></td>
<td>Like someone was talking specifically to me</td>
</tr>
<tr>
<td></td>
<td>Like the narrator really cared about me</td>
</tr>
</tbody>
</table>
Qualitative Data.

Mid-intervention interviews.

Informal interviews were also conducted during the pilot study (Appendix G2). The interviews provided an opportunity to obtain first impressions of the app from users and to see if these impressions changed over time. In addition, the interviews served as a safety precaution to ensure the app was not causing any harm or distress to users. For example, instances where users activated the safe space were logged and discussed in these interviews.

Post-intervention interviews.

After a user completed the 28 sessions, or whenever they decided to withdraw from the study, they were invited to complete the post-intervention measures and interviewed one final time (Appendix G3). Immediately before this post-intervention interview was conducted, post-treatment measures were collected and analysed along with the baseline measures and app survey data, so the information could be discussed in the interview. An example of the analysed participant data that was used along with the post-intervention interview questions is presented in Appendix H.1, H.2 and H.3.

Participants were initially asked questions about the usability and usefulness of the app. This information was prompted by responses in their app survey questions (Appendix H.3). The discussion then turned to questions relating to PC and PSE. Participants were asked to provide their own perspective on their thoughts around pain, and the confidence they had in doing things despite being in pain. The interview also provided an opportunity for participants to comment on what aspects of the therapy, if any, may have influenced changes PC and PSE, and asked to comment on why they responded to the psychometric measures (Appendix H.1) in the way they did.

The remainder of the interview was left open, so participants could provide feedback on how the intervention might be improved. This open-ended part of the interview also sought information from participants on how the measures, or their administration, might be improved if used in an RCT.
8.2 Data Analysis

Data collected from this phase come from a variety of sources collected at different times throughout the pilot study. Sources of data include psychometric measures, app usage and survey data, and a series of structured interviews. This section will detail each of these sources of data and present a rationale of the instruments used.

Primary Measures

Clinical outcomes were determined by comparing differences between baseline and post-treatment scores on each of the primary measures. To make these comparisons, two T-tests were calculated, one for the PC scale and another for the PSE questionnaire. An alpha of .05 denoted statistical significance, and although p-values were calculated, the effect size is the most reliable and informative measure to interpret given the limited sample size (Cohen, 1998).

Secondary Measures

Some of the secondary measures were explored for used as potential validation instruments, and others as potential screening tools. Non-parametric exploratory correlation calculations were planned to look for associations between changes in the primary variables and baseline scores on the secondary variables. Post-intervention scores for PC and PSE were subtracted from their respective baseline scores to create two variables called PC_change and PSE_change. Spearman’s correlation coefficient was then calculated and presented in a correlation matrix (Table 8.9) along with the secondary measures. An alpha of .05 denoted statistical significance, and p-values denoting .05 and .01 significance were noted where appropriate; however, given the sample size of the pilot study, the correlation coefficient was considered to be the most reliable and informative measure for this exploratory analysis (Cohen, 1998, 1994).

To explore factors that may have contributed to treatment adherence, participant scores from the 13 who completed all 28 sessions were compared with five who completed less than 50% of the sessions, the six participants who withdrew from the study, and all 24 participants initially participated in the study. Scores which were compared included age, year when pain first started, psychological diagnosis, previous app use, treatment expectation, BPI, PSOCQ and internal LOC. Although group sizes were too small to conduct t-tests, mean and percentage calculations were made to
explore any potential differences across the variables for each group. If trends were found, these findings were presented to participants in the post-intervention interview for further discussion.

**App Survey Data**

After users listened to a daily session they were prompted to rate the usefulness of that particular session, and then rate how much care they felt from the narrator. In addition to providing discussion points in the post-intervention interviews, these survey data were analysed as follows:

1) Each *usefulness* rating was ranked with a number from 5 (*Extremely Useful*) to 2 (*Not Useful at All*), and further assessing risk with 1 (*Potentially Harmful*). Those numbers were then averaged across participants, providing a number (from 1 to 5) rating the average usefulness of each daily session. A similar calculation was made for the *level of care* rating. Sessions were then ranked in order of most useful to most harmful.

2) Maximum number of usefulness ratings (i.e., “Extremely Useful”) and maximum level of care ratings (i.e., “I felt the narrator cared about me”) were also counted for each session to calculate percentages of participants who found the app highly satisfactory on these variables.

**Coding of Screening Interviews**

Women who were interested in participating in the pilot study were interviewed and screened for eligibility. In this interview, women were also asked questions about their clinical background, treatments sought, and technology use. Selected data from the screening interviews was coded and entered in to SPSS. The list of variables used is presented in Table 8.4. Averages and percentages were calculated for each of those variables.
### Table 8.4

*Data Collected from Structured Interviews for Each Participant*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Description</th>
<th>Response/Code</th>
<th>Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>Age when completed baseline measures</td>
<td>Number (18 – 65)</td>
<td>Mean</td>
</tr>
<tr>
<td>Sessions_No</td>
<td>Number of daily sessions completed</td>
<td>Number (0 – 28)</td>
<td>Mean</td>
</tr>
<tr>
<td>Days Taken</td>
<td>Number of days taken to complete sessions</td>
<td>Number (0 – 200)</td>
<td>Mean</td>
</tr>
<tr>
<td>Pain_Started</td>
<td>Age when pain first started</td>
<td>Number (18 – 65)</td>
<td>Mean</td>
</tr>
<tr>
<td>Initial_Pain</td>
<td>Reported initial cause of pain</td>
<td>P=Period</td>
<td>Counts</td>
</tr>
<tr>
<td></td>
<td></td>
<td>I=Injury</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>D=Disease</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>O=Operation</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>N=Pregnancy</td>
<td></td>
</tr>
<tr>
<td>Endometriosis</td>
<td>Obtained diagnosis of Endometriosis in the past</td>
<td>(1=Yes, 0=No)</td>
<td>Percentage</td>
</tr>
<tr>
<td>Psyc_Diag</td>
<td>Obtained any psychological diagnosis in the past</td>
<td>(1=Yes, 0=No)</td>
<td>Percentage</td>
</tr>
<tr>
<td>Apps_Gen</td>
<td>Does participant use any mobile phone apps?</td>
<td>(1=Yes, 0=No)</td>
<td>Percentage</td>
</tr>
<tr>
<td>Apps_Pain</td>
<td>Does participant use any mobile phone apps for pain?</td>
<td>(1=Yes, 0=No)</td>
<td>Percentage</td>
</tr>
<tr>
<td>Psyc_Exp</td>
<td>Any experience with psychologist in the past?</td>
<td>(1=Yes, 0=No)</td>
<td>Percentage</td>
</tr>
<tr>
<td>Pain_Limit</td>
<td>Rate how limiting pain is</td>
<td>Number (1-10)</td>
<td>Average</td>
</tr>
<tr>
<td>When_Used</td>
<td>When was the app used?</td>
<td>M=Morning</td>
<td>Counts</td>
</tr>
<tr>
<td></td>
<td></td>
<td>A=Afternoon</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>E=Evening</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>B=Bedtime</td>
<td></td>
</tr>
</tbody>
</table>
Qualitative Analysis of Structured Interviews

This section will present an outline of the steps used to analyse the qualitative data collected throughout the pilot study and will discuss how those data were integrated with the quantitative measures. An excerpt of the raw transcript data, and their transformation across the different stages of its analysis is presented in Appendix H, and reference will be made to each of those excerpts where appropriate.

Theory

The raw data collected throughout the pilot study included a series of psychometric measures collected before and after the intervention; usage and survey data collected from the app; and three separate interviews conducted before, during and after the pilot study. Analysing this rich dataset in an integrative manner required both a rigorous and flexible analytic approach, and so a hybrid method of thematic analysis was required (Onwuegbuzie & Leech, 2005).

The data analysis method chosen was developed by Fereday and Muir-Cochrane (2006), and has been utilised in many qualitative health studies involving women. This hybrid method utilises both a deductive (‘top-down’) and an inductive (‘bottom-up’) approach at different stages of the data analysis process (Braun & Clarke, 2006; Crabtree & Miller, 1999.)

The deductive component, as described by Fereday and Muir-Cochrane (2006) was derived from Crabtree and Miller (1999) whereby a set of themes are created, to which subsequent data conforms. In this study, these themes comprised the post-intervention interview questions. Themes created from this deductive method were then used to construct what Crabtree and Miller (1999) described as a ‘code manual’. Another full review of the coded data was made whereby individual codes were then placed within their respective and appropriate themes.

The inductive component of Fereday and Muir-Cochrane’s (2006) approach suited the open-ended interview questions, as the method allows themes to be derived from the data themselves, rather than from a theory or hypothesis (Patton, 1990). Utilising this method can facilitate the generation of innovative design ideas as the analysis does not try to fit into a pre-existing framework and is independent of the researcher’s analytic preconceptions (Braun & Clarke, 2006).
Method

This section will outline the steps taken to apply an adaptation of the method developed by Fereday and Muir-Cochrane (2006). The data analysis method presented in this section is intended to be sufficiently detailed to ensure appropriate transparency of the technique (Marshall & Rossman, 2014).

Initially, the post-intervention interview responses were transcribed verbatim from the audio recordings. A separate word document was created for each raw transcription. Instances where a participant repeated information or discussed matters not relevant to the study were then removed, leaving only key responses. A two-staged approach was then used to analyse the remaining key responses (Fereday & Muir-Cochrane, 2006).

Stage 1:

1) For each participant, a new word document was created with a separate table for each interview question. Columns in this table included participant identification number, pre- and post-intervention score (if applicable), key response, and code (Appendix H.5). These responses were coded and placed in the code column.

2) Responses that corresponded to the interview question were then removed from the original raw participant transcript documents, and placed in the appropriate table in the new participant’s word document. This process was repeated for all participants and all interview questions.

3) A separate master word document was then created which contained a table for each interview question. One interview question at a time, all participant responses were copied into the interview document, along with their codes.

4) Codes for each question were then listed and counted. The greatest number of similar codes were noted and given the highest response weighting for that question. In instances where there were multiple codes for a question, percentages were calculated to determine the proportion of participants who endorsed a particular response.
Stage 2:

Any responses that remained in the original participant word documents were classified as responses that deviated from the interview questions. A separate table was created in the interview document for these responses. At this stage, the responses were already coded; however, themes were not yet incorporated into the code manual. New themes were created to describe remaining responses. First, the responses were coded, grouped in tables by code, with each table analysed for emergent themes. All responses, including relevant interview responses from the mid-intervention interviews as well as unanticipated information relevant to the research questions were collected and placed in the relevant tables. Themes with the highest number of codes were given the greatest weighting. An example of this process can be found in Appendix I.3.

Reliability

To assess the reliability of the data analysis process, a three-step checking procedure was instituted. First, after the audio recordings were transcribed verbatim, the student researcher randomly selected three 200-word excerpts from the pool of raw transcriptions. For each of those excerpts, the audio recordings were played, and raw transcriptions reviewed to check for accuracy. In each of the samples, the transcript and audio matched correctly. This confirmed that the transcripts were accurate and would not need to be re-transcribed.

Second, a series of raw transcript excerpts were selected at random. The student researcher and senior researcher coded the data together so a protocol for adapting the method of Fereday and Muir-Cochrane (2006) could be established. This process involved discussing and negotiating disagreements around the removal of unnecessary responses, and data coding in a process Waitzkin described as “hashing out” (Waitzkin, 1991). After determining the criteria for how responses were removed and which would stay, a detailed protocol was written. Both the supervisor and student retained a copy of this protocol and referred to it when analysing the data.

Third, a consensus cross-checking procedure was used. As the student researcher created codes and themes from the data, any uncertainty or ambiguities were flagged and discussed. This involved the supervisor and student meeting at least once a week during the coding of transcripts for discussion. The student researcher presented a
rationale for why each theme was created. A resolution and consensus agreement were reached in all instances following discussion between supervisor and student.

Independent coders were not used in the analysis process as keeping the dialogue between the student researcher and data at all stages of the process was considered an important aspect of the study (Armstrong, Gosling, Weinman, & Marteau, 1997; Tyler, 1986). Although this might increase the risk of some information being missed, the initial collaborative process with the principal supervisor, along with regular meetings during the coding and analysis process was considered an appropriate means of ensuring accuracy, and maintaining the student researcher’s relationship with the data (Morse, 1994; Vidich & Lyman, 1994).

Exclusions, Inclusions and Withdrawals

Of the 24 women recruited, six (25%) withdrew from the study. Five cited lack of time as their reason for discontinuing. The other participant who withdrew completed two sessions before her phone was damaged and rendered inoperable. Only one participant in the cohort borrowed an Android phone from the student researcher.

Eighteen (75%) participants completed all interviews and measures. Two of these underwent unscheduled surgery during the pilot study, so their questionnaire and interview responses were excluded from the study. The app survey data collected prior to surgery were retained and included in the analysis pertaining to app survey responses.

Although the two participants who underwent surgery understood their interview and questionnaire responses were no longer valid, they wanted to continue with the intervention as they were obtaining benefit from it. Furthermore, both participants were keen to provide feedback on the app. To satisfy their request, the two participants were taken through the post-intervention interview. Their interviews were audio recorded and transcribed, however, the data were not included in the analysis (Figure 8.1).
8.3 Results – Quantitative

Descriptive Statistics and Screening Interviews

Twenty-four women were recruited. They each completed the initial set of online measures and participated in the baseline structured interview (Table 8.5). Of the twenty-four women, fifteen (63%) stated that their pain started when they were 15 years or younger, and seventeen women (70%) stated that the pain started after their first menstrual cycle.

A diagnosis of endometriosis had been given to eighteen women (75%) at some stage when seeking treatment, and on average, each participant rated limitation due to pain as being 5.7 out of 10 ($SD = 1.83$). Twenty women (79%) had consulted a psychologist on at least one occasion, and twenty-two (88%) had been given a formal psychological diagnosis from a health professional at some point in their life. Seventeen
participants (67%) had used mobile phone apps before, and ten (38%) had used mobile phone apps specifically in relation to CPP. Mean depression scores from the DASS were in the moderate range, although twelve participants (50%) had scores within the moderate to extremely severe range. Mean DASS scores for stress and anxiety were both in the mild range.

Table 8.5

*Descriptive Statistics for Participants Recruited at Baseline (N = 24)*

<table>
<thead>
<tr>
<th></th>
<th>Mean</th>
<th>Minimum</th>
<th>Maximum</th>
<th>Std. Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participant Age</td>
<td>31.92</td>
<td>19</td>
<td>59</td>
<td>8.97</td>
</tr>
<tr>
<td>Age When Pain Started</td>
<td>17.96</td>
<td>12</td>
<td>53</td>
<td>9.08</td>
</tr>
<tr>
<td>Years of CPP</td>
<td>13.96</td>
<td>2</td>
<td>31</td>
<td>8.16</td>
</tr>
<tr>
<td>Limited by Pain (out of 10)</td>
<td>6.58</td>
<td>0</td>
<td>9</td>
<td>1.83</td>
</tr>
<tr>
<td>Brief Pain Inventory (BPI)</td>
<td>5.71</td>
<td>2</td>
<td>10</td>
<td>1.97</td>
</tr>
<tr>
<td>DASS Depression</td>
<td>6.88</td>
<td>0</td>
<td>17</td>
<td>4.25</td>
</tr>
<tr>
<td>DASS Anxiety</td>
<td>5.75</td>
<td>0</td>
<td>12</td>
<td>3.49</td>
</tr>
<tr>
<td>DASS Stress</td>
<td>9.83</td>
<td>2</td>
<td>21</td>
<td>4.76</td>
</tr>
</tbody>
</table>

**Primary Measures**

A change of six points on the PC scale is considered clinically significant. Of the sixteen participants who completed the pilot study and did not undergo surgery, ten (63%) experienced clinically significant reductions in PC. Mean differences in PC scores between the two-time points (pre- and post-intervention) was 7.6 ($SD = 8.34$) across all sixteen participants (Table 8.6).

Any 10-point change in PSE scores is also considered clinically significant. Of the sixteen participants, nine (56%) experienced clinically significant increases in PSE. In this sample, the average mean difference in PSE scores across the two time points was 14.1 ($SD = 12.99$).
Table 8.6

Scores for Primary Measures (n = 16)

<table>
<thead>
<tr>
<th>Measure</th>
<th>Baseline (Mean)</th>
<th>SD</th>
<th>Post-intervention (Mean)</th>
<th>SD</th>
<th>Change ^ (Baseline – Post)</th>
<th>95% CI Lower</th>
<th>95% CI Upper</th>
</tr>
</thead>
<tbody>
<tr>
<td>PC</td>
<td>20.06</td>
<td>8.16</td>
<td>12.44</td>
<td>4.82</td>
<td>-7.63**</td>
<td>-3.18</td>
<td>-12.07</td>
</tr>
<tr>
<td>Rumination</td>
<td>6.81</td>
<td>3.56</td>
<td>3.94</td>
<td>2.32</td>
<td>-2.88**</td>
<td>-0.75</td>
<td>-5.00</td>
</tr>
<tr>
<td>Magnification</td>
<td>3.38</td>
<td>2.25</td>
<td>1.69</td>
<td>1.49</td>
<td>-1.69**</td>
<td>-0.48</td>
<td>-2.90</td>
</tr>
<tr>
<td>Helplessness</td>
<td>9.88</td>
<td>4.01</td>
<td>6.19</td>
<td>3.49</td>
<td>-3.69**</td>
<td>-1.93</td>
<td>-5.45</td>
</tr>
<tr>
<td>PSE</td>
<td>23.44</td>
<td>10.11</td>
<td>37.56</td>
<td>14.42</td>
<td>14.13**</td>
<td>7.20</td>
<td>21.05</td>
</tr>
</tbody>
</table>

^ t-tests to compare means between baseline and post-intervention measures.

* Differences between the time points significant for p < .05
** Differences between the time points significant for p < .01

Secondary Measures

Secondary measures were explored to determine the suitability for their use as screening and validation instruments. Along with the qualitative interviews, they were also used to determine if they could capture factors that may have influence PC and PSE scores (Table 8.7). Some changes in the secondary measures included a marginal reduction in depression, anxiety and stress scores within the DASS; however, these changes were not clinically significant. There were some improvements on an individual level with four participants (25%) recording severe anxiety scores or higher at baseline compared to one at post-intervention, and three (19%) recording severe depression scores or higher at baseline compared to one at post-treatment. Treatment expectancy was modest (M = 5.81, SD = 1.6); however, treatment credibility was high (M = 8.44, SD = 2.34) with eight participants (50%) rating 10 out of 10 when asked how much they would recommend the intervention to someone experiencing chronic pain. The SF-12 scores showed improvements in the same positive direction as the primary measures, however, the differences across times were not statistically significant.
Table 8.7  
*Scores for Secondary Measures (n = 16)*

<table>
<thead>
<tr>
<th></th>
<th>Baseline (Mean)</th>
<th>SD</th>
<th>Post-intervention (Mean)</th>
<th>SD</th>
<th>Change (^{\wedge}) (Baseline – Post)</th>
<th>95% CI Lower</th>
<th>95% CI Upper</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief Pain Inventory</td>
<td>5.69</td>
<td>1.82</td>
<td>4.94</td>
<td>1.84</td>
<td>-0.75</td>
<td>-0.09</td>
<td>1.59</td>
</tr>
<tr>
<td>DASS - Anxiety</td>
<td>5.63</td>
<td>3.63</td>
<td>3.06</td>
<td>2.77</td>
<td>-2.56**</td>
<td>0.75</td>
<td>4.38</td>
</tr>
<tr>
<td>DASS – Depression</td>
<td>6.13</td>
<td>3.98</td>
<td>4.06</td>
<td>3.36</td>
<td>-2.06</td>
<td>-0.21</td>
<td>4.34</td>
</tr>
<tr>
<td>DASS – Stress</td>
<td>9.19</td>
<td>4.78</td>
<td>6.81</td>
<td>2.99</td>
<td>-2.38</td>
<td>-0.25</td>
<td>5.00</td>
</tr>
<tr>
<td>SF-12 Mental Health</td>
<td>40.13</td>
<td>9.68</td>
<td>44.21</td>
<td>10.35</td>
<td>4.08</td>
<td>0.72</td>
<td>8.89</td>
</tr>
<tr>
<td>SF-12 Physical Health</td>
<td>31.79</td>
<td>9.06</td>
<td>34.85</td>
<td>11.10</td>
<td>3.06</td>
<td>0.60</td>
<td>6.72</td>
</tr>
<tr>
<td>LOC Internal</td>
<td>20.31</td>
<td>5.51</td>
<td>19.25</td>
<td>5.17</td>
<td>1.06</td>
<td>-1.92</td>
<td>4.04</td>
</tr>
<tr>
<td>LOC Chance</td>
<td>14.31</td>
<td>5.25</td>
<td>15.56</td>
<td>4.49</td>
<td>-1.25</td>
<td>-3.75</td>
<td>1.25</td>
</tr>
<tr>
<td>LOC Powerful Other</td>
<td>17.19</td>
<td>4.75</td>
<td>18.25</td>
<td>5.13</td>
<td>-1.06</td>
<td>-3.09</td>
<td>0.96</td>
</tr>
<tr>
<td>LOC Doctor</td>
<td>9.44</td>
<td>3.16</td>
<td>9.88</td>
<td>2.80</td>
<td>-0.44</td>
<td>-1.59</td>
<td>0.71</td>
</tr>
<tr>
<td>LOC Other</td>
<td>7.75</td>
<td>2.49</td>
<td>8.38</td>
<td>3.40</td>
<td>-0.63</td>
<td>-2.22</td>
<td>0.97</td>
</tr>
<tr>
<td>SOC Pre-contemplative</td>
<td>2.83</td>
<td>0.66</td>
<td>2.42</td>
<td>0.73</td>
<td>-0.42*</td>
<td>0.02</td>
<td>0.80</td>
</tr>
<tr>
<td>SOC Contemplative</td>
<td>3.92</td>
<td>3.84</td>
<td>3.84</td>
<td>0.76</td>
<td>-0.08</td>
<td>-0.21</td>
<td>0.37</td>
</tr>
<tr>
<td>Treatment Expect (1-10)</td>
<td>5.81</td>
<td>1.60</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Recommend 1-10)</td>
<td>-</td>
<td>-</td>
<td>8.44</td>
<td>2.34</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

\(^{\wedge}\) *t*-tests to compare means between baseline and post-intervention measures.
* Differences between the time points significant for \(p < .05\)
** Differences between the time points significant for \(p < .01\)

**App Data - Usage**

Of the twenty-four women who were initially recruited, eighteen completed the baseline and post-intervention questionnaires and participated in all the interviews. Thirteen (72%) of those women completed all 28 sessions, two (11%) completed 22 sessions, one completed 19 sessions. The remaining two completed fewer than 10 sessions. For the thirteen participants who completed all 28 sessions, the average number of days taken to complete the program was 64 (range: 35 to 123).
The usage data indicated that six participants (33%) used the safe space option, however, the post-intervention interviews confirmed that only one participant used it in response to distress within a session; the other participants reported that they had initiated it by inadvertently tapping the screen. Eight participants (44%) used the pain relief sessions but only three (61%) used them more than once. Only one participant listened to the introductory material. This was queried at the post-intervention interviews. Most users stated (94%) that they were either not aware of the extra sessions, forgot about them, or did not have time to use them.

**App Data**

Each time a participant listened to a daily session they were prompted to rate its usefulness and the level of care felt at the completion of that session. Since not all participants included in the data analysis completed all 28 sessions, not all sessions were rated with an equal number of entries. For example, Session 1 was rated by all eighteen participants, but session 28 was only rated by the thirteen participants who completed all 28 sessions. The usefulness ratings are shown in a separate column in Table 8.8 and displayed graphically across all sessions in Figure 8.2.

**Usefulness.**

The survey data collected showed that each daily session had at least one extremely useful rating and at least two very useful ratings suggesting each individual session was very useful for at least one participant (Table 8.8). Even for those sessions that had the lowest average rating, such as those involving values, some individuals still rated those sessions as extremely useful. The graph in Figure 8.2 shows the average ratings for each session with bars showing the highest and lowest ranking for each. Overall, the sessions that were rated as most useful on average included self-compassion, progressive muscle relaxation, tension and pain, and sleep and worry (Table 8.8.)

**Level of care.**

The level of care rating also showed that each daily session had at least one felt like the narrator cared about me rating (Table 8.8). The session that elicited the highest number of maximum care felt rating was progressive muscle relaxation (PMR) followed by self-compassion (Figure 8.2).
<table>
<thead>
<tr>
<th>Rank</th>
<th>Session Description</th>
<th>Average Usefulness (Min=0, Max=5)</th>
<th>‘Extremely Useful’ Counts</th>
<th>‘Narrator Cared’ Counts</th>
<th>Total Counts</th>
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</thead>
<tbody>
<tr>
<td>23</td>
<td>Self Compassion</td>
<td>4.43</td>
<td>8</td>
<td>6</td>
<td>14</td>
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<tr>
<td>06</td>
<td>PMR</td>
<td>4.06</td>
<td>4</td>
<td>8</td>
<td>16</td>
</tr>
<tr>
<td>08</td>
<td>Fear of Pain</td>
<td>4.00</td>
<td>4</td>
<td>1</td>
<td>16</td>
</tr>
<tr>
<td>25</td>
<td>Sleep and Worry</td>
<td>4.00</td>
<td>4</td>
<td>2</td>
<td>13</td>
</tr>
<tr>
<td>04</td>
<td>Tension and Pain</td>
<td>3.94</td>
<td>4</td>
<td>5</td>
<td>17</td>
</tr>
<tr>
<td>27</td>
<td>Pain Flares</td>
<td>3.92</td>
<td>3</td>
<td>3</td>
<td>13</td>
</tr>
<tr>
<td>28</td>
<td>Graduation Day</td>
<td>3.92</td>
<td>3</td>
<td>5</td>
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<td>24</td>
<td>Social Anxiety</td>
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<td>26</td>
<td>Relapse and Progress</td>
<td>3.77</td>
<td>4</td>
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<td>13</td>
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<tr>
<td>05</td>
<td>Body Scan</td>
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<td>1</td>
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<td>07</td>
<td>Self-Acceptance</td>
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<tr>
<td>22</td>
<td>Communicating Intimacy</td>
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<td>4</td>
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<tr>
<td>01</td>
<td>The Outbreath</td>
<td>3.72</td>
<td>2</td>
<td>3</td>
<td>18</td>
</tr>
<tr>
<td>21</td>
<td>Enemies of Gratitude</td>
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<td>3</td>
<td>3</td>
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<tr>
<td>13</td>
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<td>09</td>
<td>Pain Visualisation</td>
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<tr>
<td>02</td>
<td>Resting Thoughts</td>
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<td>3</td>
<td>4</td>
<td>17</td>
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<tr>
<td>16</td>
<td>Reframing &quot;Why?&quot;</td>
<td>3.60</td>
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<td>4</td>
<td>16</td>
</tr>
<tr>
<td>20</td>
<td>Gratitude and Pain</td>
<td>3.60</td>
<td>1</td>
<td>5</td>
<td>15</td>
</tr>
<tr>
<td>10</td>
<td>Values and Identity</td>
<td>3.56</td>
<td>2</td>
<td>3</td>
<td>16</td>
</tr>
<tr>
<td>17</td>
<td>Pain Education**</td>
<td>3.56</td>
<td>1</td>
<td>2</td>
<td>16</td>
</tr>
<tr>
<td>03</td>
<td>Resting Feelings</td>
<td>3.53</td>
<td>3</td>
<td>3</td>
<td>17</td>
</tr>
<tr>
<td>14</td>
<td>Unhelpful thinking Styles</td>
<td>3.50</td>
<td>4</td>
<td>4</td>
<td>16</td>
</tr>
<tr>
<td>15</td>
<td>Shoulds and Must's</td>
<td>3.50</td>
<td>3</td>
<td>4</td>
<td>16</td>
</tr>
<tr>
<td>11</td>
<td>Valued Choices</td>
<td>3.47</td>
<td>2</td>
<td>4</td>
<td>16</td>
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<tr>
<td>12</td>
<td>Valued Living Obstacles</td>
<td>3.38</td>
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<td>4</td>
<td>16</td>
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<tr>
<td>18</td>
<td>Exploring Anger</td>
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<td>16</td>
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<tr>
<td>19</td>
<td>Anger and Pain**</td>
<td>3.20</td>
<td>1</td>
<td>3</td>
<td>16</td>
</tr>
</tbody>
</table>

*Note: Number of sessions completed varies by participant.*

*Session also marked as “Potentially Harmful” by a participant*
Figure 8.2: Average usefulness rating for each session with error bars indicating the highest and lowest ratings for that session. Dotted line represents level of care felt rating for each session.
Exploratory Statistics

Non-parametric correlations between baseline scores on secondary variables and changes in PC and PSE were conducted using Spearman’s correlation coefficient, to explore factors associated with clinical outcomes (Table 8.9; Bonett & Wright, 2000). The analysis suggested that high Internal LOC scores may be related to greater changes in PC scores ($r = -.55, p < .05$). When the PC subscales were analysed individually, a positive correlation was present in the Rumination ($r = -.79, p < .05$) and Helplessness ($r = -.62, p < .05$) subscales but not in Magnification. When the LOC sub-scores were examined, the subscales that related to external factors such as Powerful Other and Doctor were negatively associated with reductions in PC but these were only moderate correlations (range $r = .47 - .48, p = n.s$). No notable associations were found between increases in PSE and scores on any of the secondary variables. Furthermore, baseline stages of change (PSOCQ) and treatment expectation were not associated with changes in either primary variable.

8.4 Results - Qualitative

Usability and Acceptability

To gather information about usability and acceptability of the intervention, users were asked when they used the app, what their impression were of the app, and to provide some suggestions on how the app could be improved.

Most participants used the app either in the evening after their children had gone to sleep, or just before going to bed (Figure 8.3). Some women who listened in the evening stated that it was the first opportunity for them to be alone in the day. One person initially tried to use it in the morning before going to work but found that evenings were generally better.

Three participants (19%) specifically mentioned the benefit and convenience of being able to use the app in their own time:

*For time-poor women it is best to do it when you are free rather than face-to-face where you have to find a baby-sitter you have to do this you have to get dressed. I so much prefer to do it through an app. – ID 2022*
It was kinda like I was in the counselling session and you were asking me these questions. There are ways to have therapy without having to see a psychologist. And this app is going to be good for women and other people that are struggling. – ID 2011

Six participants (38%) reported that they felt pressure to complete the sessions in 28 days, and found it difficult to find 10 to 15 minutes in a day to complete the exercises:

I've found the actual concepts and information helpful, but it seems I may not be cut out for something that requires it to be done every day. – ID 2009

I felt pressure to do it over 28 days, I wanted more time – ID 2024

Doing it every day is too hard. – ID 2010

Yeah kind of [felt rushed] like I go through the whole day and think "Oh..I still gotta do that". And then some days I am just too tired. – ID 2012
Table 8.9

*Correlation Matrix of Main Study Variables (n = 16)*

<table>
<thead>
<tr>
<th>PC</th>
<th>Pain Catastrophisation</th>
<th>Locus of Control</th>
<th>Stages of Change</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1.</td>
<td>2.</td>
<td>3.</td>
</tr>
<tr>
<td>1. PC</td>
<td>1.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Rumination</td>
<td>-0.66**</td>
<td>-1.00</td>
<td></td>
</tr>
<tr>
<td>3. Magnification</td>
<td>-0.72**</td>
<td>-0.24</td>
<td>-1.00</td>
</tr>
<tr>
<td>4. Helpless</td>
<td>-0.82**</td>
<td>-0.60*</td>
<td>-0.62**</td>
</tr>
<tr>
<td>5. PSE</td>
<td>-0.37</td>
<td>-0.43</td>
<td>-0.15</td>
</tr>
<tr>
<td>6. LOC Internal</td>
<td>-0.55*</td>
<td>-0.79**</td>
<td>-0.12</td>
</tr>
<tr>
<td>7. LOC Chance</td>
<td>0.10</td>
<td>-0.16</td>
<td>0.20</td>
</tr>
<tr>
<td>8. LOC Power Other</td>
<td>0.48</td>
<td>0.44</td>
<td>0.42</td>
</tr>
<tr>
<td>9. LOC Doctor</td>
<td>0.47</td>
<td>0.35</td>
<td>0.30</td>
</tr>
<tr>
<td>10. LOC Other</td>
<td>0.15</td>
<td>0.28</td>
<td>0.22</td>
</tr>
<tr>
<td>11. Pre-Contemplative</td>
<td>-0.32</td>
<td>-0.09</td>
<td>-0.36</td>
</tr>
<tr>
<td>12. Contemplate</td>
<td>-0.01</td>
<td>-0.48</td>
<td>0.15</td>
</tr>
<tr>
<td>13. Treatment Expectation</td>
<td>-0.12</td>
<td>-0.26</td>
<td>-0.08</td>
</tr>
</tbody>
</table>

* Correlation is significant at the .05 level (2-tailed).
** Correlation is significant at the .01 level (2-tailed).
Fourteen participants (88%) reported that they thought the app looked good, they thought the voice and graphics were soothing, and they enjoyed the music:

*I like the way the exercises are done. I like the format, ideas, and way it’s delivered. I enjoyed your voice. I found it calm and soothing. You sound very relaxed. Good to listen to.* – ID 1002

*I actually really liked the slow voice. I found it quite soothing and relaxing.* – ID 2016

*But hearing it with the background [music] was quite nice.* – ID 2016

One participant did not like the way the sessions were narrated:

*Your voice was patronising. It comes across stilted. It could be more conversational and less stilted. It felt like you were talking to a child or someone who could not understand English. Make it faster and more conversational.* – ID 2023

When asked what features could be improved, five participants (31%) reported that navigation to the safe space option was too sensitive and would set off too easily:

*When the screen got tapped and you went into safe place, you couldn’t go back to where you were.* – ID 2015

Three users stated that the long silent reflective gaps where there was no sound or voice were disconcerting, and in some cases would cause them to fall asleep:

*Big period of silence make you wonder if the app is on. Need something to know that the app is still working?* – ID 1003

*How do you know if it’s dropped out or working?* – ID 1004

*Then it was kinda like trying not to fall asleep in those parts. Yeah, sometimes you thought it had stopped.* – ID 2012

Seven participants (41%) made comments about the pace and order of the sessions:

*First eight or nine makes sense to have as foundational, but then free it up a bit after that.* – ID 1005

*Maybe if you had the option to work through them in a different order. Maybe if the person can pick the order they want.* – ID 2007
If I could get to the new stuff earlier I would have learned more. – ID 2023

All of it was great. Just sometimes I felt the voice could be faster. – ID 2010

Other individual suggestions included:

The only improvement would be the speed. [Adjustment option] so you can just increase the speed that would be an improvement. – ID 2008

Maybe making safe mode more user friendly with: ‘are you sure you want to activate safe mode?’. – ID 2012

It was one sided. There was nothing to say how you are progressing through it. If you went back and listened to an episode twice if would be good if the app said: ‘this is a focus area for you’. – ID 2018

Daily Sessions

Participants were then asked which sessions they thought were most helpful, which were least helpful, and to provide some suggestions for improvement. The 28-day program started with a series of sessions involving breathing techniques and relaxation exercises. These exercises were generally considered to be useful by most participants:

The reason this is better than other breathing or relaxation things I have done is you are putting it all in context. – ID 1002

When I get pain, like really bad pain, prior to doing the app the breathing stuff I just feel really low, a bit useless [and] quite helpless. And since doing the breathing when I have had pain, really bad pain flares I felt like I can cope with it better. Sometimes I will start playing some of the breathing and just really focus on that and it almost distracts me from the pain and I can get on with things a bit better. If I get a pain flare in a lecture I know [now] to take a deep breath and just release it. I can then refocus. It’s been a significant change. – ID 2011

I have used the savour the out-breath thing a lot. I found that really effective. – ID 2022

Although the Progressive Muscle Relaxation session was one of the three sessions users rated as most helpful, one participant reported that the session was potentially harmful:
I felt uncomfortable doing that one [PMR]. I think it actually could be hurtful. Especially for people who have not had any physio and don’t know their muscles. – ID 2023

Pain visualisation exercises followed the initial breathing sessions. Nine participants (56%) rated this session as very or extremely useful. One participant stated:

With visualisation I am able to identify what type of pain is it: muscle, nerve. Being more aware of what your body is doing makes you more pro-active. – ID 1004

On the other hand, two participants reported a negative response to those exercises

Did not like Pain Visualisation exercise. Found it regressive. I want to get out of my pain, not in it. I want to move on. – ID 1002

Visualise pain was tough too - I hate it. I want to be detached from the pain. I understand that realistically I shouldn’t and I should face it but it’s hard. – ID 2014

In amongst the breathing and visualisation sessions was a session titled Fear of Pain. This session was designed to help participants recognise that the distress experienced from pain can involve more than just the pain signal itself. One participant said this was the most useful chapter for her:

Yeah that’s probably been the most beneficial part to me. And for things I haven’t really thought about how there were so many elements involved and you can actually break it down. – ID 2018

The sessions then moved onto cognitive restructuring. They started with a series of three exercises on values. In these sessions, users were encouraged to think about the things that were most important to them, and then use that information to identify what choices (e.g., action or inaction) moves them towards or away from their values. These sessions borrowed from third wave CBT therapies such as ACT. Overall, these sessions were not rated as high as most others, and some reports were not positive:

Values was a bit ‘whatever’. My values haven’t changed according to my pain. I don’t let my pain rule my life. – ID 1004

Values were not something I connected with pain. For me it’s good for general philosophical life. – ID 1005

Another participant thought they seemed a little misplaced in the session:
I think the values one probably threw me a little bit. – ID 2016

Contrary to this trend, one person reported:

I also thought that the values session was quite good as well. Because it really makes you kind of think about what are the things that you really value. And focusing on those things rather than thinking you can do everything is really helpful. – ID 2016

When queried further she reported that she found the app useful in other areas of her life, not just for her pain:

I thought it was a great app and actually really helped not just with the pain but with getting me out of a slump I felt at the beginning of the year. – ID 2016

Another reported that the values session was challenging and thought provoking:

Values really hit me hard. Because I have lost friendships over the years with [because of] pain. – ID 2014

The cognitive restructuring, thought awareness and self-acceptance exercises appeared to be well received by participants in general. The cognitive restructuring chapters covering unhelpful why questions were reported as most helpful within this group of sessions:

‘Why’ chapters were very useful. Gave me new ideas new perspectives.
– ID 1004

The other one that was good was the always going back to the ‘why...why me’ that was good. I always do that. [And] I absolutely love the acceptance reflective part of session 7. Can you send the transcript? I would like to have to put in my fridge and carry it on a little card in my wallet. – ID 2014

I really liked that, and I thought that also relates to situations regardless of pain as well. – ID 2022

One participant suggested that cognitive restructuring was perhaps best for those women at more early stages of their treatment:

CBT not useful as I am not in that place - I am 24 years in my diagnosis - if I haven’t got used to my diagnosis by now then where would I be? – ID 1004
The sessions relating to cognitive restructuring concluded with a session on *Pain Education* which was narrated by a pain clinician from a leading private pain clinic in Australia. This session was rated as *very useful* by 50% of participants, but, it was not received well by all. One participant marked as *potentially harmful*:

“If its pelvic pain associated with polycystic ovaries or endo, you are talking about cysts that come or go or growth that continues to grow and contort. You think about surgery and medicine. And the session said you don’t need that [and I thought] "Yes you do" and it’s something that really frustrated me at the moment. It’s the wrong way to look at it. I understand where it comes from... If I was in a bad way I would have stopped the meditation [app.] – ID 2024

Another participant had a similar response:

*Just the lady [Pain Education] didn’t go with my groove. Lady is just not convincing me. It was like a doctor talking to me and I have had enough of that already.* – ID 2014

After the cognitive restructuring sessions, the program moved onto emotions, paying particular attention to anger, gratitude, intimacy and self-compassion. One participant who rated the anger session as *potentially harmful* stated:

*There was one about anger and pain. Because of my anxiety disorder I tend to disassociate into another personality and so that actually happened during that session which is why I put "potentially harmful" but that is just [me] personally. I have a feeling there may be some underlying issues within myself there.* – ID 2011

Another participant rated that sessions as *not useful at all* but then contradicted that rating in her interview:

*At the time it [anger session] was possibly a little triggering for I am quite stubborn and so sort of I will go "Oh you know that’s made me feel really angry or upset and I am not going to like it" and then after I reflect on it a bit it’s like "well that actually was helpful just calm down".* - ID 2007

The sessions covering gratitude were also rated as useful by some participants (50%). One stated:

*I think that’s [gratitude] very important. Yes, you are in pain, but the reality is there is more to your life than that.* – ID 2015
The self-compassion session was rated as very useful or extremely helpful by 94% of the participants:

*The compassion was very good because it helped me realise the pain is not my fault.* – ID 2011

*I love self-compassion.* – ID 2015

The sessions then moved onto social anxiety, sleep and worry. All participants rated these sessions helpful in some way. Four participants (25%) reported that they used the app to try and get to sleep:

*It has helped me tremendously with my sleep issues and pain flares. I found it quite relaxing like if I couldn’t sleep at night I would put that on and I would be asleep [laughs].* – ID 2011

*Sleep and socialising stuff were great. They should come a lot sooner in the app because they are important.* – ID 1002

*I think the sleep ones played a really big role. I have sleep issues it’s not just the pain. I found those [sleep] sessions were helpful.* – ID 1003

The app then concluded with some general skill building such as relapse prevention tools for dealing with pain flares:

*I wish the flare up one was earlier in the picture. I would have gone to pain flare up if I saw it before.* – ID 2014

Few participants listened to the supplementary material. Fifteen of the sixteen participants did not utilise the pain relief chapters and when queried, participants reported that they either did not know they existed, forgot to use them, or just did not have the time to look at them. When those chapters were explained, participants reported that they thought they were a good idea and were keen to use them. Similarly, no user reported listening to the introductory material or the supplementary motivation chapter titled “keep motivated”.

Most suggestions for improvement from participants related to the use of language within the sessions:

*The only one I didn’t like the wording on was ‘possessed’ [by the Should Tyrant]. Even if it’s a softer word like "controlled" because when you
have your eyes closed and you hear that word I don’t know I just found it a bit creepy. – ID 2022

The word ‘gratitude’ is not the best way of saying it. ‘Appreciate’ is probably a better word than ‘gratitude’. ‘Gratitude’ is implying “stop being a whinger” “be grateful for what you have” The gratitude stuff was good, but a bit vague. You don’t need to tip toe. People need to remember all the good little things they have in their life. You can be more specific and more prescriptive. – ID 1002

Maybe change the title [pain relief] to something like "quick pain relief" something that catches the eye of the person in pain. – ID 2014

Maybe say: ‘Is this what you really want’ rather than use the word: ‘values’. I thought you were talking about ‘morals’. The term ‘values’ isn’t appropriate. – ID 1004

I surprised myself because I didn’t think that intimacy one would be interesting, but it was to me. I felt that ‘communicating intimacy’ title put me off. It could be called "relationships". – ID 1005

One participants made a helpful suggestion on the way the exercises were presented:

I didn’t like "Savour the outbreath" as an idea. It put me off. But I really, really liked it when you said, "Give the outbreath your full focus, waiting a moment, and making the most of it". I always focused on in-breath. I liked the way it flipped it on its head. – ID 1005

**Therapeutic Relationship**

Five respondents (31%) stated that they felt the narrator cared about them, and attributed that level of care to the tone of voice, language used, or if the narrator sounded empathetic and non-judgmental:

Very much [cared for me], very much so. And I think your ability to speak gently is huge and that is a massive thing. - ID 2026

Yes, it did [feel like the person cared]. I felt like if I was really struggling, then I could potentially talk to that person. – ID 2011

Yes, [felt care]. Especially when you said something like “It’s not your fault that you are feeling like this” or “We are all going to have times where we feel like this”. That non-judging sort of way of talking. – ID 2007
Another participant reported that the level of care she felt depended on the information presented:

*For me it was more like whether the session resonated. So, if it resonated with me emotionally then to me it felt like it was like someone has taken their time to make my day better [cared about me]. – ID 2022*

One participant reported that she felt like the narrator was a person she could converse with:

*It felt like if I was really struggling...I could potentially talk to that person [narrator]. – ID 2011*

One possible response to the survey question concerning level of care included: *felt like narrator was talking to a group of patients.* This response was intended to signify a lower level of care felt than the response: *felt like the narrator was talking specifically to me.* Contrary to this intention, one user who selected: *felt like narrator was talking to a group of patients;* reported that she appreciated that she was part of a cohort of women undertaking therapy:

*It’s kinda like group therapy without it being group therapy. I think if it feels like you are talking to a group then that is fine. It can still be helpful. – ID 2010*

Similarly, another participant stated that feeling like the narrator was talking to a group of patients was not necessarily better or worse than feeling like they were talking specifically to them:

*...but it never felt like you were talking directly to the person, but I do not think you need to either. – ID 2024*

**Pain Catastrophising (PC)**

In the structured interviews, the PC scale was explained to participants, and sample items from the scale were presented. Women were asked to provide any comments about that scale and how they might have responded to it. They were then asked to comment on whether they noticed any difference in their pain-related thoughts before or after the intervention. Further discussion and clarification was sought to determine what might have contributed to those changes and clarify any inconsistencies between their measures and their self-reports.
Most participants (75%) reported that the questions were relevant and easy to understand and some (24%) stated they had seen them before in other surveys. Three participants (19%) stated that the questions were repetitive, and the measure could have been shorter:

*I know that you ask questions in different ways but a lot of it seemed like the same question over and over which I know you do, but I could tell it was the same question over and over.* – ID 2023.

Two participants (13%) reported that answering the questions was challenging. One respondent reported that they felt the questions were judging them about their inadequacies in dealing with their pain:

*This is bringing back bad memories...why are you putting me down?* – ID 2014

In contrast, one participant reported that answering the questions was good because it made her realise how far she had come in her pain journey:

*I have filled them out before, and it was nice filling them out this time.* – ID 2015

Two participants (13%) stated they were trying to remain positive while answering the questions, suggesting their PC score may have reflected their ideal rather than actual levels of PC:

*I completely understand [why the questions are asked] but for me, I have to sit there and think [about] how I feel and cope with the illness and it’s not good. I try to be as positive about it as possible.* - ID 2018

Although scores were generally consistent with interview responses, four participants (25%) stated that their responses to the questions would have changed depending on how much pain they were experiencing on the day.

**Mechanisms for change.**

Participants were then asked if their thoughts around their pain had changed between the two surveys, they were then presented with their scores, and then asked to comment on them. Seven (43%) participants stated that they catastrophised about their pain less and attributed that change to the new insights and skills acquired through using the app:
The app gave me some new thoughts, but it was yet another source for old things I knew. For me the journey is the more you hear the messages from yet another source, the more affirming it is. – ID 1005

Yeah, I think it was the app and in particular some of the meditation techniques. I found them quite good. – ID 2016

The app was fantastic and helped me so much and it has been really, really wonderful. – ID 2018

One participant in particular noted that while her levels of pain did not change, her distress associated with the pain did:

I think that the strategies that we went through and in meditation have allowed me to manage probably not the pain so much but the anxiety around the pain…and also the other way around. I wouldn’t say overall the pain is any different. There is just a different way of coping with it. – ID 2024

The mechanisms for change in PC scores were reported to be influenced by factors outside the intervention for three participants (19%) who attributed reductions in PC to improved circumstances around their physical condition and level of medical care received. One of these participants suggested:

Those [PC] questions should be more specific and ask questions like: “How has using the app influenced your thoughts around your pain” so changes attributed to the app could be separated from changes that happened as a result of factors outside the app. – ID 2010

Pain Self Efficacy (PSE)

The PSE questionnaire is designed to assess the confidence people with persistent pain have in performing activities while experiencing pain. As with the PC scale, the PSE questionnaire was explained to participants and sample items were presented to refresh their memory. Respondents were first asked to provide comments about the questionnaire and how they might have approached answering it. They were then asked to comment on whether there was any change in the confidence they had in doing things despite being in pain and provide details on what they thought might have contributed to that change. If there were any inconsistencies between what was recorded in the PSE questionnaire and what was reported in the interviews, they were alerted to those inconsistencies and asked to provide further clarification.
Unlike the PC scale, ten participants (63%) either could not remember the PSE questionnaire, or had no opinion about it. Three respondents (19%) thought the questions were relevant in the context of chronic pain. Four participants (25%) stated that their responses to the questions would change depending on the demands that were placed on them at the time:

*I suppose it [confidence to do things despite being in pain] depends on what I have to actually do.* – ID 2011

*I do actually remember that one ’cause I remember thinking it needs to be put in context as to when I answer it.* – ID 2024

Similar to what was reported when discussing the PC scale, four participants (25%) stated that the answers to their questions on the PSE questionnaire might have changed depending on how much pain they were experiencing on that particular day.

**Mechanisms for change.**

Participants were then asked if their confidence in doing things despite being in pain had changed between the two surveys. They were then presented with their scores, and then asked to comment on those scores. From the responses, it was not clear if the measure was reflecting the confidence participants had in doing tasks despite pain, or if it reflected the level of expectation they felt in having to do those tasks. Four participants (25%) with high PSE scores, or scores that increased over the two-time points stated that any increase in PSE that might not have occurred by choice:

*There was no one else to do it for me. I don’t have family around to help. So I have to do it myself.* - ID 1003

*Yeah. It’s [high PSE] mostly because of necessity.* – ID 2011

*I am busy, I do what I have to do regardless.* – ID 1004

One participant whose score increased by 12 points reported that she did not recognise any change and appeared determined in her response. She was a competitive sportswoman:

*No [my confidence didn’t change]. I don’t let pain stop me.* – ID 1002

Seven participants (44%) reported that the gain in confidence they experienced was directly attributed to the app:
I think the only real change was the confidence in my mental health. I have a lot of limitations physically but my ability to cope with that was better. It was easier to accept it was what it was. – ID 1003

Your app was a good part of that but even the things I learned from your app, I am still implementing. You know... it’s a whole new set of skills. - ID 1005

After the application [using app] I did feel a bit more positive about being able to do more things regardless of the pain. – ID 2014

The participant who experienced the greatest gain in PSE (score moved from 22 to 60) attributed her gain to resolving things with her dying father. She reported that although the app did not directly help her pain situation, the strategies she learned from the app helped her deal with the unresolved issues and emotions around her father. By learning how to manage her emotions and communicate with him more effectively, she reported that her mood improved. Consistent with this report, her DASS depression score moved from extremely severe to mild over the two-time points. She reported that her improved mood increased her confidence in doing things despite having pain.

Another participant whose PSE score decreased by 10 points attributed that change to a realisation that she could no longer do the things she used to enjoy:

We have an annual tennis tournament within the family and I said, "yeah, yeah, I’ll play" and then in the weeks leading up to it I thought “I can’t even walk properly why did I think I could play?” So not being able to play at that even really highlighted to me I actually am limited, whereas in my mind I wasn’t as aware because I said, “yes, I would play” – ID 2022

Secondary Measures

Secondary measures were explored to determine the suitability for their use as screening and validation instruments. Along with the qualitative interviews, they were also used to determine if they could capture factors that may have influence PC and PSE scores for each individual. Scores that were unusually high or low, and any unexpected changes in variables were discussed in the interviews with participants.
Depression anxiety and stress scale (DASS-21 short form).

The DASS-21 is designed to measure emotional states within the three domains: depression, anxiety and stress. The scale was used to determine if stress, anxiety or depression factors influenced scores or changes in PC or PSE scores. Although the intervention did not target stress, anxiety and depression, five participants (31%) reported that the app helped them manage stress and depression:

*I think my ability to recognise my feelings for what they are [helped most]. I can’t remember if it was day 4 or 5 or something when it was I there was something in there about recognising those feelings and just let them be.* – ID 2026

*I actually honestly think it [change in stress level] was again the active choice. I know at the beginning of the year I was just not feeling mentally well at all. Whereas now, yes, I do feel a lot better and I think it comes down to my outlook on life has kind of changed and I think I have made the active decision that I need to stress less and yeah there are some things I can change and there are some things I can’t.* – ID 2016

One participant’s stress score remained in the severe range over the two-time points, however, she still made clinically significant favourable changes in PC and PSE:

*It was just a really bad month. And I still managed to do the meditation and still managed and... I think that the mediation actually helped me* – ID 2024

Severe depression scores seemed to be associated with discrepancies between questionnaire responses and self-reports. One participant who started with a severe baseline depression and anxiety score reported:

*I don’t get stressed anxious or depressed* – ID 1002.

Another participant whose depression score moved from normal to severe across the two time points reported that she was catastrophising more, yet it was not reflected in her PC score which decreased between the two-time points. She started with a very low PSE score which then went down to 4 after the trial which was an unusually low score for this sample. When asked about her PSE she did not appear to have a clear insight into why it was low, however, she did report that she was on a lot of pain medication:
If I let the pain stop me doing things, then I wouldn’t do anything at all. I have to do things. I guess they [doctors] are worried because I am on a lot of medication. Medication that has side effects that depress my respiratory system. To stop pain you really need to slow down your body which is what the drugs do, but that can be dangerous. – ID 2010.

Another participant with similarly high depression scores reported that she thought her PC score increased when in fact decreased:

I thought they [PC] would have been worse. That surprises me. I have been feeling a lot worse. Even my psychologist told me I was catastrophising – not about pain, but other things. – ID 2010

**Multidimensional health locus of control (LOC) scale.**

The LOC scale was used to determine if levels of internal or external LOC could be related to treatment adherence and outcome in a self-administered intervention. The most notable finding for this measure included three participants (19%) whose internal LOC score decreased, and external LOC increased, yet they reported improvements in managing their pain and reported reductions in pain distress. For these participants, they reported that relinquishing some control of their pain was beneficial as a pain management strategy:

At the point of going in to using the app when I first started, I had to be responsible for it all. Whereas afterwards I could see that I didn’t have to do it all on my own. I could get help externally. I wasn’t trying to be independent. I put that responsibility outside myself in the hands of the specialist. I think the app did play a part in that. – ID 1005

Yeah [I was] a bit embarrassed [to ask for help] because I am quite independent. I feel like I can [now] ask my family members or neighbours I need some help. In the app there were a few themes about allowing people to help you and how it’s kinda in a way allowing them to love you. I have actually allowed them to help where before that I felt embarrassed to do so. – ID 2011.

The third participant, who experienced a reduction in her Internal LOC score, showed a decrease in her PC scores from 34 to 8, which is six times what is considered to be a clinically significant reduction. PSE also moved from 22 to 60, three times what is considered to be a clinically significant reduction. Each of these scores was consistent with what she reported in the interview:
Probably the other thing is my ability to let people know about my situation and do it without feeling sorry for myself. I think a lot of times I was blaming myself a lot. Now I am able to relinquish that a lot more. I am not afraid. It [the app] has just normalised my “condition” – ID 2026

Another participant, whose internal LOC and PSE increased by a considerable margin, reported that she now feels more confident about doing things despite her pain. Against this trend, her chance LOC score also increased considerably, suggesting she now believed chance also plays a bigger role. She attributed those peculiarities in scores to an increased awareness of her thought patterns:

It’s been a little bit strange because it’s [App] been beneficial but also made me a lot more aware of my issues. I tended to be one of those people that like to sweep it under a rug or hide it in a corner of your mind until you have to deal with it. It’s hard when you are aware of something because you know you have to kind of deal with it. And there are a lot of other issues sort of there are some things going on in my life which is probably why the depression one has spiked a little bit. - ID 2018

Pain stages of change questionnaire (PSOCQ).

The PSOCQ is used to assess patient readiness for a self-management approach to chronic pain. This scale was used to determine if treatment adherence and clinical outcomes were related to the participant’s current stage of change. The PSOCQ scores indicated that 22 of the 24 participants (92%) who were recruited were in the contemplation stage at the time of recruitment.

To try and determine if women were still searching for a way to remove their pain completely, or if they were at the stage where they were seeking self-management approaches to pain, participants were asked: do you think that surgery or medication is what is required for your pain problem? Responses to this question were unanimous. Although respondents reported that that medication and surgery were important aspects of their pain condition, all respondents understood the important role they themselves played in managing their own pain condition.
Treatment credibility and expectation rating.

At baseline participants were asked to rate, out of 10, how confident they were that the program would be successful in helping them manage chronic pain ($M = 5.81$, $SD = 1.60$). At post-intervention they were asked how confident they would be, out of ten, in recommending the program to a person with chronic pain ($M = 8.44$, $SD = 2.34$). Although these responses were not discussed in the interviews, two participants (12.5%) reported that they felt the treatment was credible:

* I trusted that you done your research, that you understand it [chronic pain], maybe not yourself but you understand what it is like to be in pain and you have done your research to know what it feels like to be in pain. – ID 2011

* I know you have worked really hard on this. And that to me is so important that these things are done and developed and trialled. – ID 2018

8.5 Discussion

The purpose of Phase 3 was to answer key questions regarding the suitability and effectiveness of a self-administered CBT therapy for managing CPP, and for evaluating the data collection instruments and methods used. The research questions proposed in Chapter 5 will now be discussed in relation to the results obtained and literature reviewed.

Research Questions

P3.Q1. Was the app engaging to use?

The structured interviews suggested that the app was engaging and easy to use for most participants. The general consensus was that the narrator had a calm and soothing voice and the accompanying sounds and music were pleasant to listen to and complemented the experience. Furthermore, treatment credibility ratings (i.e., how confident participants were in recommending the program to others) were high across all participants. Collectively, this provides supporting evidence that the co-design methodologies used were successful in creating an app that was engaging and useful.

Participant self-reports indicated that the convenience of being able to engage with therapy at home and in their own time enhanced participants’ engagement with the
intervention. This echoes literature outlining some of the advantages of self-administered therapies over face-to-face therapies, which highlight travel, cost and stigma as common obstacles to treatment (Rini et al., 2012; Rosser & Eccleston, 2011). Some technical issues still need to be addressed, and additional features added to increase the ease of use and to promote greater levels of engagement. These modifications will be covered in more detail in the concluding chapter.

**P3.Q2. Was the information within the intervention relevant and helpful for women managing CPP?**

All sessions were rated by at least one participant as extremely useful, suggesting that each session in the program was helpful in some way. Progressive muscle relaxation, self-compassion, breathing exercises utilising the out-breath, and pain visualisation exercises were among the topics highlighted as most useful by the greatest proportion of participants. Identifying all the elements of the pain experience (i.e., physical, cognitive and emotional) and learning skills and strategies to manage each of those elements were among the features participants found most relevant and helpful in the therapy sessions. Some participants also reported that the app provided them with a useful tool to help them manage sleep difficulties and help them manage tension and stress in their day-to-day life. Collectively, this suggests that the information in the intervention was relevant and helpful for women managing CPP.

**P3.Q3. Does the information gathered from the app adequately inform designers about what aspects of the app were most helpful for women managing CPP?**

The survey data on usefulness collected from the app was generally consistent with self-reports. There were, however, some instances where the usefulness of a session was not realised at the time the survey was taken. In two instances where a session was marked as ‘not useful’ at all or ‘potentially harmful’, self-reports suggested that at the time that particular session was played, the material felt confronting. However, upon later reflection, however, the session was appreciated. Therefore, for users who selected ‘not useful at all’, it may have been more helpful for the survey to then present additional questions such as ‘was that session challenging for you?’ or ‘did you disagree with the information in that session?’ Furthermore, in instances where participants have answered ‘potentially harmful’, an additional prompt to provide an option for recording
what aspects were harmful might be useful in a larger trial where interviews are not possible. Overall, the data collected were useful in determining how helpful the app was for users, and with few modifications, may provide further information for designers.

**P3.Q4. Was a therapeutic relationship present between the user and the app?**

A critical element of the therapeutic relationship is the quality of the interpersonal bond between the client and therapist (Bordin, 1994; Martin et al., 2000). In this study, a relationship between the user and the app was operationalised through the level of care survey rating. More specifically, an interpersonal bond was considered to be present in a particular session if users responded with the option, ‘felt like the narrator cared about me’. Each daily session had at least one maximum response in the level of care rating suggesting a therapeutic relationship may have been experienced by at least some individuals.

In the post-intervention interviews, close to 50% of participants stated that they felt some level of care from the narrator, citing tone of voice and use of language as important factors. The reports from participants in this pilot study are consistent with the literature, which shows that a therapeutic relationship can be present in non-face-to-face interventions and, in some cases, at levels comparable to face-to-face therapies (Martin et al., 2000).

The data from the pilot study suggest that factors associated with the narrator (e.g., tone of voice, language used, phrasing) have a significant influence on the therapeutic relationship that is felt for this client group. For example, a different narrator was used in the pain education session, and some participants reacted adversely to that session suggesting the narrator was being judgmental. The material she was presenting, however, was consistent with the other material in the program. In this instance, the only difference was the way in which it was presented; that is, the use of language and tone of delivery.

Although some participants reported that level of care felt was related to relevance of information, when analysed together, the survey data suggest that usefulness of session and care felt may not be related (Figure 8.2). Together, these findings suggest that factors like tone of voice, language use, and sensitivity of verbal phrasing need to
appeal to and be appropriate for this client base when designing for a therapeutic relationship in non-face-to-face interventions.

**P3.Q5. Does the information gathered from the app adequately inform designers about what aspects of the app contributed to the therapeutic relationship?**

Although the level of care rating was helpful in determining which sessions elicited greatest feelings of care, and provided useful discussion prompts in the interviews, the survey did not measure the quality of the interpersonal bond in a linear and progressive manner as intended. Some users who rated level of care as ‘felt like the narrator was talking to a group of patients’ reported that they felt good about being part of a group, and that it was not necessary to feel like the narrator was talking specifically to them. Furthermore, the interview responses suggested that level of care is a more general factor that may not change from session to session. Therefore, measuring level of care directly after each session may not provide meaningful data. Moreover, the data in this study suggest that ‘talking to a group of patients’ and ‘talking specifically to me’ are not incremental measures of interpersonal bond. It seems likely that those responses are unrelated to each other and therefore do not belong on the same continuum.

**P3.Q6. Does utilising a non-face-to-face intervention for CPP help reduce pain catastrophising and what are the mechanisms for these changes?**

Almost two-thirds of the sample experienced clinically significant reductions in PC. The structured interviews suggested that for some participants these changes could be directly attributed to the intervention and skill building exercises delivered through the app. In particular, the breathing techniques were noted as being useful in managing anxiety and distress associated with persistent pain. For users who had already encountered strategies for reducing PC, the app reinforced those strategies, provided a welcome reminder, and in some cases, provided a fresh perspective.

Persons who experience PC tend to ruminate on the anticipation of pain, while believing they do not have the resources to cope with it (Quartana et al., 2009). It is possible that the reductions in PC found in participants in this study were attributed, in part, to the acquisition of new resources, such as breathing and relaxation exercises. These exercises may have been helpful in giving participants reassurance that they have
the tools they need when they are experiencing pain. Furthermore, breathing exercises have been shown to help manage symptoms of anxiety, which may help with reducing the rate of ruminating thoughts around anticipation of pain (Geisser et al., 1994).

Participants generally responded positively to the cognitive restructuring sessions. These sessions were designed to increase awareness of unhelpful, catastrophic and ruminating thoughts around pain. Users were encouraged to either challenge those thoughts or move focus away from them and onto more helpful ones. Almost half the participants reported that they catastrophised about their thoughts less, which they attributed to new insights and new skills acquired through the app. These new insights could be interpreted as new-found ways of appraising pain-related thoughts, suggesting that cognitive restructuring sessions were effective in reducing PC in women with CPP.

**P3.Q7. Does utilising a non-face-to-face intervention for CPP help increase PSE and what are the mechanisms for these changes?**

More than half the participants in the study experienced clinically significant increases in PSE suggesting a non-face-to-face intervention may help increase PSE in this population. In the structured interviews, some respondents reported that that the skills learned through the app gave them more confidence in their ability to cope with pain. By learning how to cope more adaptively with pain, participants reported that they were more confident doing the things they needed to do despite experiencing pain. This appears to be consistent with the literature on self-efficacy and PSE, which cites skill building as a critical factor (Asghari & Nicholas, 2001; Tonkin, 2008).

Some questions remain about how participants conceptualised PSE. One quarter of participants stated that it was not confidence but necessity that determined whether they could do tasks despite feeling pain. Another group of participants stated that their responses to the questions would have changed depending on the demands placed on them at the time. Therefore, the mechanisms for how PSE was increased in this sample, and how this relates to reductions in pain disability are not entirely clear.
P3.Q8. Do psychometric measures such as DASS, PSOCQ, LOC, Treatment Credibility and SF-12 provide useful information about what factors may have influenced PC and PSE scores, and can these measures serve as tools for screening participant suitability?

Some of the secondary measures were explored for use in a later RCT as potential validation and screening tools, and to see if they might determine some of the factors that influence PC and PSE. Exploratory correlation analysis showed a relationship may exist between changes in PC scores, and initial scores on some variables from the LOC scale. In particular, high Internal LOC scores were associated with greater reductions in PC. This finding is consistent with the literature on LOC and the efficacy of pain coping strategies (Crisson & Keefe, 1988). Surprisingly, this study showed that reductions in Internal LOC were associated with favourable outcomes for some participants. Interview data suggested that these women liked to be independent and did not feel comfortable asking for help from others. They reported that the app helped them relinquish some of that independence and allowed them to be open to receiving the help and care they needed from their social and family circles. Therefore, Internal LOC did provide some useful information about the mechanisms for change in PC and PSE, however, not in the way that may have been expected.

Scores on the PSOCQ suggested most participants were not in the pre-contemplation stage and were therefore willing to try a self-management approach to their pain. Since scores did not vary between participants, exploratory correlational analysis was unable to provide insight into how readiness-to-change influenced clinical outcome or treatment adherence (Kerns & Rosenberg, 2000). The data may, however, provide some indication of selection bias in the sample. Furthermore, the screening interviews indicated that on average participants had been experiencing CPP for almost 14 years. The post-intervention interviews confirmed that managing CPP had been a long journey and they are “further down the road”, suggesting that the pilot data may reflect a self-selected sample of women who were already willing to try something new for their pain. Therefore, this sample did not provide information about how useful these measures could be used as a tool for screening suitability.

Although the DASS did not provide useful information about what emotional factors contributed to changes in the primary variables, for some participants who
recorded severe depression scores, inconsistencies were found between their scores on the primary variables, and their self-reports for those variables. Therefore, the DASS may be a useful measure to use in an RCT where qualitative data is not available. It could be used to explore potential inconsistencies within and across data variables for participants who score in the severe range for depression. However, the measure might not be a reliable means in an RCT as a tool for validating data.

**Strengths and Limitations**

The data collection methods (i.e., multiple interviews; app usage and survey data; and psychometric measures captured at two time-points) may be considered a strength of this study. This combination of data provided opportunities to obtain useful insights into the factors that may have influenced reductions in PC and increases in PSE. This information may help in determining which psychometric measures (e.g., LOC scale) may be useful in capturing those factors in a larger RCT. The survey and usage data gathered also provided unique opportunities to gather information from participants while they were engaging with the intervention, overcoming common problems associated with memory and time lag. These real-time data also provided useful design information for determining which components of the intervention were utilised the most and therefore deemed most useful.

The findings on the primary outcomes in this phase of the study need to be interpreted with caution for several reasons. Firstly, the sample size was small. As a pilot study, the findings are preliminary until confirmed and that the small sample size may provide an indication of trend, or areas for further research, but should not be extended beyond that. Secondly, the recruitment process was conducted via invitation, not random allocation, indicating that the sample was self-selected and skewed towards participants who were ready for to adopt a self-management approach for their pain. This may have rendered the screening tools ineffective. Thirdly, the six participants who withdrew from the study were not available for interview and may have provided valuable insights and design improvements from persons who did not wish to continue with the intervention. Also, some discrepancies occurred between self-reports in the interviews and the psychometric data collected in this sample prompting possible suggestions for future exploration.
Finally, the student researcher who conducted the interviews was also the narrator of the scripts within the intervention. Therefore, the results of the pilot study may not be generalisable to users who have not initially conversed with the narrator. Furthermore, participants in the post-intervention interviews may have been reluctant to provide honest negative feedback directly to the person who narrated the scripts and may have been more comfortable providing such feedback to an anonymous third party. The merging roles of the researcher also made the data vulnerable to some biases which were covered in the concluding section of Chapter 5.

Conclusion

PC and PSE appear to be relevant measures for quantifying how effective an intervention can be for women who experience CPP. However, the mechanisms which led to increases in PSE are not clear in this study. The app and survey data were helpful in determining what aspects of the technology were most useful, what factors contributed to feelings of care felt from an intervention. However, response options in the level of care felt rating did not appear to operationalise the level of therapeutic alliance in the manner intended. Therefore, the scale may require further refinement before utilising it in a larger study.

Some secondary measures, such as LOC scale, may be useful as potential validation and screening tools. However, given the nature of the self-selected sample, this study could not determine if any of the secondary measures could be useful as screening tools.

The results from the pilot study not only provided support for the efficacy of appEase, but also for the use of self-administered CBT by women with CPP. Participants were exposed to over eight hours of audio-based CBT and yet only minor alterations to the therapy were suggested by participants in the post-intervention interviews. For this small sample, it showed that with a few small modifications, the intervention is likely to be safe to administer to a larger sample. Some useful design improvements were suggested, all of which are likely to be straightforward for a software developer to implement.

This project also extends design research by providing an example of how co-design methodologies can be applied to women experiencing CPP. It also provides some important methodological and design considerations both for the intervention and
the empirical investigations proposed in the intended RCT. These considerations will be presented in more detail in the final chapter along with details of the clinical and research implications of this phase of the study.

The qualitative interviews also provided insights into the experience of CPP in women. Some of these were not explicitly stated in the literature and were alluded to in the first phase of the study. In particular, some women with CPP tend to prioritise their family over their own well-being, given many participants found it difficult to find 15 minutes in a day to engage with the app. A strong message delivered through the app was that caring for yourself is an important part of caring for others. Although some women found that idea helpful, it was one of the bigger challenges for them. Additionally, some women like to be independent and not ask for help or rely on others. They did not want to complain and sometimes were hard on themselves for cancelling social engagements and letting others down. Given self-compassion was the most session rated as the most helpful, the app provides an element of hope.

The results from this phase of the study suggest that a self-administered CBT intervention for chronic pain may be suitable for women experiencing CPP and can play a role in managing their pain. The data suggest that the intervention created was easy to use, and helpful in reducing PC and increasing PSE. Furthermore, some of the skills acquired by participants were not only useful for managing pain, but also helpful in managing anxiety, stress and low mood.
Chapter 9.
Discussion and Conclusion

This concluding chapter presents an integrative discussion incorporating the literature review undertaken, research questions proposed, and data collected from each stage of the project. It begins by discussing some of the contributions this research could make in the fields of clinical psychology and design and suggests opportunities for further investigation. A summary of the strengths and weaknesses outlined in the earlier chapters will be presented with reference to a reflexive summary of the project. The chapter then suggests design improvements to the app and its methods of evaluation, and concludes by presenting details of a planned RCT.

9.1 Overview

CPP is a complex, distressing, and debilitating condition. It is costly for both the individual and the community. Medical and pharmacological interventions are generally limited to symptom relief; while psychological interventions such as CBT, although effective, are often not utilised or available. To improve access and engagement, technology-based interventions have been developed as an alternative means of delivering psychological therapies. In some instances, they show clinical efficacy comparable with face-to-face therapies. Despite their advantages, technology-based interventions have their own limitations: attrition rates are generally high, end-users and medical professionals are often not involved in the design process, and most interventions have not been adequately tested in clinical trials.

To overcome these limitations, co-design methodologies have been adopted as these methods can produce more effective interventions for end-users. The overall aim of this research was to design and evaluate a technology-based self-administered CBT intervention for women experiencing CPP. Utilising a co-design approach, it sought to overcome the limitations of non-face-to-face technological interventions and create an intervention that was both engaging and effective. The results of this project would inform an RCT in future.
9.2 Contribution and Opportunities for Future Research

This research offered some important implications for technology design in the area of chronic pain and contributed a further understanding of women’s experience of CPP. It incorporated CBT research within co-design and by doing so may have provided some important contributions to clinical practice for a population group that is considered difficult to treat. Contributions from this project will be discussed in this section, considering the literature and research questions proposed. Where appropriate, opportunities for future research will be presented.

Understanding Women with CPP

The data in this project mirrored findings in the literature stating that CPP is highly distressing for women, associated with disability, comorbid with other mental health conditions; and often involves inconclusive and unsatisfactory medical investigations (Dalpiaz et al., 2008; Ghaly & Chien, 2000; Weijenborg et al., 2007). Some further insights were obtained in this study that were not explicitly stated in the literature but provided useful information for design and evaluation. Although specific to the participant group in this study, this information may contribute a further understanding of women with CPP. These insights related to women’s responses to self-compassion, their sometimes-unhelpful tendency to want to maintain their independence, and the difficulties in recruiting for this participant group.

CPP and self-compassion.

Contribution: The focus groups and structured interviews suggested that women with CPP tend to be hard on themselves (Dalpiaz et al., 2008); many feel they are failing, that their body is letting them down, and that they are disappointing their family and friends (McGowan et al., 2007). In the focus groups some women reported feeling isolated. Although they felt the need for affection and wanted intimate relationships, they avoided them as they felt they could not meet the demands of physical intimacy (Brauer et al., 2007). Some women reported that in social situations they do not want to be seen to complain and are sometimes hard on themselves for cancelling social engagements and letting others down. Furthermore, it is common for women with CPP to prioritise their family commitments over their own well-being (Werner et al., 2004) and in the pilot study, this was an obstacle for daily utilisation of the intervention. Yet
despite the tendency for these women to be hard on themselves, the session on self-compassion was rated as ‘highly useful’ by more participants than any other.

**Opportunity:** It may be possible that women are aware that they are being too hard on themselves, and welcome tools that help them adopt a more self-compassionate approach to themselves and their situation. This information may be helpful in diagnostic interventions and examinations. By learning techniques that evoke feelings of self-compassion, clinicians may help some women overcome the feelings of distress that can be associated with difficult clinical investigations and inconclusive diagnoses. Furthermore, although self-compassion has been explored in some chronic pain studies, research investigating self-compassion as an intervention for women with CPP may warrant further investigation. The data in this study show encouraging signs that self-compassion is an area to which women with CPP may respond well.

**Maintaining independence.**

**Contribution:** In this study, three participants who experienced clinically favourable outcomes in their primary measures also recorded notable reductions in internal LOC. When interviewed, each of these participants attributed the positive effects of the therapy to relinquishing some of their independence. Although the sample in this case is small, it suggests a possibility that a reduction in internal LOC may be a mechanism for positive clinical change for some women with CPP who might value independence over well-being.

**Opportunity:** The literature review showed that personality factors such as perfectionism have been implicated as a distress factor for persons with chronic pain (Bonica et al., 2010). Rigid thinking styles (e.g., black and white thinking) have also been implicated in the increase of anxiety related thoughts including catastrophisation (Keefe et al., 2004). Therefore, further research investigating instances of high internal LOC in women with these personality traits and thinking styles may be warranted. Utilising the LOC scale, along with personality and anxiety measures, may help in identifying potential risk factors for CPP.

**Difficult sample to recruit.**

**Contribution:** The difficulty in recruiting participants both in the focus groups and pilot study warrants some attention, as it may provide useful information for those
seeking to conduct future research with women experiencing CPP. For both the focus groups and pilot study, there was a notable discrepancy between enthusiasm for joining the study and actual participation. All women who were scheduled to attend the focus groups stated that the primary reason for joining the study was to try and help women who are experiencing CPP. Unfortunately, only half the scheduled participants were able to physically attend. Limitations due to pain and anxiety were stated as primary reasons for those who could not attend. Recruiting for the pilot study was also difficult. Although difficulties are expected when conducting research with clinical samples, the apparent lack of interest from women on the waiting list for treatment was surprising. Some women were waiting for over a year to see a specialist at the hospital. It was expected that they would be interested in an intervention that might help them manage their pain while they were waiting, however, this was not the case.

Opportunity: In this sample, most women had been experiencing CPP for at least 12 years, and most had already tried medical and pharmacological interventions for their pain. It may be possible that women are more willing to try psychological interventions for their pain only after they have exhausted all medical and pharmacological options. Further research examining the suitability of women to self-administered therapies for CPP may shed more light on this hypothesis.

Intervention for CPP and Other Disorders

The mobile phone intervention appEase, after tested in an RCT, may be considered a noteworthy contribution providing hope for women experiencing CPP, as well as their family, friends, and loved ones. With some minimal design modifications, appEase may also be helpful in managing anxiety and mood disorders.

appEase.

Contribution: For women who do not wish to engage in psychotherapy because of stigma, or those who cannot attend therapy because of cost or disability, appEase contributes a new treatment option. It provides evidence-based CBT which women can utilise in the privacy of their own home, or in acute instances where it is urgently needed. Clinicians who treat women with CPP may also find it a useful inclusion in their practice as it provides structured daily exercises that can augment weekly or
fortnightly face-to-face sessions. Furthermore, the ability for it to be distributed to many women at minimal cost may contribute significant cost savings to the community.

**Opportunity:** CPP is comorbid with other psychological conditions such as depression and anxiety. Some participants reported that the intervention was also helpful in managing stress, anxiety and low mood. The overall reductions in depression and anxiety scores seem to support this. Four participants recorded extreme anxiety scores at baseline compared with one at post-intervention, and three reported severe depression scores compared with one at post-intervention. With very few modifications to the daily sessions, appEase could be adapted as an anxiety or depression intervention targeting catastrophisation (rather than PC) and self-efficacy (rather than PSE). A co-design approach involving the modification and evaluation of appEase for mood or anxiety disorders may also warrant further investigation.

**Designing for Therapeutic Alliance**

Therapeutic alliance is influenced by factors such as whether a patient feels their feelings are validated, whether they feel understood by their therapist, and whether patient and therapist develop mutual respect (Bordin, 1994). A therapeutic relationship involving trust and empathy may be possible in non-face-to-face contexts, and, in some cases, at levels comparable to face-to-face therapies (Martin et al., 2000).

**Contribution:** Close to half the participants in the pilot study reported that they felt a level of care from the narrator. Factors such as tone of voice, use of language, and relevance of information were all reported to contribute to this perceived feeling of care. All these factors were suggested by participants and clinicians in the first phase of the study. This suggests that elements of therapeutic alliance gathered in the early stages of co-design may generalise to end-users in the latter stages. Therefore, this project illustrates that co-design methods may produce features that help facilitate therapeutic relationship.

**Opportunity:** Consulting the user group in the design process implied an indirect, but potentially helpful, collaborative process for women utilising the intervention. The literature shows that women with CPP often feel dismissed in their concerns about their condition, and do not always have input into their treatment approaches (Price et al., 2006). Collaboration and mutual goals are an important element of a therapeutic
relationship (Bordin, 1994; Martin et al., 2000). Furthermore, the literature suggests that individuals are more likely to engage and persevere with a treatment plan if they are collaboratively involved in the design of that plan (Engeler et al., 2013; Singh et al., 2014). Although therapeutic alliance has been investigated in non-face-to-face interventions, the perception of mutual goals through co-design and how this influences therapeutic alliance for women with CPP has not been explored. The data from this study suggest this may warrant further investigation.

**Audio-Only Interventions**

Applying co-design methodologies in this study yielded design ideas that were unlikely to have been considered had the user group not been consulted.

*Contribution:* It was not anticipated that women with CPP would prefer audio-only as the primary mode of delivery. Given the vast amount of mobile phone apps that utilise text and video, it was surprising that women in the focus groups were averse to those particular modes of delivery. This information may be useful for designers of other therapies targeting women with CPP.

*Opportunity:* Although the literature shows that sound and music have often been used in the treatment of chronic pain (Guetin et al., 2012; Newbold et al., 2016) there was no design precedent for an audio-only CBT intervention for chronic pain. Therefore, this research may prompt designers to consider audio-only modes of delivery for other chronic pain interventions.

### 9.3 Preparing for Future RCT

The final stage of the co-design process involves modifying the intervention and its methods of evaluation in response to the information gathered in the pilot study, and evaluating it in an RCT (Hagen et al., 2012). In the pilot study, suggestions for how the intervention could be improved ranged from ideas on improved user interface, through to ideas about the use of language and information covered within the audio scripts. This section will present these suggestions along with some suggestions on how the methods of evaluation might be improved. It will conclude with an outline of the various contexts in which the final evaluation could occur.
User Interface Modifications

The most frequently reported suggestion from the post-intervention interviews was to reduce the sensitivity of the ‘safe space’ option. This was a source of frustration for some users who inadvertently activated it by touching their screen while listening to a session. To rectify this problem, the safe-space feature could be activated by some alternative means, such as tapping physical buttons on the phone multiple times.

It is important to note that users who kept completely still during the session did not inadvertently activate the safe space feature. Therefore, a design improvement may involve reconfiguring the original safe space mode of activation as Mindfulness radar. The Mindfulness radar could reward users for keeping still during sessions, and its sensitivity could be increased as the user becomes more advanced in their mindfulness skills. Users could also be rewarded with bonus points during the audio sessions. Reviewing the literature on biofeedback and technological adjuncts for psychological interventions may be necessary to help refine this feature (Clough & Casey, 2011).

Some comments from participants were also made about the way in which the sessions were activated across the 28 days. Although users could replay previous sessions and repeat current sessions, some users were unhappy with the inability to skip ahead. This was particularly restrictive for some who wanted to skip material already familiar to them. One possible solution could include creating a group of foundational sessions that need to be completed one day at a time first, and then allow the remaining sessions to be accessed freely. Alternatively, users could be screened for, or voluntarily select either beginner, intermediate, or advanced in their CBT skill set. Those with advanced CBT skills may then have the option to skip ahead whenever it suits them.

Finally, some users also suggested an option to adjust the speed of the voice. This feature may require more consideration. Mindfulness exercises are designed to slow down the rate of nervous system activity and slow down the rate of thoughts. Rather than speeding up the pace, it may be more helpful to encourage users to acclimatise to the rate of delivery. This way, they can incorporate speech speed into their mindfulness awareness in the same way they were encouraged to incorporate noises from outside the room and notifications from their phone into their daily practice.
Improvements to the Daily Sessions

Some suggestions were made regarding the use of language in the daily sessions. Throughout the intervention, users were sometimes instructed to give the out-breath their full attention, and at other times they were instructed to savour the out-breath. One user took exception to being asked to savour an experience and thought it was more appropriate for the instruction to just ask them to focus on the out-breath. Although this is a common mindfulness exercise, it is sometimes considered poor clinical practice to ask a person to feel a certain way during an exercise (Turk & Gatchel, 2002). Rather, it is generally better practice to provide exercises with instructions that can be completed regardless of how they feel. Therefore, instructing users to focus on the out-breath, and then suggesting the possibility of savouring the out-breath may be a more appropriate way of presenting those exercises.

The cognitive restructuring exercises were designed to increase participants’ general awareness of the over-use of certain words (e.g., ‘should’ and ‘must’) particularly in instances of increased stress and anxiety. The exercises were also designed to make participants aware of the valence of such language. To illustrate this point in the intervention, self-talk that involved the word ‘should’ was characterised as being a ‘should tyrant’. Instances where ‘should’ self-talk was overused was illustrated with the metaphor: being possessed by the should tyrant. One participant took exception to the use of the word ‘possessed’. She reported that she found it unsettling. Therefore, this session will be modified, and the word possessed will be replaced with ‘overcome’.

Language was also a consideration in the sessions on values. Although these sessions were generally well received, they were not rated as useful relative to the rest of the intervention. When queried about this, some participants did not think the word ‘values’ was appropriate. One participant interpreted values as ‘morals’. Another participant suggested that the language should be more explicit, and the exercise should just explicitly state: ‘is this what you really want?’

There were also some suggestions for the ways in which the pain visualisation and progressive muscle relaxation exercises were instructed. Pain visualisation is a technique commonly used to help a person disassociate from their pain. The approach is paradoxical as it requires a person to focus on their pain, but in an objective manner. In the intervention, users were trained to release tension in their body first, and then focus
on the area of pain without adding further tension. They were then asked to describe the pain sensation in detail (e.g., shape, size, texture). This exercise was trialled effectively in the focus groups, but during the intervention some women reported that it was a difficult exercise to do. Instructions for this exercise may need to be modified, or the exercise may need to be presented in two parts over two days.

Progressive muscle relaxation is a technique that is used to build an awareness of tension stored in the body. It can also be used as a stress relief exercise. It was rated amongst all participants as one of the most helpful of the sessions. However, one participant labelled the session as potentially harmful. She reported feeling uncomfortable during the session and suggested that for women who do not see a physiotherapist, this session could be physically harmful. Although users were instructed at the start of the session to stop the exercise if they felt uncomfortable and revert to the body scan, it may be necessary to make those recommendations more explicit throughout the entire exercises.

**Improvements to the Methods of Evaluation**

Results and self-reports around the PSE remain unresolved for some participants in this study. Bandura (2006) states that self-efficacy captures perceived capability (i.e., I can do), rather than intention (i.e., I will do). However, in some cases, self-reports of PSE, and the inconsistencies with the PC scale suggest that PSE may be capturing perceived necessities or obligations (I have to) rather than the level of confidence (‘I can do’) women had in performing tasks despite their pain. No distinction was made in Bandura’s guide on self-efficacy about need versus want. Further, no provision was made in his guide for instances where a person feels they must do an activity. Therefore, for this sample it is unclear if PSE is capturing the confidence women have in doing their tasks, or if it is capturing how many tasks they feel they must do out of necessity. It is possible for some women to have a high PSE score, but still feel helpless and lack confidence in doing the things they want to do as they are only capable of doing the things they need to do. Persons who score high on self-efficacy may not be thinking about their aspiration in an optimistic manner as Bandura suggested but may be thinking about their obligations in a pessimistic manner.

Overall, the both the primary measures were useful in this study, however inconsistencies between self-report and scores on both the PC and PSE scales occurred
for women with high depression scores. This suggests that severe depression scores may need to be considered when interpreting these scores in an RCT. For example, secondary analysis may be conducted where persons with extreme or severe depression scores are removed from the analysis.

The survey data collected from the app was generally accurate in determining which sessions were most useful to participants, however, clarification might be useful in an RCT in instances where a session is marked as ‘not useful at all’ or ‘potentially harmful’. For users who select ‘not useful at all’, it may be helpful for the survey to then present additional questions such as ‘was that session challenging for you?’ or ‘did you disagree with the information in that session?’ Furthermore, in instances where participants answered, ‘potentially harmful’, an additional prompt to provide an option for recording what aspects were harmful may provide helpful safety information for when the intervention is administered to a larger sample.

The level of care rating from users matched self-reports in most instances. However, the measure did not reflect level of care felt from the narrator in a linear and progressive manner as intended. Some users who rated the level of care as ‘felt like the narrator was talking to a group of patients’ reported that they felt good about being part of a group, and that it was not necessary to feel like the narrator was talking specifically to them. Furthermore, the interview responses seem to suggest that level of care is a more general factor that may not necessarily change from session to session. Therefore, measuring level of care directly after each session may not necessarily provide relevant and meaningful data in an RCT. It may only be necessary to ask the question at the end of the intervention.

**Research Context**

The portable nature of appEase provided opportunities for its administration in several different contexts. appEase could be administered as a standalone downloadable app for women who are open to utilising a self-administered CBT pain management program. In this context, women experiencing CPP can simply download the app and start the therapy in their own time. Self-administered interventions have the potential to reach greater proportions of the population than face-to-face interventions. The ability to produce small clinical effects across a large proportion of users suggests that on a population level, self-administered therapies may produce superior results to face-to-
face therapies (Buntrock et al., 2014; Ebert et al., 2014; Heber et al., 2013; Lin et al., 2015; Macea et al., 2010).

The app could be utilised within the context of a multi-disciplinary team, reducing costs and easing the resource burden. The gold standard treatment for chronic pain conditions is CBT within a multi-disciplinary setting (Flor et al., 1992; Scascighini, Toma, Dober Spielmann, & Sprott, 2008). However, these interventions are costly, and resources are scarce. In this context, physiotherapists, occupational therapists or pain doctors in a multi-disciplinary pain clinic may administer appEase to women who are already taking part in a chronic pain program. This not only frees up resources and reduces costs, but it provides much-needed psychological expertise for a complex and highly distressed clinical population. If utilising a self-administered intervention over 28 days can reduce psychological distress in women experiencing CPP; and increase the confidence they have in participating in activities despite their pain, then for some people, this may provide a cost-effective alternative to the psychological component of multi-disciplinary approaches. Rather than waiting for treatment in a multi-disciplinary clinic, it may be possible for patients to utilise the app in conjunction with their physiotherapist and doctor to create a ‘virtual multi-disciplinary clinic’ and therefore access the gold standard therapy for chronic pain sooner.

appEase could also be used to augment face-to-face psychotherapy by providing an engaging set of daily exercises women can utilise in between their weekly, monthly or fortnightly sessions. As discussed earlier, appEase provides structured daily exercises that may augment (or replace) weekly or fortnightly face-to-face psychotherapy. Testing the clinical efficacy of CBT plus appEase against CBT alone may be another useful study. This may determine if the app can be a useful clinical tool for psychologists to utilise within their practice.

9.4 Strengths, Limitations and Reflexive Statement

Strengths and limitations of the individual phases of this project have been discussed in previous chapters. Overall strengths included the variety of data collection methods utilised and the skill set of the student researcher who facilitated and analysed the focus group data, narrated the intervention, and produced a professional product that users reported was engaging and helpful. The nature of this research project also produced some limitations including small sample size, selection bias, limited
generalisability of results, and the student researcher’s merging role between narrator, developer and evaluator.

Qualitative data collection and analysis features heavily in this research project, and although the range of data collected was a strength of the study, it made this project vulnerable to some reflexivity biases (Finlay, 2002; Shaw, 2010). A personal reflexivity statement from the student research was presented in Chapter 5.

9.5 Final Conclusion

Creating a self-administered intervention for a complex clinical population comes with a unique set of design challenges. In this research, involving patients and treating clinicians in the design process resulted in an intervention that users reported to be engaging and helpful in managing CPP. Therefore, this project provides support for the use of co-design for women with CPP. It highlights the value in seeking a richer understanding of women’s experiences of chronic pelvic pain and illustrates the complexities and sensitivities that are intrinsic to designing technology-based therapy for people experiencing chronic pain and other complex conditions amenable to psychological interventions. The findings in this study may be useful to other researchers designing self-administered interventions for chronic pain. The study also provides a good basis for modifying the app and testing it in an RCT.

Co-design is increasingly utilised in technology-based mental health interventions (Dohery et al., 2014; Hagen et al., 2012; Orlowski et al., 2015). This is the first study to utilise this approach for women experiencing CPP and it provides some support that co-design methodologies can produce engaging and relevant interventions for this population. The pilot study provided positive support for the intervention. Participants found the app easy to use, appreciated the audio-only format, and for the most part, considered the information to be useful and relevant for managing their pain. The clinically significant reductions in PC and increases in PSE for this small sample were also encouraging. Furthermore, half the participants selected a maximum score when asked if they would recommend the intervention to another person experiencing chronic pain. Therefore, this project provides a justification for moving to the final stage of co-design: evaluating it in an RCT.
The results from this research suggest that a self-administered CBT intervention for chronic pain may be suitable for some women experiencing CPP and can play a role in helping them manage their pain. This project is the first to apply co-design methodologies to treatment of CPP in women. Using co-design has yielded new insights into the personal experiences and complexities of CPP in women. The app created, appEase, is the first technology-based CBT intervention for this population. This research also provides a strong basis for testing the efficacy of appEase in an RCT with women experiencing CPP.


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Appendix A: Focus Group Phase Recruitment Material

A1: Invitation Flyer (Phase 1)

We are Developing Technology to Help Women with Chronic Pelvic Pain
And we would like your Help...

We are looking for Women who experience Persistent Pelvic Pain to come together in a small group and attend a 1 – 2 hour workshop to discuss:

- How you use the Internet, Mobile Phones and any Hand-held technologies
- Why you do not like using the Internet, Mobile Phones and any Hand-held technologies
- How Web pages or Phone-Apps might be helpful to persons with Chronic Pelvic Pain
- Why Web-pages or Phone-Apps are never going to help people with chronic pain

There are no wrong or right answers. We just want your opinions and ideas. You do not have to know anything about Computers to join in.

The session is designed to be fun and friendly. Refreshments will be provided and you will receive a $40 gift voucher as a thank you for your help.

If you are interested, please read the Invitation Letter that is attached and visit www.website.com to register in a Workshop.

The University of Melbourne
INITIATION LETTER/PLAIN LANGUAGE STATEMENT

You are invited to participate in a research project conducted by a Clinical Psychology PhD student (Arthur Stabolidis) and supervised by Associate Professor Christina Bryant of the Royal Women’s Hospital, Associate Professor Lisa Phillips of the University of Melbourne School of Psychological Sciences and Dr Greg Wadley of the School of Information Systems. The aim of the study is to develop a web page or mobile phone app to help women who are experiencing persistent pelvic pain. We would like your input so we can make sure that the technology we design is fun, easy to use and relevant for women with pelvic pain.

If you decide to participate, you will attend a two-hour workshop with up to 12 other women at the Royal Women’s Hospital. As part of the group you will learn about psychological therapies for chronic pain and then be asked some questions about how you use technology (mobile phones, web pages) in your day to day life. The group will then be presented with ideas about how an electronic therapy might look, and then a discussion about those ideas will take place in an open and friendly manner. Refreshments will be provided and you will receive a $40 Myer gift voucher in appreciation of your help.

Participation in this project is completely voluntary and you are free to withdraw at any stage. The workshop will be audio recorded, but you will remain anonymous as no real names will be used in the workshop. We will require you to complete some short screening questionnaires (attached) and this information will be stored in a file on a secure website and it will not be possible to identify it. The data will be deleted seven years after the publication of any article arising from it. Findings will be reported as group results only and individuals will not be identified in any publication resulting from this work.

If you would like to participate, please visit: www.website.com and complete the consent form. A page will then appear with a list of workshop dates. Please place a tick
besides the date(s) you are able to attend and press “Submit”. Two weeks following the submission of your form, a member of the research team will contact you.

Note: This study has been approved by the Royal Women’s Hospital and the University of Melbourne Human Research Ethics Committee. If you have any concerns regarding the conduct of this research project, please contact do not hesitate to contact your clinical doctor at the Chronic Pelvic Pain Clinic. If you have any questions about the research itself, please contact Arthur Stabolidis (email: arthurs@student.unimelb.edu.au).

Thank you kindly for your time.

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A3: Consent Form (Phase 1)

Consent form for persons participating in a research project

Name of participant:

Name of investigator(s): Associate Professor Christina Bryant, Associate Professor Lisa Phillips, Dr Greg Wadley, and Arthur Stabolidis

1. I consent to participate in this project, the details of which have been explained to me, and I have been provided with a written plain language statement to keep.

2. I understand that after I sign and return this consent form it will be retained by the researcher.

3. I understand that my participation will involve a participatory workshop/focus group and I agree that the researcher may use the results as described in the plain language statement.

4. I acknowledge that:
   (a) the possible effects of participating in the participatory workshop/focus group have been explained to my satisfaction;
   (b) I have been informed that I am free to withdraw from the project at any time without explanation or prejudice and to withdraw any unprocessed data I have provided;
   (c) the project is for the purpose of research;
   (d) I have been informed that the confidentiality of the information I provide will be safeguarded subject to any legal requirements;
   (e) I have been informed that with my consent the participatory workshop/focus group will be audio-recorded and I understand that the digital files of the recordings will be stored at University of Melbourne and will be destroyed after five years;
   (f) my name will be referred to by a pseudonym in any publications arising from the research;
   (g) I have been informed that a copy of the research findings will be forwarded to me, should I agree to this.
   (h) I have been informed that this study is fairly small therefore it may be possible for someone to identify me from the things I have said during the participatory workshop/focus group or by my characteristics and I understand that any personal reference in publications that might allow someone to guess my identity will be removed.

I consent to this participatory workshop being audio-taped □ yes □ no (please tick)

I wish to receive a copy of the summary project report on research findings □ yes □ no (please tick)

I am willing to be contacted again for further research participation opportunities □ yes □ no (please tick)

Participant signature: Date:
Dear Professor Bryant,

Re: Project 15/06 – Developing an E-therapy for women with chronic pelvic pain (DECP)

Thank you for submitting the clarification and amendments as requested by the RWH Human Research Ethics Committee.

I confirm the project is now approved.

Enclosed please find Project Approval and Notification of Project Commencement Forms for your record.

Prior to commencement of your project, you are reminded that you must contact the relevant RWH Divisional Directors / Department Heads to confirm your actual commencement date. Failure to inform these RWH personnel may jeopardise their approval and support for your project.

Please return the completed Notification of Project Commencement Form to me when the project begins.

Yours sincerely,

A. C. B. Hui
Administrative Officer
Research and Ethics Secretariat
Appendix B: Focus Group Protocol

1. Introductory remarks

General reminder that:

- We do not expect anyone to have any prior knowledge about Computers and the Internet
- We are not looking for clever answers – only your opinions
- Answering questions is completely voluntary and there is no need to feel any pressure to contribute
- If you feel uncomfortable at any stage, you are welcome to leave and still keep the Myer voucher
- The information in this session is considered confidential so please do not let it leave the room
- There are a series of fictitious name-tags here on display, please select one you like the most
- Please be respect to anyone providing an opinion in the session

2. Experience of Pain and Psychology

- Does anyone want to discuss their pain experience and the impact CPP has had on their life?
- Do you think psychology can play a role in helping women with CPP?
- Can you think of any times when your thoughts influenced your pain experience?

Present CBT Examples for Discussion

- Could anxiety, stress and tension influence a pain experience?

Present Examples of Psychoeducation around Chronic Pain for Discussion

Mindfulness Exercise

- Please describe your experience of the mindfulness exercise and rate its usefulness?

3. Technology and Design

- Do you use digital technology, or any health-related apps or websites?
- If you were to receive therapy outside of a face-to-face context, how would you prefer to receive it?

Present Design Examples For Discussion

- Do you have any suggestions on how this therapy could look, how it would work, and what features it should have?

Present Materials for Creating Design Examples

- If you could design the perfect mobile phone app for people with Chronic Pelvic Pain, what features would it have and how would it look

<Conclusion>

- Offer the option to stay behind and speak with psychologist
- Sign attendance, Gift Vouchers & Parking
Appendix C: Summary of 28 Day Program

Day 1: The Out-Breath. A simple technique to help manage your nervous system.
1. Savour the out breath
2. The nervous system
3. Full Outbreath Focus

Day 2: Resting In Thought. Using the out-breath to rest your thinking mind
1. Savour the Recap
2. Nature of thoughts
3. Rest on the Outbreath

Day 3: Rest Your Feelings. Accommodating unpleasant feelings
1. Thought with Outbreath
2. Focus and Feeling
3. Welcome your Feeling

Day 4: Tension and Pain. Tension as a major part of the pain experience
1. Feeling without Breath
2. Tension and Pain
3. Upper Tension Release

Day 5: The Body Scan. Learning the body scan
1. Outbreath Release
2. Autonomic Release
3. Short Body Scan

Day 6: Prog Muscle Relax. Learning Progressive Muscle Relaxation (PMR)
1. Introducing PMR
2. Understanding PMR
3. Experiencing PMR

Day 7: Practical Acceptance. Practicing acceptance and pragmatic self-kindness
1. A Kind Orientation
2. Practical Acceptance
3. Internal Acceptance

Day 8: Pain Fear. Experiencing the difference between pain and fear
1. Upper Sound Release
2. Pain and Pain-fear
3. Knowing Pain-fear

Day 9: Pain Visualisation. Observe your pain areas while releasing tension
1. Guided Release
2. Pain Visualisation
3. Pain without Tension

Day 10: Identifying Values. Identifying what is most important with who you are
1. Valued Friendships
2. Values and Identity
3. Acknowledging your Values

Day 11: Valued Choices. Making choices that move you toward your values
1. Identifying Values Recap
2. Values and Choices
3. Visualising Valued Choices

Day 12: Valued Living Obstacles. Recognising Obstacles to valued living
1. Brief Values Check
2. Choices and Habits
3. Obstacles to Valued Living

Day 13: Thought Awareness. Becoming aware how thoughts inform feelings
1. Same Rain Different Thoughts
2. Thought Awareness
3. Practicing Thought Awareness

Day 14: Unhelpful Thinking Styles. Catastrophising, Black and White Thinking and Emotional Reasoning
1. Building Thought Awareness
2. Common Thinking Styles
3. Recognising Thinking Styles
Day 15: Shoulds and Musts.
Understanding how language and self-talk affects mood
1. Should Awareness
2. The Should Tyrant
3. Countering the Tyrant
Day 16: Reframing “Why?”
Understanding the emotional quality of “Why” questions
1. A Should Standoff
2. Why Questions
3. Reframing Why
Day 17: Pain Education. First Forehead, Second Sensations, Third Thoughts, Fourth Feelings, Fifth Full-body
1. Your Pain Audit
2. NSW Hunter Pain Education (HIPS)
3. Training in five-breath
Day 18: Exploring Anger. Exploring and understanding the physiology of anger
1. 5 Breath Recap
2. Relating to Anger
3. Tuning Into Anger
Day 19: Anger and Pain. Understanding and experiencing expressions of anger
1. Skills Recap
2. Anger and Pain
3. Encountering Anger
Day 20: Gratitude and Reminders. Training in Gratitude and evoking the feelings you really want
1. Free five-breath
2. Gratitude and Values
3. Evoking Gratitude
Day 21: Enemies of Gratitude.
Maintaining gratitude among noise and its many enemies
1. Free breath recap
2. Enemies of Gratitude
3. Gratitude Amongst Chaos
Communicating Intimacy
1. Free five-breath
2. Fear and Intimacy
3. Modes of Communicating
Day 23: Self-compassion. The elements of self-compassion and its health benefits
1. Acclimatise
2. Self-compassion Elements
3. Self-compassion Exercises
Day 24: Socialising in Pain. Pain, nerves and the challenge of socialising
1. Acclimatise
2. Social Nerves and Pain
3. Visualising Social Anxiety
Day 25: Sleep and Worry. Techniques for better sleep and less worry
1. Acclimatise
2. Sleep and Worry
3. Sleep Hygiene Visualisation
Day 26: Relapse and Progress. Progress is Not Always a Straight Line Up
1. Progress Check
2. Progress in Waves
3. Stages of Change
Day 27: Pain Flares. Planning for and Coping with Pain Spikes
1. Progress Check 2
2. Importance of Planning
3. Coping Reflections
Day 28: Graduation Day. Recap and Moving Forward
1. Recap Pt I
2. Recap Pt II
3. Moving Forward
Appendix C continued: Supplementary Sessions

<table>
<thead>
<tr>
<th>Pain Relief</th>
<th>Introduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relief with Visualisation</td>
<td>About the Program</td>
</tr>
<tr>
<td>Sound Breathing</td>
<td>Keep Motivated</td>
</tr>
<tr>
<td>Breathing in Tune</td>
<td>Safe Space</td>
</tr>
</tbody>
</table>

Appendix D: Sample Audio Scripts

D1: Session 1 Day 1

Chapter 1 Savour the out-breath:

Welcome to day 1.

In this session we’ll start with a short relaxation exercise involving a simple breathing technique.

This will be followed by education around breath and how it can be used to manage an over-active nervous system.

You will then learn a breathing technique that will help you find a calm space.

This technique you can use at any time, in any place, and in any state of mind.

The skills that you will learn today [t-day] are foundational, and we’ll build on them through the week.

Now find a position that is most comfortable for you at this moment

It may be lying down, sitting, it may be standing.

While we are building up the foundational skills

It is important that you choose the most comfortable position that you can find.

Move into that position now

And when you are ready, gently close your eyes

There will be sounds occurring all around you,

Just allow them to be there

They are all part of the session

And now, just notice your breath

Notice the air entering, and leaving your body

Wherever you feel it most

You can keep your mouth closed the whole time

Or if you prefer, you can breathe in through your nose and out through your mouth

At this stage it doesn’t matter

Just choose the method that comes most natural to you

So breathe in - Notice the air entering

Breathe out - Notice the air leaving

Notice the difference

When you next breathe out

Savour the feeling of release

Just savour that feeling of release…for the next few breaths

Just focus on that out breath

Really savour that out-breath feeling
Chapter 2: The Nervous System

When you breathe in,
Your muscles naturally tighten as your chest expands and takes in air
And when you breathe out,
Those muscles release
So naturally tension in your body releases as you breathe out
This is happening to you all the time
See most of the time, our breathing occurs automatically and unconsciously
And it responds to whatever state that the nervous system is in
But breathing is unique in that it can also be controlled consciously and deliberately
With the mind
This means that through deliberate breathing exercises
We can influence the way our nervous system responds
In a way - you can think of breathing exercises as a gateway to the nervous system
It is the key to nervous system retraining
In coming weeks, you will learn how to retrain your nervous system
Retrain how it reacts to thoughts, feelings, and pain - with only your breath
See when the body is in pain, under stress, experiences anxiety, or experiences cravings
The nervous system responds
It becomes activated
Our heart rate increases and breathing becomes heavier
Our thoughts become more alert to danger
And we feel tense
Our mood is more reactive
For most people who experience persistent pain
The nervous system is overactive
Which makes the experience of pain more acute
The good news is we can retrain our nervous system
By breathing in a manner
That tells our body we are safe
Even when your nervous system is provoked by pain, stress or a difficult encounter with another person
You can teach it to maintain a calm state
Over time, with correcting
The body reconditions itself
Your body learns that it does not need to react automatically Whenever it is provoked And so a new choice becomes available to you It takes a little time to learn this skill, And you are likely to experience some resistance Because the nervous system is used to reacting a certain way But eventually, the system will learn how to remain calm Giving you just enough time To consciously choose how you want to react So now I will guide you through a simple breathing exercise To help you manage and maintain your nervous system Just follow the instructions

Chapter 3: Full Out-breath Focus

Gently place your hands just below your ribs Notice the movement under your hands with each breath Without forcing Increase that movement, ever so slightly With the next few breaths Now really focus on the feeling of the out-breath Notice what happens as the air leaves your body Really savour that out-breath feeling [outbreath sound effects start] Now add a brief pause between the in breath and the out breath Just pause for a moment after you fully breathe in This gives you a slight feeling of anticipation before you breathe out This pause gives you a moment to gather yourself Before you experience that out breath feeling Really savour that out-breath feelings [sound effects now stop] If you feel like resting after the out-breath You can do that too, if it helps Do whatever feels most natural to you [single note sound] Really savour that outbreath experience Now, extend the out-breath a bit more [beach sounds] Make it slightly slower, slightly longer Make the journey outward a little further, a bit deeper [beach sounds stop] Don’t force it
Just extend it enough so you are able to extend that out-breath experience
Rest at the end of each cycle if it helps
The out-breath is your space
Every breath is an opportunity
An opportunity to experience the surrender of the out-breath
If you find your mind is wandering [single note sounds]
Thinking about other things
Let yourself think whatever you want to think on this inbreath
Then pause
Give the out-breath your full focus
Experience the surrender of the out-breath [single notes stop, outbound sound effects start]
Never mind what happens on the in-breath
Just give the out breath feeling your full focus
Rest before the in-breath if it helps
No matter what is going on in your life [sound effects stop, silence]
You can always return to the out-breath
The out breath is your time
Your special place
You can savour it whenever you want
The more you practice savouring the out-breath
The better you will get at it
So you can think of today as your first experience
In nervous system retraining [Ending music starts]
Now just some final notes, until next time
We often over-breathe without realising it
As we get busy, overwhelmed, upset
And it can also happen when pain hits
As the nervous system reacts
Breathing get shorter
More intense
And you will be surprised how often you take in big gulps of air
without realising it
Try to notice this as it happens to you
In your normal day
And when you do notice yourself over-breathing
Tune down your nervous system
By savouring the out-breath a few times
You could if you wanted to
Set yourself a reminder every hour
To reward your system with three savoured out-breaths
See in doing this exercise regularly
You will not only retrain your body
But you will find that you will get a lot more out of these sessions
Tomorrow we will use the out breath
To learn how to release tension in the body
Finally, just take a moment to thank yourself for prioritising your own well-being
Caring for yourself is an important part of caring for others
The kinder you are on yourself - the more you learn how to optimise your health
The more you can enjoy the quality of your life and the people around you
See you tomorrow.
Safe Place

What is most important for you to know right now
Is that regardless of how you are feeling
You are safe
Something has alerted your nervous system
You have experienced a surge
But that surge cannot hurt you
Feelings, although real and confronting
Can be distressing
But they do not last forever
So just let your body know you are safe
Do this by breathing in all the cares, feelings, stresses and worries with the in-breath
Pause
And then giving your outbreath your full focus
You mind knows you are safe
And so we are just using your breath
To let your body know you are safe
Breathe in
Feel the in-breath
Pause
And then give the outbreath your full focus
Know that you are safe
Safe with your breath guiding you
Safe in your own company
Your feelings won’t last forever
They will pass
You are in a safe place now
That feeling of safety with now accompany you
You can continue with the exercise
Or just keep listening and breathing with the sounds
Appendix E: Pilot Phase Recruiting Materials

E1: Advertising Flyer used at Chronic Pelvic Pain Clinic

Invitation to trial a Mobile Phone App for women with Chronic Pelvic Pain

We would like to invite you to participate in our research project. Our research project aims to help women who are experiencing chronic pelvic pain.

In order to be eligible to join this study:

- You will have been experiencing chronic pelvic pain for over six months
- You are not pregnant or due for surgery within the next 4 weeks
- You would have read the PARTICIPANT INFORMATION AND CONSENT FORM attached to this letter

If you are interested in taking part, this is what you would need to do:

- Send an email to appEase2016@gmail.com and provide us with your name and telephone number, and a list of days/times you would prefer to meet (after business hours is also an option).
- We will contact you to arrange a meeting at the RWH. This meeting will take no more than 30 minutes and you will be reimbursed $15 for your travel parking.
- In this meeting, we will explain the project to you and ask you to sign a consent form.
- If you agree to take part, we will ask you to fill in a questionnaire about your experience with pain will ask some brief questions about your mood and general well-being. We will then install a mobile phone app on your phone.
- You will need to use the app every day over a 28 day period. This involves opening the app and listening to an audio script. The audio script runs for 15 minutes. At the end of each audio script, you will be asked to rate that particular script.
- During each week you are using the app, we will contact you via telephone to see how you are finding the app.
- After 28 days, you will be asked to fill in another questionnaire.

The app runs on an Android operating system. If you do not have a mobile phone, or use an iPhone, we have a limited number of Android phones available for you to borrow for the duration of the trial.

Note: This study has been approved by the Royal Women's Hospital and the University of Melbourne Human Research Ethics Committee.

Thank you for your time.

Christina Bryant
Associate Professor| Centre for Women's Mental Health
The Royal Women's Hospital | Locked Bag 300, Parkville VIC 3052
P: +61 3 8345 3906 F: +61 3 8345 2076
Christina.Bryant@thewomens.org.au | www.thewomens.org.au

Arthur Stefancic
PhD Candidate
University of Melbourne
P: 0481 369 861
E2: Invitation Letter Sent to Women on Waiting List

INVIGATION LETTER
Using a Mobile Phone App for Chronic Pelvic Pain

We would like to invite you to participate in our research project. This is because you are on or have been on the waiting list for an appointment at the RWH. Our research project aims to help women who are experiencing chronic pelvic pain.

In order to be eligible to join this study:

- You will have been experiencing chronic pelvic pain for over six months
- You are not pregnant or due for surgery within the next 4 weeks

If you are interested in taking part, this is what you would need to do:

- Send an email to apprene2016@gmail.com and provide us with your name and telephone number, and a list of days/times you would prefer to meet (after business hours is also an option).
- We will contact you to arrange a meeting at the RWH. This meeting will take no more than 30 minutes and you will be reimbursed $15 for your travel/parking.
- In this meeting, we will explain the project to you and ask you to sign a consent form.
- If you agree to take part, we will ask you to fill in a questionnaire about your experience with pain will ask some brief questions about your mood and general well-being. We will then install a mobile phone app on your phone.
- You will need to use the app every day over a 28 day period. This involves opening the app and listening to an audio script. The audio script runs for 15 minutes. At the end of each audio script, you will be asked to rate that particular script.
- During each week you are using the app, we will contact you via telephone to see how you are finding the app.
- After 28 days, you will be asked to fill in another questionnaire.

The app runs on an Android operating system. If you do not have a mobile phone, or use an iPhone, we have a limited number of Android devices available for you to borrow for the duration of the trial.

Note: This study has been approved by the Royal Women’s Hospital and the University of Melbourne Human Research Ethics Committee.

Thank you for your time,

Christina Bryant
Associate Professor | Centre for Women’s Mental Health
The Royal Women’s Hospital | Locked Bag 300, Parkville VIC 3052
P: +61 3 8345 3906 | F: +61 3 8345 2076
Christina.Bryant@thewomens.org.au | www.thewomens.org.au

Arthur Stobolidis
PhD Candidate
University of Melbourne
P: 0481 369 861
E3: Social Media Post Inviting Participants to Join the study

Chronic Pelvic Pain Pilot Trial for appEase

Chronic Pelvic Pain Pilot Trial for appEase updated their status.
11 December 2016

Receive a $50 Gift Voucher for taking part in a 28 day Pain Education, Mindfulness and CBT program for Chronic Pelvic Pain developed by clinicians, patients and researchers from the Royal Women's Hospital and University of Melbourne. To find out more, call Arthur on 0413 311 817.

*** Android Only ***

We would like to invite Women who have been experiencing persistent or recurring pelvic pain for more than 6 months to participate in our research project.

The project involves using a mobile phone app for 15 minutes a day over 4-weeks. The app has been designed to help women who are experiencing Chronic Pelvic Pain and has been created in conjunction with patients and clinicians from the Royal Women's Hospital Chronic Pelvic Pain Clinic.

In order to be eligible to join this study:
* You will have been experiencing persistent or intermittent chronic pelvic pain for over six months
* You are not pregnant or due for surgery within the next 4 weeks
* You have an Android Mobile Phone (this pilot study is not available for iPhone users unfortunately)

If you are interested in taking part, call Arthur Stabolidis on 0413 311 817. You will then be provided with a link to a Plain Language Statement and Consent Form and will fill in a survey which will take 15 minutes.

If you are eligible we will send you an installation link and further instructions via email. You will be asked to fill that survey in again when you finish using the app and then receive a $50 Myer Gift Voucher.

This study has been approved by the Royal Women’s Hospital and the University of Melbourne Human Research Ethics Committee.
E4: Plain Language Statement

Melbourne School of Psychological Sciences
Plain Language Statement
PROJECT TITLE: Designing E-therapies for Women with Chronic Pelvic Pain
Associate Prof Christina Bryant (Principal Researcher)
Tel: 03 8345 3906; email: lisajp@unimelb.edu.au
Associate Professor Lisa Phillips (Researcher), Dr Greg Wadley (Researcher)

Mr Arthur Stabolidis (PhD student) email: arthurs@student.unimelb.edu.au

Introduction

We would like to invite you to participate in our research project. Our research project aims to help women who are experiencing chronic pelvic pain. The purpose of this study is to see if using a mobile phone app for 15 minutes a day over 28 daily sessions will help you manage your pain, and help you manage the psychological and physical stressors that are often associated with the experience of persistent pain. This project has been approved by the University of Melbourne Human Research Ethics committee. The results of this research project will be used by the student researcher, Arthur Stabolidis, for the purpose of obtaining a Doctor of Philosophy (PhD) degree.

In order to be eligible to join this study:

1. You will have been experiencing chronic pelvic pain for over six months
2. You will have an Android mobile phone.
3. You are not pregnant or due for surgery within in the next 4 weeks

This Participant Information Sheet/Consent Form tells you about the research project. It explains the process involved if you choose to participate. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don’t wish to take part, you don’t have to.
If you wish to participate simply read through to the Consent Form and click on 'I agree' at the bottom.

By agreeing you are telling us that you:

• Understand what you have read

• Consent to take part in the research project

• Consent to the use of your information as described.

What I would be asked to do?

You will be asked to fill in a questionnaire about your experiences with pain, anxiety and treatments. The questionnaire should take no more than 15 minutes to complete. If you agree to take part, and are eligible, you will need to:

I. **Install a mobile phone app on your Android phone.** You will get a link to the app and instruction from Arthur Stabolidis.

II. **You will need to** use the app every day over a 28 day period. This involves opening the app and listening to an audio script. The audio script runs for 15 minutes. At the end of each audio script, you will be asked to rate that particular audio script.

III. Participate in an on-line forum (voluntary) where you will have an opportunity to ask questions, discuss the app with other participants, and make suggestions for how the app can be improved.

IV. **After 28 days,** you will be asked to repeat this questionnaire again. If you would like to take part in a post-trial interview, you may be contacted again via telephone to answer some more questions about your experience with the app. This interview will take 30 minutes, and we will also ask you for any suggestions on how the app could be improved for any future users.

**What are the risks?** We do not foresee any significant risks from participating in this project. It is possible, however, that some of the breathing and relaxation exercises may cause you discomfort, particularly those that ask you to focus on problematic areas.
in your body. We aim to minimise this risk by checking in with you on a weekly basis to see how you are going. If you are feeling stressed or upset, Associate Professor Christina Bryant is available to talk with you. She is an experienced psychologist who works at the Chronic Pelvic Pain Clinic of the RWH. She will listen to your concerns and if she feels it is necessary, she will make some suggestions to you about further counselling.

The app also contains a “Safe Space” audio script which you can switch on at any time, if you experience distress while using the app.

If in any way you feel that the study has raised questions or concerns for you, the research team will be happy to speak to you or to organise additional information or counselling to address your questions.

What are the benefits? The app has been designed in conjunction with patients and clinicians from the Chronic Pelvic Pain Clinic of the RWH, and so it is our hope that after 4-weeks of using the app you will learn a set of skills that will help you manage your pain, and manage the psychological and physical stressors that come with that. We also hope that you will feel encouraged by the content of the app, and will be able to enjoy some of the activities you may have stopped doing as a result of your pain.

You will be trialling the app for the first time, and so we cannot guarantee or promise that you will receive any benefits, however, we hope that your feedback will enable us to modify the app so it can have more far reaching benefits to women who experience chronic pelvic pain.

How would my confidentiality be protected?

We do many things to make sure that your answers and any information about you are kept secure. All information is kept in a separate, password-protected computer and only available to the researchers. We also separate your name and other information that may identify you from your answers. Only the researchers can link to your responses to your name, which they may need to do to contact you for a follow-up phone call to see how you are progressing during and after the study period. In any report, you will not be able to be identified, instead your data will be combined with the rest of the study participants. We will remove any references to personal information that might allow
someone to guess your identity. The data will be kept securely for seven years from the
date of publication, before being destroyed.

What if I want to withdraw from the Research?

If you decide to leave the project, the researchers would like to keep the
information about you that has been collected. This would allow us to know if those
who complete the project are different in any way to those who do not. Your
information would remain confidential at all times. If you don’t want us to do this, you
can tell us before you leave the project. Whether you choose to take part in the study or
not will not affect any current treatment you are receiving.

Where can I get further information?

If you have not understood any of this information please contact any of the
researchers listed above. This research project has been approved by the Human
Research Ethics Committee of The University of Melbourne. If you have any concerns
or complaints about the conduct of this research project, which you do not wish to
discuss with the research team, you should contact the Manager, Human Research
Ethics, Office for Research Ethics and Integrity, University of Melbourne, VIC 3010.
Tel: +61 3 8344 2073 or Fax: +61 3 9347 6739 or Email:
HumanEthicscomplaints@unimelb.edu.au. All complaints will be treated confidentially.
In any correspondence please provide the name of the research team or the name or
ethics ID number of the research project.

**How do I agree to participate?** If you wish to participate simply proceed to the
next page, read through the Consent Form and click on 'I agree' at the bottom. You will
then receive an email about your eligibility.
**E5: Consent Form (Phase 3)**

Melbourne School of Psychological Sciences

Consent form for persons participating in a research project

**PROJECT TITLE:** Designing E-therapies for Women with Chronic Pelvic Pain

Associate Prof Christina Bryant (Principal Researcher)

Tel: 03 8345 3906; email: lisajp@unimelb.edu.au

Associate Professor Lisa Phillips (Researcher)

Dr Greg Wadley (Researcher)

Mr Arthur Stabolidis (PhD student) email: arthurs@student.unimelb.edu.au

1. I consent to participate in this project. The purpose of this research is to help women who are experiencing persistent pelvic pain.

2. I understand that this project is for research purposes.

3. In this project I will be required to complete a questionnaire (on pain, anxiety and pain treatments). The details of this have been explained in the Plain Language Statement.

4. I understand that there are risks involved in participating in this research project. Specifically, that focusing on problematic parts of my body may trigger feelings of discomfort. These risks have been addressed through providing me with the contact details of an experienced psychologist who works at the Chronic Pelvic Pain Clinic of the Royal Women's Hospital.

5. My participation is voluntary and that I am free to withdraw from the project at any time without explanation or prejudice and to withdraw any unprocessed data I have provided. Withdrawing from the project will not affect my relationship with the Melbourne School of Psychological Sciences or the Royal Women's Hospital. Specifically, it will not affect any ongoing assessment/grades or treatment that I would otherwise be eligible for.

6. I have been informed that the data from this research will be stored at the University of Melbourne and will be destroyed after 5 years.

7. I have been informed that the confidentiality of the information I provide will be safeguarded subject to any legal requirements; my data will be password protected and accessible only by the named researchers.

8. I agree to have the findings of this study emailed to me.

9. I understand that proceeding to the next screen indicates that I consent to involvement in this study.

I DO NOT AGREE

I AGREE
E6: Ethics Approval Letter (Phase 3)

11.8.16

Mr A. Stabolidis
Centre for Women’s Mental Health
RWH

Dear Mr Stabolidis,

Re: Project 16/17 – Designing and piloting a technology based therapy for women with chronic pelvic pain (Phase 2)

Thank you for submitting the clarification and amendments on as requested by the RWH Human Research Ethics Committee.

I confirm the project is now approved.

Enclosed please find Project Approval and Notification of Project Commencement Forms for your record.

Prior to commencement of your project, you are reminded that you must contact the relevant RWH Divisional Directors / Department Heads to confirm your actual commencement date. Failure to inform these RWH personnel may jeopardise their approval and support for your project.

Please return the completed Notification of Project Commencement Form to me when the project begins.

Yours sincerely,

A. C. B. Hui
Manager
Research and Ethics Secretariat
Appendix F: Baseline and Post Intervention Questionnaire

F1: General Information

Personal Details

Full Name and Login ID ______________________________________________

Date of Birth ________________________________________________

Mobile Phone ________________________________________________

Email Address ________________________________________________

Is English Your First Language? Yes / No

If you are receiving any treatment (e.g., medical, psychological, complimentary) besides pain relief medication, please specify here.

_________________________________________________________________

_________________________________________________________________

_________________________________________________________________

_________________________________________________________________

_________________________________________________________________
### F2: Pain Catastrophizing Scale

Using the scale, please indicate the degree to which you have these thoughts and feelings when you are experiencing pain.

<table>
<thead>
<tr>
<th>I worry all the time about whether the pain will end</th>
<th>Not at all</th>
<th>To a slight degree</th>
<th>To a moderate degree</th>
<th>To a great degree</th>
<th>All the time</th>
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<tbody>
<tr>
<td>I feel I can't go on</td>
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<tr>
<td>It's terrible and I think it's never going to get any better</td>
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<tr>
<td>It’s awful and I feel that it overwhelms me</td>
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<td>I feel I can’t stand it anymore</td>
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<td>I become afraid that the pain will get worse</td>
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<td>I keep thinking of other painful events</td>
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<td>I anxiously want the pain to go away</td>
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<td>I can’t seem to keep it out of my mind</td>
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<td>I keep thinking about how much it hurts</td>
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<tr>
<td>I keep thinking about how badly I want the pain to stop</td>
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<tr>
<td>There’s nothing I can do to reduce the intensity of the pain</td>
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<tr>
<td>I wonder whether something serious may happen</td>
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</tbody>
</table>
### F3: DASS

Please read each statement and select the option that indicates how much the statement applied to you over the past week. There are no right or wrong answers. Do not spend too much time on any statement.

<table>
<thead>
<tr>
<th>Statement</th>
<th>Did not Apply to Me</th>
<th>Applied to Me to Some Degree, Some time</th>
<th>Applied to Me a considerable degree, good part of time</th>
<th>Applied to me very much, or most of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>I found it hard to wind down</td>
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<tr>
<td>I was aware of dryness of my mouth</td>
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<tr>
<td>I couldn't seem to experience any positive feeling at all</td>
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<td>I experienced breathing difficulty (e.g., excessively rapid breathing, breathlessness in the absence of physical exertion)</td>
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<td>I found it difficult to work up the initiative to do things</td>
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<td>I tended to over-react to situations</td>
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<td>I experienced trembling (e.g., in the hands)</td>
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<td>I felt that I was using a lot of nervous energy</td>
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<td>I was worried about situations in which I might panic and make a fool of myself</td>
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<td>I felt that I had nothing to look forward to</td>
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<td>I found myself getting agitated</td>
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<tr>
<td>I found it difficult to relax</td>
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<tr>
<td>I felt down-hearted and blue</td>
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<tr>
<td>I was intolerant of anything that kept me from getting on with what I was doing</td>
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<tr>
<td>I felt I was close to panic</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I was unable to become enthusiastic about anything</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I felt I wasn't worth much as a person</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I felt that I was rather touchy</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I was aware of the action of my heart in the absence of physical exertion (e.g., sense of heart rate increase, heart missing a beat)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I felt scared without any good reason</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I felt that life was meaningless</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**F4: Pain Stages of Change Questionnaire**

Using the scale, please indicate how much you agree or disagree with each statement

<table>
<thead>
<tr>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>I have tried everything that people have recommended to manage my pain and nothing helps.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>My pain is a medical problem and I should be dealing with physicians about it.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Everybody I speak with tells me that I have to learn to live with my pain, but I don’t see why I should have to.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I still think despite what doctors tell me, there must be some surgical procedure or medication that would get rid of my pain.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The best thing I can do is find a doctor who can figure out how to get rid of my pain once and for all.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Why can’t someone just do something to take away my pain?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All of this talk about how to cope better is a waste of my time.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I have been thinking that the way I cope with my pain could improve.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I have recently realized that there is no medical cure for my pain condition, so I want to learn some ways to cope with it.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Even if my pain doesn’t go away, I am ready to start changing how I deal with it.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I realize now that it’s time for me to come up with a better plan to cope with my pain problem.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I am beginning to wonder if I need to get some help to cope with my pain problem.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I have recently figured out that it’s up to me to deal better with my pain.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I have recently come to the conclusion that it’s time for me to change how I cope with my pain.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I’m starting to wonder whether it’s up to me to manage my pain rather than relying on physicians.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I have been thinking that doctors can only help so much in managing my pain and that the rest is up to me.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I have been wondering if there is something I could do to manage my pain better.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## F5: Locus of Control

Using the scale, please indicate how much you agree or disagree with each statement

<table>
<thead>
<tr>
<th>Strongly Disagree</th>
<th>Mod. Disagree</th>
<th>Slightly Disagree</th>
<th>Slightly Agree</th>
<th>Mod. Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
</table>

If my condition worsens, it is my own behavior which determines how soon I will feel better again.

As to my condition, what will be will be.

If I see my doctor regularly, I am less likely to have problems with my condition.

Most things that affect my condition happen to me by chance.

Whenever my condition worsens, I should consult a medically trained professional.

I am directly responsible for my condition getting better or worse.

Other people play a big role in whether my condition improves, stays the same, or gets worse.

Whatever goes wrong with my condition is my own fault.

Luck plays a big part in determining how my condition improves.

In order for my condition to improve, it is up to other people to see that the right things happen.

Whatever improvement occurs with my condition is largely a matter of good fortune.

The main thing which affects my condition is what I myself do.

I deserve the credit when my condition improves and the blame when it gets worse.

Following doctor's orders to the letter is the best way to keep my
condition from getting any worse.

If my condition worsens, it's a matter of fate.

If I am lucky, my condition will get better.

If my condition takes a turn for the worse, it is because I have not been taking proper care of myself.

The type of help I receive from other people determines how soon my condition improves.
F6: SF-12

In general, would you say your health is?

<table>
<thead>
<tr>
<th>Excellent</th>
<th>Very Good</th>
<th>Good</th>
<th>Fair</th>
<th>Poor</th>
</tr>
</thead>
</table>

Select the most appropriate answer

The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

<table>
<thead>
<tr>
<th>Yes, limited a lot</th>
<th>Yes, limited a little</th>
<th>No, not limited at all</th>
</tr>
</thead>
</table>

Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf

Climbing several flights of stairs

During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
</table>

Accomplished less than you would like?

Were limited in the kind of work or other activities

During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
</table>

Accomplished less than you would like?

Did work or activities less carefully than usual
During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

<table>
<thead>
<tr>
<th>Not at all</th>
<th>A little bit</th>
<th>Moderately</th>
<th>Quite a bit</th>
<th>Extremely</th>
</tr>
</thead>
<tbody>
<tr>
<td>Select the most appropriate answer</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

These questions are about how you have been feeling during the past 4 weeks. For each question, please give one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks...

<table>
<thead>
<tr>
<th>All of the Time</th>
<th>Most of the Time</th>
<th>Some of the Time</th>
<th>A Little of the Time</th>
<th>None of the Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Have you felt calm and peaceful?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did you have a lot of energy?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you felt downhearted and depressed?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with:

<table>
<thead>
<tr>
<th>All of the Time</th>
<th>Most of the Time</th>
<th>Some of the Time</th>
<th>A Little of the Time</th>
<th>None of the Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Your social activities (like visiting friends, relatives, etc.)?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
F7: Brief Pain Inventory

Please rate your pain by marking the box beside the number that best describes your pain on the AVERAGE:

0 1 2 3 4 5 6 7 8 9 10

F8: Pain Self Efficacy Questionnaire

Using the scale, please rate how confident you are that you can do the following things at present, despite the pain.

<table>
<thead>
<tr>
<th></th>
<th>Not At All Confident</th>
<th>Completely Confident</th>
</tr>
</thead>
<tbody>
<tr>
<td>I can enjoy things, despite the pain.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I can do most of the household chores (e.g. tidying-up, washing dishes, etc.), despite the pain.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I can socialise with my friends or family members as often as I used to do, despite the pain.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I can cope with my pain in most situations.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I can do some form of work, despite the pain. (“work” includes housework, paid and unpaid work).</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I can still do many of the things I enjoy doing, such as hobbies or leisure activity, despite pain.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I can cope with my pain without medication.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I can still accomplish most of my goals in life, despite the pain.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I can live a normal lifestyle, despite the pain.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I can gradually become more active, despite the pain.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**F9: Treatment Expectation**

How confident are you that this program will be successful in helping you cope with chronic pain?

0 1 2 3 4 5 6 7 8 9 10

**F10: Treatment Credibility**

How confident are you in recommending this program to a person with chronic pain?

0 1 2 3 4 5 6 7 8 9 10

**F11: App Use (Baseline Only)**

Do you currently use any health-related mobile phone apps, websites, or health related audio books? If so, which ones?

________________________________________________________________
________________________________________________________________
________________________________________________________________
________________________________________________________________

That is all of the questions. Please proceed to the next page for the Debriefing Statement.
F12: Debriefing Statement

Melbourne School of Psychological Sciences

Debriefing Statement

Principal Researcher: Associate Professor Christina Bryant
Royal Women’s Hospital (RWH) 03 8345 3906
Co-researchers: Associate Professor Lisa Phillips, Dr Greg Wadley and Arthur Stabolidis

Thank you for participating in a project.

You completed a questionnaire comprising of scales around anxiety and pain. It is possible that completing the questionnaire may have triggered some unpleasant feelings. Should this have occurred, and you require further support, please contact the University of Melbourne Psychology Clinic (Tel: 03 9035 5180; email: clinic@psych.unimelb.edu.au) or Lifeline (13 11 14).

This research has been cleared by the Human Research Ethics Committee (HREC 1647890). If you have any concerns about this project please contact the Executive Officer, Human Research Ethics, The University of Melbourne (Tel: 8344 2073; Fax: 9347 6739).

F13: Concluding Questions (Post-intervention Only)

After you have completed the telephone interview, where would you like us to send your $50 Myer Gift Voucher?

_______________________________________________

How confident would you be in recommending this program to a friend with chronic pain? 0 1 2 3 4 5 6 7 8 9 10

Please suggest two days and times that would suit you to chat about your experiences with the app, allow 20 minutes.

______________________________________________________________

Optional: Do you have any comments or suggestions about the app or program that in general?

______________________________________________________________
Appendix G: Interview Questions

G1: Screening interview Questions

Q1: Please provide me with some background on your pain.

   (a) When did it start?
   (b) What treatments have you sought?
   (c) Do you have a formal diagnosis for your pain?
   (d) How has pain affected your life?
   (e) How are you currently managing your pain?

Q2: Have you had any experience with psychology?

   (a) Have you been given any formal psychological diagnosis?

Q3: Have you used any apps before?

   (a) General apps?
   (b) Apps for your pain?

G2: Mid-intervention Interview Questions

Q1: Have you experienced any difficulties or distress while using the app?

Q2: What are your impressions of the app?

Q3: Do you have any comments about any of the sessions?

Q4: In your survey you stated … tell me more about that?
G3: Post-intervention Interview Questions

Usability and Acceptability
When did you use the app?
What is your impression of the app and the way the sessions are presented?
Any improvements in the way the app could look or work?

Usefulness
What sessions were most helpful for you?
Which sessions were least helpful?
Are there any other improvements you can think of for the daily sessions?

Therapeutic Relationship
Tell me about the level of care you did or did not feel when using the app?

Pain Catastrophisation Scale
There was a section in the survey about the thoughts that go through your mind when experiencing pain [Pain Catastrophisation Scale] e.g., I can’t cope, the pain will never go away; I feel helpless.
What did you think of those questions in the survey?
Have your thoughts around your pain changed between the two surveys you filled in?
Your score on that scale decreased/increased/stayed the same between the surveys, would you say that’s consistent with your situation?

Pain Self-Efficacy Scale
What did you think of those questions in the survey?
Has your confidence in doing things changed between the two surveys you filled in?
Your score on that scale decreased/increased/stayed the same between the surveys. Any comment?

Depression Anxiety Stress Scale (DASS)
Your depression/anxiety/stress score were high/low/consistent. Any comment?

Locus of Control
When it comes to treating your pain condition, how much of a role do you play, how much of a role do doctors or others play, and has that changed since using the app?

Pain Stages of Change
Do you think that surgery or medication is what is required to for your pain problem?

Other comments
Do you have any other general comments?
Appendix H: Post-intervention Interview Data

H.1 Sample Post-intervention Survey in Table Form [Participant 2016]

Prior to the interview, survey and post-intervention measures were collected and summarised in a table like the one below. This table was referred to throughout the interview.

<table>
<thead>
<tr>
<th>Measure</th>
<th>Pre</th>
<th>Post</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCS</td>
<td>Rumination (Mean 10.1) 8</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>Magnification (Mean 4.8) 5</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Helplessness (Mean 13.3) 13</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Overall (Mean 20.9 or 28.2) 26</td>
<td>14</td>
</tr>
<tr>
<td>DASS-21</td>
<td>Stress</td>
<td>Extremely</td>
</tr>
<tr>
<td></td>
<td>Anxiety</td>
<td>Severe</td>
</tr>
<tr>
<td></td>
<td>Depression</td>
<td>Normal</td>
</tr>
<tr>
<td></td>
<td>Pre-Contemplative 17</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>Contemplative  8</td>
<td>Mild</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>Normal</td>
</tr>
<tr>
<td>PSC</td>
<td>Pre-Contemplative 3.57</td>
<td>2.57</td>
</tr>
<tr>
<td></td>
<td>Contemplative  3.70</td>
<td>4.00</td>
</tr>
<tr>
<td>MHLOC</td>
<td>Internal</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>Chance</td>
<td>6 to 36</td>
</tr>
<tr>
<td></td>
<td>Powerful Others 22</td>
<td>19</td>
</tr>
<tr>
<td></td>
<td>Doctors</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>Other People  12</td>
<td>10</td>
</tr>
<tr>
<td>BPI</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>SF-12-PCS</td>
<td>Physical plus 41.00</td>
<td>47.21</td>
</tr>
<tr>
<td>SF-12-MCS</td>
<td>Mental plus  32.88</td>
<td>42.67</td>
</tr>
<tr>
<td>PSE</td>
<td>Low &lt;20, High &gt; 40 26</td>
<td>35</td>
</tr>
<tr>
<td>Treatment Expectation (Pre)</td>
<td>7/10</td>
<td></td>
</tr>
<tr>
<td>Recommendation (Post)</td>
<td>10/10</td>
<td></td>
</tr>
</tbody>
</table>

Survey Question: Do you have any comments about the app?:

I thought it was a great app and actually really helped not just with the pain but with getting me out of a slump I felt at the beginning of the year. The meditation and breathing exercises were actually incredibly useful! The only thing I would suggest is not doing it in the evening in bed because I was often so tired I fell asleep listening to it.
<table>
<thead>
<tr>
<th>Session</th>
<th>Use</th>
<th>Interaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>01 The Outbreath</td>
<td>Very Useful</td>
<td>Like someone was talking specifically to me</td>
</tr>
<tr>
<td>02 Resting Thoughts</td>
<td>Mildly Useful</td>
<td>NO COMMENT</td>
</tr>
<tr>
<td>03 Resting Feelings</td>
<td>Very Useful</td>
<td>Like someone was talking specifically to me</td>
</tr>
<tr>
<td>04 Tension and Pain</td>
<td>Very Useful</td>
<td>Like someone was talking specifically to me</td>
</tr>
<tr>
<td>05 Body Scan</td>
<td>Very Useful</td>
<td>Like someone was talking specifically to me</td>
</tr>
<tr>
<td>06 PMR</td>
<td>Very Useful</td>
<td>Like the narrator really cared about me</td>
</tr>
<tr>
<td>07 Self-Acceptance</td>
<td>Very Useful</td>
<td>Like the narrator really cared about me</td>
</tr>
<tr>
<td>08 Fear of Pain</td>
<td>Very Useful</td>
<td>Like someone was talking specifically to me</td>
</tr>
<tr>
<td>09 Pain Visualisation</td>
<td>Mildly Useful</td>
<td>NO COMMENT</td>
</tr>
<tr>
<td>10 Values and Identity</td>
<td>Mildly Useful</td>
<td>Like the narrator really cared about me</td>
</tr>
<tr>
<td>11 Valued Choices</td>
<td>Very Useful</td>
<td>Like someone was talking specifically to me</td>
</tr>
<tr>
<td>12 Valued Living Obstacles</td>
<td>Mildly Useful</td>
<td>Like someone was talking specifically to me</td>
</tr>
<tr>
<td>13 Thought Awareness</td>
<td>Mildly Useful</td>
<td>Like someone was talking specifically to me</td>
</tr>
<tr>
<td>14 Unhelpful thinking Styles</td>
<td>Mildly Useful</td>
<td>Like someone was talking specifically to me</td>
</tr>
<tr>
<td>15 Shoulds and Musts</td>
<td>Mildly Useful</td>
<td>Like someone was talking specifically to me</td>
</tr>
<tr>
<td>16 Reframing &quot;Why?&quot;</td>
<td>Very Useful</td>
<td>Like someone was talking specifically to me</td>
</tr>
<tr>
<td>17 Pain Education</td>
<td>Very Useful</td>
<td>Like someone was talking specifically to me</td>
</tr>
<tr>
<td>18 Exploring Anger</td>
<td>Mildly Useful</td>
<td>Like someone was talking specifically to me</td>
</tr>
<tr>
<td>19 Anger and Pain</td>
<td>Very Useful</td>
<td>Like someone was talking specifically to me</td>
</tr>
<tr>
<td>20 Gratitude and Pain</td>
<td>Very Useful</td>
<td>Like someone was talking specifically to me</td>
</tr>
<tr>
<td>21 Enemies of Gratitude</td>
<td>Mildly Useful</td>
<td>Like someone was talking specifically to me</td>
</tr>
<tr>
<td>22 Communicating Intimacy</td>
<td>Very Useful</td>
<td>Like someone was talking specifically to me</td>
</tr>
<tr>
<td>23 Self Compassion</td>
<td>Extremely useful</td>
<td>Like someone was talking specifically to me</td>
</tr>
<tr>
<td>24 Social Anxiety</td>
<td>Mildly Useful</td>
<td>Like someone was talking specifically to me</td>
</tr>
<tr>
<td>25 Sleep and Worry</td>
<td>Very Useful</td>
<td>Like someone was talking specifically to me</td>
</tr>
<tr>
<td>26 Relapse and Progress</td>
<td>Mildly Useful</td>
<td>Like someone was talking specifically to me</td>
</tr>
<tr>
<td>27 Pain Flares</td>
<td>Very Useful</td>
<td>Like someone was talking specifically to me</td>
</tr>
<tr>
<td>28 Graduation Day</td>
<td>Not Useful At all</td>
<td>Like the narrator really cared about me</td>
</tr>
</tbody>
</table>
**H.3 Sample Summarised App Survey Data [Participant 2016]**

Data Taken from App

<table>
<thead>
<tr>
<th>Usefulness</th>
<th>Count</th>
<th>Level of Care Felt</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extremely useful</td>
<td>1</td>
<td>Like listening to a robot/computer</td>
<td>0</td>
</tr>
<tr>
<td>Very Useful</td>
<td>15</td>
<td>Like listening to a radio announcer</td>
<td>0</td>
</tr>
<tr>
<td>Mildly Useful</td>
<td>11</td>
<td>Like someone talking to a group of patients</td>
<td>0</td>
</tr>
<tr>
<td>Not Useful At all</td>
<td>1</td>
<td>Like someone was talking specifically to me</td>
<td>22</td>
</tr>
<tr>
<td>Potentially Harmful</td>
<td>0</td>
<td>Like the narrator really cared about me</td>
<td>4</td>
</tr>
<tr>
<td>NO COMMENT</td>
<td>0</td>
<td>NO COMMENT</td>
<td>2</td>
</tr>
</tbody>
</table>

Notable Sessions

<table>
<thead>
<tr>
<th>Extremely useful</th>
<th>Level of Care Felt</th>
</tr>
</thead>
<tbody>
<tr>
<td>23  Self Compassion</td>
<td>Like someone was talking specifically to me</td>
</tr>
<tr>
<td>Very Useful</td>
<td></td>
</tr>
<tr>
<td>06  PMR</td>
<td>Like the narrator really cared about me</td>
</tr>
<tr>
<td>07  Self-Acceptance</td>
<td>Like the narrator really cared about me</td>
</tr>
<tr>
<td>Mildly Useful</td>
<td></td>
</tr>
<tr>
<td>10  Values and Identity</td>
<td>Like the narrator really cared about me</td>
</tr>
<tr>
<td>Not Useful At all</td>
<td></td>
</tr>
<tr>
<td>28  Graduation Day</td>
<td>Like the narrator really cared about me</td>
</tr>
</tbody>
</table>

Supplementary Usage Counts

<table>
<thead>
<tr>
<th>Session</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safe Space</td>
<td>3</td>
</tr>
<tr>
<td>Pain Relief</td>
<td>0</td>
</tr>
<tr>
<td>Introduction</td>
<td>0</td>
</tr>
</tbody>
</table>

General Usage:

- Number of session completed: 28
- Number of days taken to complete: 70
H.4 Sample of Raw Transcription Data [Participant 2016]

[Pain catastrophising]

I: There was a section in the survey about the thoughts that go through your mind when experiencing pain [Pain Catastrophisation Scale] e.g., I can’t cope, the pain will never go away, I feel helpless. What did you think of those questions in the survey?

2016: They are ok. I think it usually depends on the day I am having. Sometimes if you are having a good day it’s easy to say things are fine, but I think usually when I am having a bad day I tend to overreact. So I don’t know how accurate it [the scale] would be. It just depends on whether I am having a good or a bad day.

I: Have your thoughts around your pain changed in any way between the two surveys you filled in?

2016: When I first answered them going into the trial I think I was probably optimistic but kind of unsure how it [the app] would help. At that time I don’t know [don’t remember] how bad I was having the pain. I think it was in January so I think by the time I finished i think I was a little bit better at coping with the pain. And realising that um I might not be able to control the pain but I can control my own reaction to the pain.

I: What do you think led to the change in your PC thoughts?

2016: I think it was the app and in particular some of the meditation techniques I found them quite good/ But I think it was also the fact that I told my physio I was taking part in the trial and we were having a discussion about how yes we can’t really change things because I think at that time I was doing a lot of work stress and was particularly stressed out and she said we have a choice how we react to stress and I think the app kind of highlighted that but in relation to how you react to your pain.

I: Your scale decreased significantly [explains scores in detail] would you say that’s consistent with your situation?

2016: Yeah I definitely agree. I think that’s quite accurate. I have kind of noticed It’s like a conscious change to how I react to the pain. Rather than exactly feeling helpless and thinking "what am I going to do" [I think] "well it’s there, there is nothing I can really do to change it but I can change how I react”. So it’s good that it actually reflects [talking about PC score].

I: So the app was being consistent with what your physio was saying as well?

2016: Yeah, absolutely.
# H.5 Sample Coding of Transcription [Participant 2016]

**Pain Catastrophising Scale**

Do you have any comments about those questions?

<table>
<thead>
<tr>
<th>ID</th>
<th>Scores</th>
<th>Quotes</th>
<th>Coding</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016</td>
<td></td>
<td>It just depends on whether I am having a good or a bad day.</td>
<td>Response may vary depending on day.</td>
</tr>
</tbody>
</table>

Have your thoughts around your pain changed between the two surveys you filled in?

<table>
<thead>
<tr>
<th>ID</th>
<th>Scores</th>
<th>Quotes</th>
<th>Coding</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016</td>
<td>Pre: 26 Post 14</td>
<td>I think by the time I finished I think I was a little bit better at coping with the pain. And realising that I might not be able to control the pain but I can control my own reaction to the pain.</td>
<td>Cope better with pain Better reactions to pain Self-report Consistent</td>
</tr>
</tbody>
</table>

What do you think has led to the change in your PC thoughts?

<table>
<thead>
<tr>
<th>ID</th>
<th>Scores</th>
<th>Quotes</th>
<th>Coding</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016</td>
<td></td>
<td>I think it was the app and in particular some of the meditation techniques I found them quite good I have kind of noticed a conscious change to how I react to the pain. I can change how I react”.</td>
<td>Mindfulness Exercises from app Thought awareness and challenging from app</td>
</tr>
</tbody>
</table>

Your scores decreased by 12 points which is considered a clinically significant change. Do you have any comments about that score?

<table>
<thead>
<tr>
<th>ID</th>
<th>Scores</th>
<th>Quotes</th>
<th>Coding</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016</td>
<td>Pre: 26 Post 14</td>
<td>Yeah I definitely agree. I think that's quite accurate.</td>
<td>Agrees with score</td>
</tr>
</tbody>
</table>
### H.6 Sample Coding of Question Data

**What is your impression of the app and the way the sessions are presented?**

<table>
<thead>
<tr>
<th>ID</th>
<th>Scores</th>
<th>Quotes</th>
<th>Coding</th>
</tr>
</thead>
<tbody>
<tr>
<td>1002</td>
<td>N/A</td>
<td>I like the format, ideas, and way its delivered</td>
<td>Usable</td>
</tr>
<tr>
<td></td>
<td></td>
<td>I enjoyed your voice. I found it calm and soothing. You sound</td>
<td>Good structure</td>
</tr>
<tr>
<td></td>
<td></td>
<td>very relaxed.</td>
<td>Calm voice</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Good to listen to.</td>
<td>Relaxing Voice</td>
</tr>
<tr>
<td>1003</td>
<td>N/A</td>
<td>I like how all education components have music</td>
<td>Music good</td>
</tr>
<tr>
<td>1004</td>
<td>N/A</td>
<td>I think its great</td>
<td>Usable</td>
</tr>
<tr>
<td></td>
<td></td>
<td>I liked the voice, it was relaxing. Non-judgmental.</td>
<td>Relaxing Voice</td>
</tr>
<tr>
<td></td>
<td></td>
<td>For something that is more supportive a compassionate voice is</td>
<td>Non-judgmental voice</td>
</tr>
<tr>
<td></td>
<td></td>
<td>better - authentic - non judging</td>
<td>Compassionate voice</td>
</tr>
<tr>
<td>1005</td>
<td>N/A</td>
<td>It provided me with some additional information about taking</td>
<td>Helpful Information</td>
</tr>
<tr>
<td></td>
<td></td>
<td>responsibility and control</td>
<td>Information not entirely new</td>
</tr>
<tr>
<td></td>
<td></td>
<td>It wasn’t first time I came across those messages before</td>
<td></td>
</tr>
<tr>
<td>2007</td>
<td>N/A</td>
<td>Like the way you talk in it its very soothing</td>
<td>Relaxing voice</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Your voice came across very caring and I could tell you put a</td>
<td>Caring Voice</td>
</tr>
<tr>
<td></td>
<td></td>
<td>lot of effort into it.</td>
<td>Usable</td>
</tr>
<tr>
<td></td>
<td></td>
<td>I appreciate the slow pace because it gives me time to process</td>
<td>Appreciate slow pace</td>
</tr>
<tr>
<td></td>
<td></td>
<td>everything and work through it.</td>
<td></td>
</tr>
<tr>
<td>2008</td>
<td>N/A</td>
<td>For me it didn’t really have any new information</td>
<td>Information not new</td>
</tr>
<tr>
<td>2009</td>
<td>N/A</td>
<td>Great app</td>
<td>Usable</td>
</tr>
<tr>
<td>2010</td>
<td>N/A</td>
<td>I think its fantastic</td>
<td>Usable</td>
</tr>
<tr>
<td>2011</td>
<td>N/A</td>
<td>Its a very pretty app. [laughs].</td>
<td>Aesthetics Good</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Usability wise its very simple and easy to use.</td>
<td>Usable</td>
</tr>
<tr>
<td></td>
<td></td>
<td>I like that when you opened it up it would go to the day you</td>
<td>Convenient interface</td>
</tr>
<tr>
<td></td>
<td></td>
<td>were on you didn’t have to go searching on &quot;what day am I up to?&quot;.</td>
<td></td>
</tr>
<tr>
<td>2012</td>
<td>N/A</td>
<td>I found the safe mode activated easily.</td>
<td>Safe space activating too easily</td>
</tr>
<tr>
<td>Year</td>
<td>ID</td>
<td>Comment</td>
<td></td>
</tr>
<tr>
<td>------</td>
<td>-----</td>
<td>---------</td>
<td></td>
</tr>
<tr>
<td>2014</td>
<td>N/A</td>
<td>Your voice is always very calm. I felt you believed it [subject material]. I absolutely Love it. I think I am going to be a bit sad when it finishes because I really like it!</td>
<td>Calm voice Authentic voice Positive impression</td>
</tr>
<tr>
<td>2015</td>
<td>N/A</td>
<td>I prefer your voice to Russ Harris. Russ Harris annoys me/ I think it was calming and soothing I thought it was really good</td>
<td>Relaxing Voice Soothing Voice Usable</td>
</tr>
<tr>
<td>2016</td>
<td>N/A</td>
<td>I like the app I find it really relaxing I actually really liked the slow voice. I found it quite soothing and relaxing. [laughs]</td>
<td>Usable Positive Relaxing Voice Soothing Voice</td>
</tr>
<tr>
<td>2018</td>
<td>N/A</td>
<td>It was a really enjoyable app to use Liked the music Voice was relaxing I liked eyes-closed part</td>
<td>Usable Liked music Relaxing Voice Liked using with eyes closed</td>
</tr>
<tr>
<td>2022</td>
<td>N/A</td>
<td>I loved the app and will continue to use it every day</td>
<td>Usable</td>
</tr>
<tr>
<td>2023</td>
<td>N/A</td>
<td>The silent gaps are good because it gives you time to digest</td>
<td>Likes gaps</td>
</tr>
<tr>
<td>2024</td>
<td>N/A</td>
<td>I really enjoyed it But hearing it with the background was quite nice. It wasn’t you know like a deep gruff voice. If it was a deep gruff voice you potentially would not be listening to it. And you wouldn’t have same responses.</td>
<td>Usable Liked music Liked Voice</td>
</tr>
<tr>
<td>2026</td>
<td>N/A</td>
<td>I love the app. I love using it Liked the way information was divided into pieces</td>
<td>Usable Good Structure</td>
</tr>
</tbody>
</table>

Note: ID 1003 & ID 2007 are greyed as they underwent surgery and were excluded from the analysis.
## Appendix I: LoFrisco (2010) Review

<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>n</th>
<th>Initial Outcome</th>
<th>Follow-Up Length</th>
<th>Follow-Up Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Backman, Widenbrant, Bohm-Starke, &amp; Dahlöf (2008)</td>
<td>Individual psychosexual therapy combined with physical therapy</td>
<td>24</td>
<td>Three fourths found it effective</td>
<td>No follow up</td>
<td>NA</td>
</tr>
<tr>
<td>Bergeron et al. (2001)</td>
<td>Randomized to vestibulectomy, biofeedback, or GCBT</td>
<td>78</td>
<td>All methods effective, but vestibulectomy more effective</td>
<td>Six months and 2.5 years</td>
<td>Same</td>
</tr>
<tr>
<td>Brown, Wan, Bachmann, &amp; Rosen (2009)</td>
<td>Randomized to one of two medication groups or self-management CBT group</td>
<td>43</td>
<td>Results not statistically insignificant (power issue), but participants found all methods somewhat effective, with the CBT group slightly more effective</td>
<td>No follow up</td>
<td>NA</td>
</tr>
<tr>
<td>Kabakçı &amp; Batur (2003)</td>
<td>Individual CBT treatment with physical therapy</td>
<td>16</td>
<td>All participants had improved sexual function</td>
<td>Four weeks</td>
<td>Same</td>
</tr>
<tr>
<td>Masheb, Kerns, Lozano, Minkin, &amp; Richman (2009)</td>
<td>Individual CBT or SPT</td>
<td>50</td>
<td>Approximately one half found it effective</td>
<td>One year</td>
<td>Same or better</td>
</tr>
<tr>
<td>Ter Kuile et al. (2007)</td>
<td>GCBT, bibliotherapy CBT, or waitlist</td>
<td>117</td>
<td>Approximately one third achieved intercourse</td>
<td>Three months and 12 months</td>
<td>Same</td>
</tr>
<tr>
<td>Van Lankveld, Everaerd, &amp; Grotjohann (2001)</td>
<td>Bibliotherapy CBT or waitlist</td>
<td>199</td>
<td>Approximately one half found it effective for vaginismus but not dyspareunia</td>
<td>Ten weeks</td>
<td>Not effective</td>
</tr>
<tr>
<td>Van Lankveld et al. (2006)</td>
<td>GCBT, bibliotherapy CBT, or waitlist</td>
<td>117</td>
<td>GCBT: 9% achieved intercourse Bibliotherapy CBT: 18%</td>
<td>Twelve months</td>
<td>GCBT: 21% Bibliotherapy CBT: 15%</td>
</tr>
</tbody>
</table>

Note. GCBT = group cognitive–behavioral therapy; CBT = cognitive–behavioral therapy; SPT = supportive psychotherapy. a Reported in same terms as study.
Minerva Access is the Institutional Repository of The University of Melbourne

Author/s:
Stabolidis, Arthur David

Title:
Self-administered cognitive behavioural therapy for women with chronic pelvic pain: design and pilot evaluation

Date:
2018

Persistent Link:
http://hdl.handle.net/11343/212283

File Description:
SELF-ADMINISTERED COGNITIVE BEHAVIOURAL THERAPY FOR WOMEN WITH CHRONIC PELVIC PAIN: DESIGN AND PILOT EVALUATION

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