UNDERSTANDING PAIN IN PEOPLE WHO HAVE HAD BREAST CANCER

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The candidate confirms that the work submitted is her own and that appropriate credit has been given where reference has been made to the work of others.

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Abstract

Background: The number of people surviving breast cancer is increasing. Pain is rarely a symptom of breast cancer and for many individuals their first experience of cancer pain is during treatment. Individuals who have been treated for cancer may experience 'long-term effects', symptoms which arise from treatment but persist into remission, or 'late effects', symptoms which commence after remission. This is an emerging area in the cancer literature and the prevalence, degree and management of these effects are currently being explored. Electronic pain monitoring offers a potential solution to the clinical issue of managing pain in survivors of breast cancer, but at present pain in breast cancer survivors is not routinely monitored. It is yet to be found exactly which information and at what frequency will be most reliable, tolerable and useful.

Aims: Therefore this study aimed to compare pain diaries completed either when pain occurred (pain event driven) or at specific times (time driven). These online pain diaries included rating pain on a pain scale, its interference with daily activities and a requirement to predict pain for the following 12 hours. The study also explored how the individuals experienced using the online diaries and the pain scales.

Design & methods: The study used a mixed methods case series design consisting of visual analysis, correlation and thematic analysis. Ten participants were recruited who had all previously been diagnosed with breast cancer and were at least 2 years post-surgery and currently cancer-free, having received a number of different treatments. Participants were required to complete pain diaries, including predicting their pain, over a 12 day period switching between pain event driven and time driven (twice daily) schedules according to a predetermined pattern. Participants then took part in a semi-structured interview and a scaling task involving the 10 point pain scale.

Results: Pain levels and interference from pain varied greatly within and between individuals. The total number of diaries completed by each participant varied from four to seventeen. There were no significant differences in responses between the two diary types, and participants did not express a strong preference for one over another. The majority of predictions made were either 'same as today' or 'don't know'. It was not possible to determine prediction accuracy in most cases. Thematic analysis of interview data generated three meta-themes: (1) making sense of experiences, (2) uncertainties about the future and (3) research is beneficial.

Conclusions: This technology has shown great promise as an engaging, practical way to monitor pain. Predicting pain remains a difficult yet interesting task for participants. Limitations and wider implications are discussed.

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Abbreviations

ACT	Acceptance and commitment therapy
CBT	Cognitive behavioural therapy
CFT	Compassion focussed therapy
EMDR	Eye movement desensitisation and reprocessing
GP	General practitioner
IMPACCT	Improving the Management of Pain from Advanced Cancer in the Community
PTSD	Post-traumatic stress disorder
SCF	Supraclavicular fossa
SNB	Sentinel lymph node biopsy
TRAM	Transverse rectus abdominis myocutaneous reconstruction
WLE	Wide local excision

Aims

This research aims to:

1. Compare event-driven pain monitoring and regular pain monitoring in people who have had breast cancer in terms of:
    a. Pain ratings
    b. Accuracy of predictions
    c. Completion rate of the pain diaries
2. Explore how individuals understand their pain in terms of:
    a. How they define a pain 'event'
    b. Their reflections on making pain predictions
    c. Their use of pain scales

Introduction

This research aims to understand pain in people who have had breast cancer and are in the initial years after successful treatment. Various models of pain will be explored including the psychological components of pain (perception, attention, coping and memory). In addition, the research literature on pain prediction will also be explored. Finally, methods of assessing and recording pain will be outlined in order to select the appropriate methodology to record current and predicted pain in participants who have survived breast cancer.

Breast cancer was the most commonly diagnosed cancer in England in 2011 (Office for National Statistics, 2013b). Western Europe has the highest rates of breast cancer in the world, with the UK sixth highest at 120 female cases per 100,000 of the population (Cancer Research UK, 2014a). Of the cases diagnosed in 2010, 99% were in women (Cancer Research UK, 2014a). It is one of the few cancers where rates are in fact lower in people living in more deprived areas (National Cancer Intelligence Network, 2004).

In the UK more than 50% of cancer survivors now live for 10 years or more (Cancer Research UK, 2015a) and 10 year survival rate for breast cancer in women is 78% (Cancer Research UK, 2014c). As the number of breast cancer survivors increases (Office for National Statistics, 2013a), some geographical regions are altering the structure of healthcare services to cope with the increased demand. Traditionally cancer survivors have attended an annual review at their regional cancer centre, but as the view of cancer changes from a specific palliative illness to a chronic condition (White, 2011), services are also changing. Some areas of the UK, such as Sheffield, are working with Macmillan Cancer Care to pilot a new scheme whereby breast and colorectal cancer survivors are discharged from the hospital to primary care (Sheffield Clinical Commissioning Group, 2013). These patients will see their GP for their annual reviews. If any symptoms are present, the GP then refers them back to the cancer centre. If this pilot is deemed a

success and this GP review system becomes commonplace there is a risk that knowledge of late effects will be too dispersed or inconsistently collected to enter the research community and subsequently benefit other patients.

The aim of this thesis is to focus on one of these late effects, pain, in women who have undergone treatment for breast cancer and are now cancer-free. The current study will compare two types of pain monitoring among women who have been successfully treated for breast cancer. Monitoring pain will always present challenges, not least due to its complex and subjective nature. Pain has been monitored in a myriad of ways over the last century. The development of pain monitoring has been influenced by an increased understanding of pain, developments in technology and specific work with certain patient populations, including cancer patients.

This thesis was originally developed as an adjunct to a larger research project entitled Improving the Management of Pain from Advanced Cancer in the Community (IMPACCT), led by Professor Michael Bennett in Leeds Teaching Hospitals NHS Trust. This project has a number of workstreams. The second workstream is led by Dr Bridgette Bewick, one of the supervisors for this thesis, and involves developing an information management system and ensuring engagement of patients and professionals. Workstream two will investigate the feasibility of using an electronic system to monitor and communicate cancer pain. In the development grant project qualitative work was undertaken to understand the way in which cancer patients manage their pain in their day-to-day lives (Godfrey, Manzano, Ziegler, & Bennett, 2012), and how healthcare professionals manage advanced cancer pain. However, during the planning phase of the thesis the decision was made to focus on survivors of cancer rather than those with active cancer, and this thesis therefore no longer directly links to the IMPACCT study.

Cancer and pain

There is much variety in the experiences of both cancer and pain. For many, pain is the most feared symptom of cancer (Peretti-Watel, Bendiane, Spica, & Rey, 2012). However, not all cancers have pain as a primary symptom, and therefore often it is something else which leads the individual to be assessed and diagnosed with cancer. Cancer may be diagnosed following routine screening, or by the individual actively seeking assessment, for example after detection of physical changes such as a lump. Although pain is a common breast symptom in the general population, it remains a rare symptom of cancer in the breast (Smith, Pruthi, & Fitzpatrick, 2004). Therefore cancer and pain are not coterminous as there are pains unrelated to cancer and cancers which do not cause pain.

In cancer it is likely that both acute pain and chronic pain are present. For example, acute pain may be caused by soft tissue damage from medical investigations. Chronic pain may be caused directly by the cancer itself, the treatments (Cancer Research UK, 2014d), or by complications; breast cancer is the most common cause of spinal cord compression in females (Das, Khurana, Gupta, Mishra, & Bhatnagar, 2009), and this causes extreme pain. Other pains

found in cancer patients include visceral pain, myofascial pain, pain from constipation, spasm pains or lumbar pain (Twycross & Lack, 1984), although the prevalence of these symptoms is unclear. Although the cancer itself may be stable, pain can still fluctuate (McGrath & Dade, 2004).

Cancer is an umbrella term for over a hundred different diseases where cells develop in an unregulated way, usually leading to a tumour. Given the huge variability within cancer, it is perhaps not surprising that the painful experiences associated with it vary just as much, thus presenting challenges for treatment. Many different words have been used to describe pain, some of which refer to its intensity and others to its nature or quality. This variety in pain experiences may in part arise from our physiology in that nociceptors are polymodal and can be activated by thermal, mechanical or chemical stimuli (Meyer, Ringkamp, Campbell, & Raja, 2006). The use of words to describe pain appears to vary greatly between individuals, but even so, differences have been found between how people with cancer describe pain compared to healthy controls. In one study healthy controls favoured emotional labels over intensity labels while intensity labels were favoured by the cancer patients (Clark, Ferrer-Brechner, Janal, Carroll, & Yang, 1989). Less is known however about whether these descriptors change over time within individuals or whether they are different for different types or locations of cancer, which may be plausible given the differences found between different groups of patients with different sources of chronic pain (Morley & Pallin, 1995). If group differences do exist, it is not yet known how robust this effect is and whether they apply to subgroups. In breast cancer for example, one study showed that there was no difference in pain descriptors used by women who had a mastectomy compared with mastectomy and reconstruction (Passavanti et al., 2006), suggesting that group norms in describing pain may only apply to the broader group (such as patients with breast cancer) and are not altered within subgroups (such as individuals who had different treatments).

Pain is experienced by the majority of cancer patients and can have a large negative impact on quality of life (Caraceni & Portenoy, 1999; The British Pain Society, 2010). The frequency of pain increases from 50% at diagnosis to around 75% in advanced cancer (Soyannwo, 2010). Pain is also associated with reduced functionality, reduced quality of life, increased medication and increased hospital visits (Brennan, 2004; van den Beuken-van Everdingen et al., 2007), meaning that it has a significant impact not only on individuals but also on the economic cost to society.

The risks of having pain and of it being moderate to severe is high in breast cancer when compared with other cancers (van den Beuken-van Everdingen et al., 2007). Around half of patients with active breast cancer report experiencing pain, and these reports are associated with a younger age (under 40), radiotherapy and axillary lymph node dissection (Gärtner et al., 2009). Gärtner's study also found that pain in other parts of the body was associated with surgery pain (Gärtner et al., 2009), suggesting that sensitisation processes have a role in pain in patients with active breast cancer. A recent meta-analysis suggests that a third of survivors experience ongoing pain after curative treatment has finished (van den Beuken-van Everdingen et al., 2007). In

survivors who had received radiotherapy for breast cancer a younger age was also associated with an increased occurrence of long-lasting breast pain, as was the addition of chemotherapy (Lundstedt et al., 2012).

Breast cancer has a number of treatment options, including chemotherapy, radiotherapy and surgery. The surgery will cause acute pain, but may also cause chronic pain, including phantom pain or referred pain, which is experienced in a location distal from the source. Although the exact mechanisms underlying referred pain are not yet fully understood, it has been shown to relate to the structure of the nervous system. Peripheral surface nerves in the hands, feet and face greatly outnumber those in the centre of the body, as shown by the 'two point discrimination test' and there are very few sensory nerves within the trunk of the body. Each of these nerves enters the spinal column before synapsing and ascending to the brain. In the case of our organs (excluding skin), the structure of the nerve branches means that the source of the stimulus cannot be identified reliably and may be misattributed to another place. For example, liver pain may be felt in the shoulder, cardiac pain in the left arm and kidney pain in the lower back. In the case of breast cancer pain, sensations may be experienced in the hands (pain), extremities (tingling) or back.

The quality and longevity of pain after breast surgery is variable, with reviews suggesting that the pain is mostly neuropathic in nature (Chang, Mehta, & Langford, 2009). One consistent predictor of post-surgical pain in the wider literature is pre-surgical pain (Rotbøll Nielsen, Rudin, & Werner, 2007), and this has also been found to apply to breast cancer patients (Sipilä, Estlander, Tasmuth, Kataja, & Kalso, 2012). Given that pain is rarely a symptom of breast cancer (Smith, Pruthi, & Fitzpatrick, 2004), it is assumed that preoperative pains are due to other causes.

Other treatment options include radiotherapy and chemotherapy, and both of these can be painful. While the radiotherapy itself is painful, in chemotherapy it is the associated elements which can be uncomfortable. For example, the needle used to deliver the chemotherapy can be painful, and if chemotherapy leaks into the tissues of the hand it can cause lasting painful damage. Damage to veins can cause longer term ischaemic pain in the lower arms. In recent years patients undergoing chemotherapy have been offered a 'cold cap', which reduces the blood flow to the scalp, and in doing so dramatically reduces hair loss. However, the temperature of the cap itself can be very painful to wear, and is remarkably similar to the cold pressor test used to induce pain experimentally. hormone therapies used after surgery, radiotherapy and chemotherapy treatments for breast cancer can cause side effects such as painful joints (Glare et al., 2014; Macmillan Cancer Support, 2013). Joint and muscle pain and stiffness has been found to be more prevalent, but not more severe, in women who have had breast cancer when compared with an age-matched non-cancer sample, and quality of life was significantly worse for women who have had cancer (Fenlon et al., 2013). Such side effects can lead individuals to cease treatment, which will in turn affect longer term prognosis and survival (Smith & Wu, 2012).

Of these pains associated with treatments, many can persist beyond the duration of the cancer itself. For example, radiotherapy may cause changes in skin elasticity or cause lymphoedema (Cancer Research UK, 2014d), both of which can be uncomfortable or painful; chemotherapy can cause peripheral neuropathy sometime after treatment has finished (Cancer Research UK, 2015b; Glare et al., 2014), which is often painful; and surgical treatment for cancer is associated with a risk of longer term pain, nerve damage or lymphoedema. It is worth noting that many patients receive more than one type of treatment and it can therefore be difficult to discern which pains might have been caused by which treatment.

Pain after cancer

As more people survive cancer, there will be more opportunities to learn about their experiences and how healthcare can evolve to respond to their needs. Longitudinal studies are notoriously difficult to carry out for a number of reasons, not least resources. In oncology, where treatments and technologies develop year on year, the value of longitudinal studies is questionable if the treatments the individuals received are no longer in use. However, longitudinal studies are carried out which focus on survival and residual symptoms and some cover an impressive time period of 10, 20 or 30 years. Surprisingly, one 20-year follow-up study concluded that 'the impact of breast carcinoma on survivors' adjustment was minimal' (Kornblith et al., 2003). Kornblith et al. did not record pain, suggesting that the presence of pain is sometimes neglected in this group of people.

Longitudinal studies which include pain found that the pain journey after breast cancer is complex and that pain fluctuates over time. For example one study found that when comparing the same women at 40 month and 10 year follow-ups, some women's pain had remained low, for some it had remained above average, for some it had improved and for some it had worsened (Forsythe et al., 2013). Pain was classified as above or below the population average using the SF-36 (Ware & Sherbourne, 1992) quality of life measure at each of the two time points, giving four possible categories. In other words, all possibilities of pain classification were in fact observed in this sample of 522 women. For 10% of these women, pain had worsened between the 40 month and 10 year follow ups; at the 10 year follow up a third of the total number of women experienced above average pain. Multiple regression analyses showed that pain was associated with a higher body mass index and lower amounts of physical activity (Forsythe et al., 2013), although exploring causality was beyond the scope of the research.

As described above, pain has a complex relationship with a number of affective states, such as depression and anxiety, and also with physiological processes such as the immune system. Pain may also impact upon other activities which are both psychological and physiological, such as sleep and appetite. Additionally, studies of other symptoms found that non-pain symptoms were strongly negatively associated with quality of life, and researchers concluded that systematic recording of non-pain symptoms is essential in all treatment phases including in the months

following treatment (van den Beuken-van Everdingen et al., 2009). Given the relationship between pain, emotion and other non-pain symptoms, the increasing research on non-pain symptoms is welcome as it provides further opportunities to intervene and potentially reduce distress and increase quality of life of people who have completed cancer treatments.

There appears to be an open dialogue and plenty of freely available information about the possible side effects of cancer treatments, including pain. However, one must dig deeper in publicly available literature to find information about pain with persists beyond cancer and its treatments. Research charities such as Cancer Research UK have a primary aim of reducing cancer deaths, and do this by raising money to invest in research. Their fundraising has raised the profile of cancer with the general population and cancer is much less hidden than it used to be. Recently charities such as Macmillan and Cancer Research UK have also become active in policy making and have developed information and education resources for both public and professionals, and it is these resources that focus on active cancer which are most accessible to the public. This is not a criticism however, as their aim is to reduce deaths and promote research, not to focus on life after cancer.

Pain which is experienced at the same moment as a treatment is attributed to that treatment almost without question, and the pain may be understood and treated in physiological terms within the biomedical model (Somers, Keefe, Kothadia, & Pandiani, 2010). As time progresses, persistent pain presents psychological challenges, both when the cause is known and when the cause is less clear. Uncertainty is known to be psychologically threatening and can lead to high levels of anxiety. Some researchers have explored the specific role of threat in painful experiences. Arntz and Claassens (2004) found that an identical stimulus was perceived to be more painful when participants were told it was hot, and therefore perceived to be causing tissue damage, compared to when they were told it was cold. An increased level of threat can lead to an increased level of pain experienced.

When the cause of the pain is related to cancer, the threat level will be higher than the threat level of pain caused by non-life threatening conditions. Increased threat results in an increase in pain intensity (Arntz & Claassens, 2004), and therefore pain which is known to originate from cancer and its treatments but is not fully understood may represent maximal threat and result in an increased pain experience. The meaning of the pain is important when considering both the levels of pain experienced and the degree of distress associated with that pain. Some patients with active cancer interpret pain in a new location as a sign that the cancer has spread or progressed (Levy, 2008; Ward et al., 1993), and in survivors the pain can represent the threat of cancer having returned (Brummett, 2011).

The role of the biopsychosocial model is increasing in active cancer (Somers et al., 2010) and its role is arguably even more vital once treatment is complete and late effects become apparent given the presence of psychological components such as threat, uncertainty and anxiety.

Qualitative studies have explored ways in which women understand the pain they experience in the months and years after their treatment for breast cancer has finished. When considering these studies together, an overarching theme emerged which was concerned with *time*. Some women felt that the pain was 'normal' – something they had been told by their healthcare team – and was therefore part of their recovery; something transient which was a necessary part of the journey (Peretti-Watel et al., 2012). For other women, the cancer was in the past and therefore pain had no place in their post-cancer life. For others still, pain was viewed as a new permanent chronic condition. Each of these views on the place of pain within time directly affected their opinions and behaviours around pain management, including whether they took analgesic medication or not (Peretti-Watel et al., 2012). Pain was also used to understand the future. Some women feared that pain meant the cancer had returned, and were understandably concerned about the future. Others interpreted pain as healing and looked instead towards a future with increased abilities.

In many respects cancer is increasingly viewed as a chronic condition rather than a palliative one (Burton, Fanciullo, Beasley, & Fisch, 2007). This shift greatly affects the treatment of pain: guidelines for palliative pain management differ significantly from those for chronic pain management. Cancer pain has traditionally been treated using the World Health Organisation analgesic ladder, which focuses on pharmacological treatments (Somers et al., 2010). Chronic pain management however focuses on a multidisciplinary approach (Scottish Intercollegiate Guidelines Network, 2013). Consider multiple sclerosis (MS) for example, a condition where central nervous system lesions can cause a number of symptoms including altered sensation, weakness, tremor and pain (Colman, 2006). There are a number of subtypes of MS, but in most cases the condition features fluctuation in symptoms. For some people there may be no symptoms for a number of years during a remission, while for others there is a baseline level of symptomatology followed by periods of worsening of these symptoms.

Therefore in many ways individuals with MS have similar issues to negotiate as cancer survivors, such as fear of relapse, energy, pain, uncertainty about the future and having a 'hidden' or 'invisible' condition that may be difficult for others to understand. However, the crucial difference between a condition like MS and surviving cancer is the issue of mortality. While superficially these individuals experience the same difficulties, interpretation of bodily sensations arguably has greater threat value in cancer as it is a condition which can directly lead to death, unlike MS or chronic pain conditions such as arthritis where life expectancy is reduced by other complications.

It is therefore proposed here that there are common underlying processes which underpin both pain in cancer and pain due to other causes. Although new pains in cancer survivors should be investigated to exclude recurrent or secondary cancer, many believe that pain in cancer survivors would benefit from management which is closer to that used in chronic pain rather than

in active cancer, with the main distinguishing features being use of opioids and psychological treatments (Glare et al., 2014). With this in mind, models of pain will now be briefly explored.

Models of pain

The current accepted definition of chronic pain is pain that lasts for three months or more (International Association for the Study of Pain, 1986). To meet the Diagnostic and Statistical Manual (DSM-4) criteria for pain disorder, pain must have been present for at least six months to be considered chronic (American Psychological Association, 1994), and there is no minimum duration given in the International Classification of Diseases (World Health Organisation, 1992). In the DSM-5, pain disorder has been combined with somatization disorder, hypochondriasis and undifferentiated somatoform disorder to form a single 'somatic symptom disorder', which also requires symptoms to be present for at least six months (American Psychological Association, 2013).

Chronic pain can only very rarely be completely eradicated. It is a complex phenomenon which has been described in many ways, including being 'poorly understood' (Ramachandran & Blakeslee, 1998) and 'puzzling' (McGrath & Dade, 2004). It is therefore not surprising that something which is not fully understood does not have a single obvious treatment. Pain can be managed in some people some of the time, but pharmacological treatments are often insufficient and so individuals find other ways of coping with the pain if it cannot be satisfactorily reduced by medication. Even if pain is generally well controlled, individuals can experience 'breakthrough pain', brief increases in pain over and above typical background pain (The British Pain Society & Royal College of General Practitioners, 2004). There are a number of models which have been proposed and revised with the aim of providing a robust framework which represents the experience of pain. Before presenting a summary of notable pain models, first two categories of pain, acute and chronic, will be outlined.

Acute pain

Acute pain is severe short-lived pain (Colman, 2006) which typically occurs suddenly and reaches its peak almost instantly, decreasing over time. Acute pain may be due to accidental injury, surgery or dental treatment, all of which include injury, but in some cases individuals experience acute pain without injury, such as a headache. In the case of minor accidental injury, over-the-counter pharmaceutical analgesics are effective and any emotional distress is minimal because the source of the pain and how to manage it effectively are well understood, and intervention from a healthcare professional is not normally required (McGrath & Dade, 2004; Turk & Burwinkle, 2011). In the case of minor acute pain caused by medical procedures, the emotional distress can be much higher and is now termed *procedural distress*. This wider term has replaced terms such as 'needle phobia' for example as there is a greater understanding now that the distress can be due to many aspects of the procedure such as the clinic room, healthcare professionals, smells of antiseptic to name but a few, as well as the needles or injuries themselves (Duff, 2003).

Although at first glance acute pain seems less complex, there are examples from the literature which show that it is multifaceted. For example, the peak of acute pain does not necessarily occur at the exact time of the injury. In experiments using laser pain, pain ratings peaked just *prior* to the laser stimulus (Brown, Seymour, El-Deredy, & Jones, 2009). That tissue damage and acute pain may not be proportionate or simultaneous impacts on both methods of pain monitoring and psychological processing of these experiences.

Although cancer pain literature focuses on chronic pain, there are a number of instances of acute pain both during and after cancer. For example, a tissue biopsy, mammogram or insertion of a chemotherapy needle may cause acute pain. Additionally, surgery causes acute pain and disease progression or recurrence may also cause acute pain. Although pain protocols are commonplace and have been shown to improve management of acute pain (Chang et al., 2009), a review of the literature failed to identify a 'gold standard' for breast surgery analgesia and post-operative acute pain management techniques were found to vary considerably (Chang et al., 2009).

Transition from acute pain to chronic pain

Many textbooks neatly compartmentalise acute and chronic pain. Such a distinction is not necessarily realistic or helpful in understanding clinical pain. For example, the concept of 'recurrent acute pain' (Turk & Burwinkle, 2011) or 'episodic pain' (The British Pain Society & Royal College of General Practitioners, 2004) does not fit neatly into either category. Examples of recurrent acute pain include migraine, rheumatoid arthritis and multiple sclerosis, all of which can have discrete pain episodes which alternate with sometimes extensive pain-free periods. In the case of multiple sclerosis, painful episodes may be associated with new lesions (Truini et al., 2012), but in migraine, there is usually no physical cause or function, and in rheumatoid arthritis, the biochemical markers do not necessarily correlate with painful or pain-free episodes.

The transition from acute pain to chronic pain is not inevitable. A number of moderators of this transition have been proposed including altered cortical white matter structures (Mansour et al., 2013), reduced grey matter (Baliki et al., 2012), secondary gains (Turk & Burwinkle, 2011), trauma and depression (Young Casey, Greenberg, Nicassio, Harpin, & Hubbard, 2008) and a complex interaction of genetic, psychological and social-environmental factors (Chang et al., 2009; Katz & Seltzer, 2009).

In particular, severe acute post-operative pain has been found to have a key role in the development of chronic pain and there is a large literature on the importance of managing post-operative pain in breast cancer in order to minimise the development of chronic pain in these individuals (Chang et al., 2009; Gärtner et al., 2009). In breast cancer, reviews of the literature have identified that the development of chronic pain following breast cancer treatment has been associated with nerve damage, radiotherapy, pre-existing pain and demographic factors (Andersen & Kehlet, 2011; Brummett, 2011).

Chronic pain

Chronic pain has a number of definitions, such as pain which persists beyond healing with no obvious physical function, and chronic pain is the most frequent reason for primary care general practitioner visits in the USA (Turk & Burwinkle, 2011). Unfortunately comparison figures are not available for the UK because pain is not one of the 19 conditions listed in the NHS Quality Outcomes Framework (QOF) and therefore data are not routinely or consistently collected. Reports such as those from the National Pain Audit (National Pain Audit, 2012) and British Pain Society (The British Pain Society & Royal College of General Practitioners, 2004) both rely on a Scottish epidemiology study from over a decade ago by Elliott et al (1999) to estimate the appointments and associated costs attributable to chronic pain. Chronic pain is often complex, with a number of causes requiring a number of different treatment approaches (McGrath & Dade, 2004; Turk & Burwinkle, 2011).

Biomedical model

Various models have been proposed to describe pain. These models can be broadly categorised as bottom-up or top-down in their approach. An example of bottom-up processing is the biomedical model which states that pain is indicative of and proportional to physical tissue damage (Somers et al., 2010), which may be the case in cancer patients, for example pain immediately following surgery. The process of nociception, where nerve fibres are activated, is functional and adaptive because it tells us either that damage has occurred or that a disease is present. The biomedical approach is dominant in cancer diagnosis and treatment and aims to treat the disease itself, or when this is not possible, treat pain and other symptoms with treatments such as medication, surgery or radiotherapy (Somers et al., 2010).

However, it is now accepted that pain can exist in the absence of physical damage (Reneman, Poels, Geertzen, & Dijkstra, 2006) and that physical damage can exist in the absence of pain (Borenstein et al., 2001). Pain in the absence of damage may be termed ‘psychogenic’ or ‘somatized’ when both its onset and maintenance arise from psychological states. There is limited empirical support for this approach beyond correlation of chronic pain and mood disorder. The ‘antecedent hypothesis’ (Surah, Baranidharan, & Morley, 2013) states that pain is more likely to *precede* the mood changes rather than be caused by it (Turk & Burwinkle, 2011), but others refute this and have concluded that there is no temporal relationship (van Dartel et al., 2013). Psychological or behavioural elements have also been discussed in the maintenance of pain, particularly in the context of financial gains such as compensation or disability benefits. Such elements range from subconscious classical conditioning to more conscious operant conditioning, social learning or secondary gains.

Gate control theory

In the 1960s more complex pain models were published such as the gate control theory by Melzack and Wall (McDowell, 2006; Melzack & Wall, 1965). This approach was the first attempt

to integrate top-down and bottom-up theories and states that descending signals from the brain can affect the physiological pain experience. There is a wealth of empirical support for this model with a number of studies and meta-analyses demonstrating that top-down psychological processes moderate painful experiences, such as the placebo response (e.g. Morton, Watson, El-Deredy, & Jones, 2009), attention studies (e.g. Crombez, Van Ryckeghem, Eccleston, & Van Damme, 2013) and those directly comparing bottom down and top-up processes (e.g. Tiemann et al., 2015).

In this model it is proposed that the 'gate' is located in the dorsal horn of the spinal cord where peripheral nerve fibres synapse onto both inhibitory interneurons and projection cells, the latter of which extend to the brain. If there is no input, the gate is closed. Similarly, if only large-diameter fibres are stimulated, the gate remains closed because the inhibitory neuron has been activated, preventing a signal to the brain. If predominantly small-diameter fibres are stimulated, the inhibitory neuron is not stimulated, therefore allowing the projection neuron to carry a signal to the brain (Moayedi & Davis, 2012). Additionally, descending pathways can inhibit projector neurons, thus reducing pain perception. This is a crucial part of the model which acknowledges that psychological processes can influence sub-cortical pain processing and pain perception (Smith & Dalen, 2007): the gate can be opened by injury, negative emotions and attention; it can be closed by traditional analgesic medication, positive mood and distraction.

The gate control theory is almost fifty years old but continues to feature in more recent pain literature. For example, Ramachandran uses the gate control theory in explaining his findings from work with people who experience phantom limb (Ramachandran & Blakeslee, 1998). He has concluded that phantom limb pain (or other sensations) arise when parts of the brain previously used to process the lost limb become co-opted for use with other areas of the body. If this remapping in the brain and spinal cord is not precise, the gate is not functional and abnormal signals entering the brain are interpreted as pain (Ramachandran & Blakeslee, 1998). The research literature also shows that following a mastectomy some women experience phantom breast pain which can fluctuate over time within the same individuals (Björkman, Arnér, & Hydén, 2008). In addition, patients after mastectomy found it more difficult to describe and locate their sensations than those who had had a limb amputated (Björkman, Arnér, Lund, & Hydén, 2010).

The gate control theory was the one of the first attempts to explain pain anomalies, such as the pain experienced by some cancer patients, when pain is not always proportionate to actual tissue damage (Olson & Pienta, 1999). It also acknowledges that pain can be influenced by psychological factors such as improved mood and increased distraction from pain (Buck & Morley, 2006), phenomena which were not adequately explained by the biological model. It is now widely accepted that pain only occurs within the influence of context and meaning (Price & Bushnell, 2004), but this understanding arguably only arose because the gate control theory began an important discussion around the complexities of pain and how a wider approach – including the field of psychology – might aid understanding.

In summary, the gate control theory was the first to attempt to synthesise ascending and descending signals. Although some aspects of the model have been disproven, such as some of the assumptions of neuroanatomy made in the model (Moayedi & Davis, 2012), it remains influential and has inspired a wealth of research which has both developed and refined the original model. The gate control theory of pain, like many others, focuses on acute cutaneous pain and neglects mechanisms involved in the transition to chronic pain (Moayedi & Davis, 2012), and is therefore not immediately applicable in a clinical setting where pain has become chronic in nature. One must go beyond the gate control theory to understand how other factors impact upon the pain experience.

The psychology of pain

As described above, it is now understood that psychological processes influence the pain experience, although exactly how this happens has not yet been revealed. Psychological processes involved in pain include perception, mood, memory and attention, and each of these will be explored below.

Pain perception

While some pains such as neuropathic pain are experienced in a similar way across individuals, many are not. Even neuropathic pain is described differently by different people such as burning, electric shock or stabbing (Chang et al., 2009). The perception of pain is described using language and narratives and these vary considerably and suggest that even when the cause of the pain may be similar, individual psychological processes mean that the pain experiences are very different. The quality of pain is therefore arguably both a physiological and psychological process.

The multidimensional definition of pain includes three dimensions: sensory-discriminative, affective-motivational and cognitive-evaluative (Auvray, Myin, & Spence, 2010; Melzack & Casey, 1968). The sensory-discriminative dimension includes the intensity, location, quality and duration of pain experienced. The affective-motivational dimension includes the unpleasantness and behavioural response to escape pain, and finally the cognitive-evaluative dimension includes culture, values, context and cognitive state. While many see pain as a perception, others categorise it as a motivation to act (Auvray et al., 2010).

Neither acute nor chronic pain are experienced consistently either across people or within the same individual over time. In chronic pain, the experiences of pain can change markedly over time such that overall pain levels may increase, decrease, become more widespread or more localised. In breast cancer specifically, patients and survivors have reported both sensitisation and habituation of pain. These concepts will be explored below.

Chronic pain is not a gradual recovery process whereby pain decreases over time as healing occurs. Instead, the fluctuations observed in chronic pain over time and the persistence of chronic pain over years and decades suggests that there are more complex processes at work.

In neurological terms, increases in pain when there is no change in stimulus may be due to sensitisation. Pain sensitisation is a fundamental pain mechanism and may include both hyperalgesia and allodynia. In hyperalgesia, existing pain networks activated with reduced stimulus, which is observed as a lowered pain threshold. In the case of allodynia, a stimulus which was not previously painful is able to activate the pain networks.

Sensitisation can be caused both peripherally and centrally. A patient with phantom limb experienced pain in his lost arm when his face was touched in a non-painful way because the cortical restructuring of the Penfield map had resulted in significant changes to the way inputs were processed and mapped (Ramachandran & Blakeslee, 1998): an example of central sensitisation caused by cortical scar tissue, neuromas, which formed during the cortical restructure after the limb was lost (Ramachandran & Blakeslee, 1998). Women with breast cancer who have undergone axillary lymph node dissection may be particularly vulnerable to central sensitisation (Steegers, Wolters, Evers, Strobbe, & Wilder-Smith, 2008). In peripheral sensitisation the gate in the dorsal horn is opened too easily, perhaps as a result of sensitisation of individual nerve fibres or even phenotypic changes of Aδ fibres (Manning, 2004). For example, an individual with burned skin can experience hyperalgesia if the burned skin is cut, as this cut would also be painful without the burn present. They can also experience allodynia if warm water touches the burn as this would feel painful, whereas warm water on undamaged skin would not be painful.

Decreases in pain may be due to habituation, when the same or even larger pain stimulus produces a reduced effect. This can be central in nature and can act to inhibit opening of the gate. As described earlier, the function of the gate can be altered by many factors, including mood, and this altered functionality can manifest as either sensitisation or habituation. These processes may take place gradually, over a number of months or years, or can happen quickly. Some people report altered pain perceptions after a single painful event. When conducting pain research with a painful stimulus it is interesting to observe how some individuals sensitise or habituate within a number of minutes of receiving repeated painful stimuli while others continue to give constant pain ratings during a number of trials.

These examples of chronic pain modulation highlight the complexities of pain processing and show that pains interact within individuals. Multiple pains are common in both chronic pain patients and cancer patients, and studies have shown that breast cancer patients with active cancer have the greatest number of additional pains (Twycross, Harcourt, & Bergl, 1996). The interaction of multiple pains is an important consideration in pain management.

Emotion

Mood disorders, such as anxiety and depression, are common comorbidities of chronic pain (Kato, Sullivan, Evengard, & Pedersen, 2006; Surah et al., 2013). A number of other conditions are found in individuals who experience chronic pain, and it is not always possible to establish causality. Conditions found alongside chronic pain include fatigue (Lamino, Mota, & Pimenta,

2011; Thornton, Andersen, & Blakely, 2010), irritable bowel syndrome (Kato et al., 2006), sleep disorders (Davis, Robinson, Le, & Xie, 2011) and impairments of memory and attention (Berg et al., 2009; Iezzi, Duckworth, Vuong, Archibald, & Klinck, 2004; Melkumova, Podchufarova, & Yakhno, 2011). Animal studies suggest that chronic pain causes neuroanatomical changes which lead to altered mood states and impaired attention some months after the original injury (Bushnell, Ceko, & Low, 2013). Reduced quality of life (Baliki et al., 2006) and altered immune system functionality (Ren & Dubner, 2010) are also associated with chronic pain.

This thesis is mainly concerned with physical pain. The research literature on psychological distress and how this is processed in the brain also contributes to the discussion on pain after breast cancer. Depression and anxiety are commonly found alongside chronic pain. Social pain is processed in the brain in a very similar way to physical pain (Eisenberger, 2012; Kross, Berman, Mischel, Smith, & Wager, 2011). Additionally, research has identified a correlation between early emotional trauma and unexplained widespread chronic pain in later life such as fibromyalgia (Van Houdenhove, 2003), a link which is still under intense debate, especially as recent events such as the World Trade Centre terrorist attacks have provided an opportunity to show that people with fibromyalgia symptoms prior to trauma were more likely to exhibit PTSD symptoms following such a traumatic event, suggesting common vulnerabilities rather than causality (Raphael, Janal, & Nayak, 2004).

As well as the potential longer term impacts of emotional states, emotions can also mediate the pain response in the immediate term. For example, fear and anxiety have both been shown to have a relationship to pain. this may be confounded by a tendency to use the two terms interchangeably despite them being shown to be two distinct constructs each with their own validated self-report measurement tools (Carleton & Asmundson, 2009). Studies with experimentally induced emotional states show that fear has an analgesic effect whereas anxiety has a hyperalgesic effect (Rhudy & Meagher, 2000), although others posit that fear and anxiety are less distinct in a clinical setting (Petrovic, 2010).

Research has consistently shown that affective states alter pain perception, for example that a worse mood state is associated with increased pain unpleasantness (Berna et al., 2010; Loggia, Mogil, & Bushnell, 2008) and positive mood state reduces pain intensity (Bushnell et al., 2013). Many of these studies are experimental in nature and focus on short-term effects of induced mood states. However, emotion can also moderate pain in the longer term: the same brain areas are affected by emotion and chronic pain and this interaction may underpin the sensitisation processes described earlier, either by altering modulation of pain or using novel circuitry in pain processing (Berna et al., 2010; Bushnell et al., 2013). Additionally, the changes in the brain in chronic pain patients may also underpin observed cognitive difficulties (Bushnell et al., 2013).

Emotion has also been found to mediate other previously anecdotal pain phenomena, such as the use of swearing to cope with pain (Stephens & Umland, 2011). Emotion has also been found to contribute to gender differences in pain (Rhudy & Williams, 2005). All of these studies

show that emotion plays a key role in the pain experience. Emotion therefore can also serve as an additional target in pain management.

Attention and interference

As mentioned above, attentional biases can have an impact on pain processing and perception. This is a vast area in the research literature and will not be covered in detail here; see reviews by Bushnell et al., (2013), Schoth, Nunes, & Liossi, (2012) and Crombez et al., (2013). However, it is important to consider in a study such as this one where participants are required to attend to their pain during the study.

Studies have shown that attention and emotion affect pain in different ways (Bushnell et al., 2013). Attention and emotion remain closely linked however. For example, the effects of anxiety and fear on pain perception may be mediated by attention: hypoalgesia as a result of external threat and fear is adaptive because attention is focussed away from pain and towards danger, and likewise hyperalgesia from fear of physical harm, including illness, directs attention inwards (Petrovic, 2010). In both of these examples attention, emotion and pain perception all work together to increase the chances of survival. These mechanisms also explain how an individual with cancer might become hyper vigilant and sensitised to internal sensations.

This 'limited capacity model' of human attention has been developed by Legrain and colleagues into a more complex 'neurocognitive model' which includes both top down and bottom up processing. Top-down processing is goal-directed and increases or decreases responses to stimuli; bottom-up processing involves stimuli demanding attention in their own right (Legrain et al., 2009). Stimuli which will achieve this level of attention will be salient either due to their novelty, rarity, intensity or threat value, and serve to alarm us (Legrain et al., 2009). These bottom-up processes can be modulated by top-down factors however, and studies have shown that pain processing is reduced during a distracting task, consistent with the 'limited capacity model'. What is not consistent with this model however is when top-down processes magnify incoming stimuli from the external environment to such a degree that non-painful stimuli are experienced as very painful (Legrain et al., 2009). This neurocognitive model of attention to pain offers a two-part explanation of chronic pain and its associated cognitive deficits. First, in the bottom-up system, more inputs may be coded as salient, a notion that is supported by meta-analysis (e.g. Schoth, Nunes, & Liossi, 2012). Second, in the top-down system, individuals may be less able to use executive functions to modify these inputs (Legrain et al., 2009); this has been supported by subsequent research (Apkarian et al., 2004).

Coping with pain

An important element of the psychology of pain which is related to both emotion and attention is that of coping. Coping is an attractive area of pain research but can pose difficulties because it is often intangible (Van Damme, Crombez, & Eccleston, 2008), however, if half of breast cancer survivors live with ongoing pain, it is worth exploring how they manage this pain. Some of the

coping mechanisms used to live with chronic pain may be adaptive, whereas other coping mechanisms may present barriers to effective pain management. Ways of coping may be instigated by individuals, their families, social care staff or healthcare staff. There are a number of ways in which the concept of coping can be classified. Coping may be active, where the individual tries to control pain or continue to function, such as distraction. Alternatively coping may be passive, where the individual withdraws from activity (Van Damme et al., 2008).

Cognitive strategies

There are a number of cognitive strategies which can be used to reduce the distress and negative impacts of chronic pain including ignoring the pain, using coping self-statements, diversion, praying and hoping (Somers et al., 2010). While some of these may be introduced in a therapeutic context, others already feature in people's ways of coping. Cognitive behavioural therapy works on the premise that the way in which we interpret events is influenced by our beliefs and previous experiences, and these interpretations affect our mood and behaviour (Turk & Burwinkle, 2011). The three main components of this approach are reconceptualization, skills training, and maintenance.

Reconceptualization involves gathering information about the problem and in particular the thoughts, feelings and behaviours associated with it. This is commonly achieved by using a diary. Often such diaries can reveal patterns of behaviour and multiple, sometimes conflicting, beliefs about the problem. The skills section of therapy includes awareness and use of relaxation, problem solving, distraction and communication and the maintenance section includes relapse prevention, anticipation of future challenges and a consolidation of the changes made during therapy (Turk & Burwinkle, 2011).

As mentioned above, emotional states can have a profound impact on the pain experience. It can be argued that the cognitive behavioural approach aims to reduce the emotions experienced alongside chronic pain by appraising situations differently and making more measured choices about how to respond to challenges. Distraction in particular may act to reduce the fear of pain rather than the pain itself (Buck & Morley, 2006).

Another cognitive strategy which is growing in popularity within the field of pain and in psychological wellbeing more generally is mindfulness. The term mindfulness is relatively recent, but the concept is much older. Much of mindfulness originates in Buddhism, one of the oldest religions in the world (Gunaratana, 2002). Mindfulness can help individuals notice and observe their own patterns of behaviour, thoughts and emotions, which in turn increases wellbeing. Recently western cultures have adopted these Eastern techniques and have recognised the potential in healthcare, particularly pain management (Bushnell et al., 2013).

Acceptance and Commitment Therapy (ACT), along with Compassion Focussed Therapy (CFT), is considered to belong to the 'third wave' of cognitive behavioural therapies and borrow from both Eastern and Western philosophies. However, there are a number of distinctions between

the two schools of CBT and third wave approaches. It is also worth noting that although CBT has a strong evidence base for use with individuals with chronic health conditions and chronic pain, and therefore features in a number of guidelines, this is not to the exclusion of other therapeutic modalities. In fact often the evidence cited in support of CBT is a randomised controlled trial where it has been compared to a waiting list control or 'inactive' therapy such as relaxation (e.g. Clark et al., 2006), rather than to other therapies. Such equivalency studies do exist, but rarely a difference is found (Green & Latchford, 2012) and therefore equivalent therapies are not cited in guidelines. Third wave therapies emerged in part due to dissatisfaction with the efficacy of CBT for chronic health conditions. The language of 'maladaptive' thoughts or 'cognitive errors' is rejected in favour of more positive, general language such as 'helpful' or 'unhelpful'. The aim is not to control unwanted thoughts and feelings as in CBT; instead in ACT the aim is psychological flexibility and in CFT the aim is to balance the three systems of drive, threat and compassion (Gilbert, 2009).

The focus in ACT is to find ways to live a valued life, that is, to behave in a way which is consistent with one's own goals. This is consistent with 'motivational coping' described by Van Damme and colleagues (2008), who describe how in chronic pain the challenge is deciding whether to overcome obstacles to their goals or reappraise the goals themselves.

Behavioural strategies

There are also a number of behavioural strategies available to help people cope with chronic pain such as changing activity levels, taking part in pleasant/distracting activities, seeking support or information (Somers et al., 2010), and are often used alongside cognitive strategies. Pain catastrophizing can be seen as both an emotional and a behavioural response to pain: cancer patients who catastrophize more reported higher levels of social support, as catastrophizing behaviours tend to lead to greater responses from others (Somers et al., 2010).

Behavioural activation in its simplest form encourages individuals, particularly those who are depressed, to become more active. This works on the basis that activity involves raised heart rate, purpose, and interactions with others. In the case of chronic pain it is often combined with pacing and graded activity increase whereby individuals, who have become afraid of activity in case it leads to pain or damage, gradually increase their levels of activity and aim for a sustainable level. This gradual increase is designed to avoid the familiar 'boom and bust' cycle of a sudden increase in activity followed by pain and/or injury and an extended recovery period with little or no activity.

There are no obvious indicators to suggest which strategies would be most helpful for any given individual at any particular time. What appears to predict success in chronic pain management is a multidisciplinary approach (Haldorsen et al., 2002), which is recommended in a number of pain management guidelines (e.g. The British Pain Society, 2010). The cognitive and behavioural coping strategies described above may either reduce the perception of pain or reduce

the distress associated with pain. Therefore coping strategies are an important component of pain monitoring.

Although the concept of coping may be challenging to research, its links with emotion, pain perception and pain monitoring mean that it is worthy of further understanding. The research literature shows there are numerous cognitive processes involved in the pain experience, and each of these is a potential opportunity for intervention. One such cognitive process is that of memory. The impact of memory on pain processing and prediction will now be explored.

Memory

There are a number of theories and models concerning memory, some of which are of relevance to the present study. As pain is a subjective experience, during a pain assessment the healthcare professional will usually build a pain history from patient report. Such reports rely on memory, which is also subjective. The subjective nature of pain and memory can be difficult to accept when a scientific, objective and effective pain management regime is sought by both patients and professionals. This introduction discusses pain processing, coping with pain and pain prediction. All of these are affected by memory, and specifically memories of past pain experiences.

Pain memory is not straightforward and can be difficult to describe. That said, some clear distinctions can be made. Generally speaking, pain is an adaptive survival experience and memory serves to increase learning and therefore survival. There are occasions when memory is disrupted. In post-traumatic stress disorder (PTSD) painful memories (of an emotional and physical nature) are not merely recalled, but are relived (Creamer & Carty, 2011). The three core symptoms required for a diagnosis of PTSD are intrusive thoughts, avoidance/numbing and increased arousal (Matsuoka et al., 2002). This distinction between recall and re-experience is crucial because while recall is adaptive and mostly voluntary, reliving is involuntary and potentially harmful. Individuals who are reliving traumatic events are disconnected from their surroundings and may present a risk to themselves or others.

Broadly speaking, psychological interventions for PTSD such as cognitive behavioural therapy (CBT) or eye movement desensitization and reprocessing (EMDR) aim to help the individual process the event, thus allowing it to enter their memory in a more organised way (Creamer & Carty, 2011). As a result, the individual will not relive the experience and instead will recall it, just like other memories.

PTSD is a useful example of the importance of memory in understanding pain. Usually, however physically or emotionally painful a memory may be, it is recalled, not re-experienced. The same is true for pleasurable memories. We may experience emotions as we recall the memory, but we do not repeat the same responses as at the time of the event. Despite this, pain remains an extremely aversive experience. Although we cannot truly recall the experience of pain, we know that it is something to be avoided or prevented. That is, the emotional and cognitive response to a memory of an event guides our behaviour, not the event itself. Estimates of PTSD

symptoms in breast cancer survivors vary from 8%-48%, with some suggesting that symptoms are sub threshold for a diagnosis due to partial recovery and that at earlier points in the treatment journey a full diagnosis of PTSD may have been warranted (Matsuoka et al., 2002).

The relationship between pain and memory is complex in that it is bidirectional and is influenced by context. While subjective verbal accounts of past pain experiences might seem inadequate when planning treatment the alternatives, such as re-experiencing pain, are less desirable. The relationship between memory and pain processing varies greatly between individuals and across different situations. Perhaps 'accurate' pain processing is neither achievable nor desirable. The different courses of pain processing have different consequences for different individuals and those around them. While pain memories have some unique attributes they also share common features with other memories, such as a dependency on cues. We are more likely to remember where we put our keys if we retrace our steps as we are more likely to recall information in the location we learned it. We are more likely to recall pain when we are in pain, which is part due to the influence of current pain on recalling past pain (Schneider, Stone, Schwartz, & Broderick, 2011), and the influence of cues in retrieving memory (Kopelman & Kapur, 2001). Pain is an experience with an emotional component, but remembering pain does not induce pain. Brain imaging studies have shown that the sensory and cognitive aspects of pain perception are recalled but unpleasantness is not (Albanese, Duerden, Rainville, & Duncan, 2007). This is in contrast to remembering an emotional event which does induce those emotions at the time of recall (D'Mello & Mills, 2014).

For many years now pain memories have been shown to differ significantly from momentary pain ratings. For example, a study which explored pain recall and prediction in individuals with recurrent pain (headaches and menstrual pain) found that both groups of patients recalled pain instances as more painful than they had rated them at the time (Rachman & Eyrl, 1989).

Predicting pain

Throughout our day-to-day lives we make a number of predictions about what might happen. These predictions might concern our environment, the behaviour of others or our own wellbeing. The prediction of pain in both the general population and clinical populations has received much attention over the last few decades, with a large contribution to the field by Arntz and colleagues from the 1980s onwards. Individuals who live with chronic pain from any cause arguably have a greater need than others to predict their pain. Daily activities such as work, shopping or driving may all be affected by their pain (Finan, Zautra, & Tennen, 2008). It is therefore important that predictions are accurate enough to allow the individual to be as active as possible yet rest when required. Decision making around taking medication, carrying out certain tasks or committing to future events will involve making predictions about the possible outcomes and how likely they are. This process is not straightforward as rarely is all the required information available.

Regardless of the perceived likelihood of each possible outcome, the salience may have a greater impact on the decision than the likelihood alone. This decision making process is not necessarily a conscious process, which provides an additional challenge to those wishing to understand it further.

Prediction of pain is not just important to the individual. Their families and healthcare professionals would also benefit from understanding what an individual's pain might be like in the coming hours, weeks or months. On a larger scale, in the UK there is increasing use of individual funding requests whereby individuals must apply for funding from their local clinical commissioning group in order to receive certain treatments. Such applications must include the perceived benefits of the treatment and also the impact of withholding treatment, and therefore an overview of past pain along with a projection of future pain would help inform decision making.

The term used here when considering future events is *prediction*. A number of terms are used in the literature when thinking about future events such as anticipation, expectation and prospection (Bubic, von Cramon, & Schubotz, 2010). Although occasionally used interchangeably, Bubic et al propose that each of these terms is subtly different and describes a specific process within an overall phenomenon which will be referred to as prediction.

In particular, experimental pain studies tend to focus on anticipation, which from Bubic et al's description appears to be the creation of short term expectations at a physiological level whereby neural networks are primed ready to receive an activating input. Anticipation is an important part of the pain experience as it has been shown to have more influence on the pain experience than the stimulatory input itself, and that altered anticipation may underpin placebo analgesia (Watson et al., 2009).

Expectation is more of a cognitive process whereby individuals create a representation of a possible future in an abstract sense. It is not known when or how the transition occurs from physiological anticipation to cognitive expectation, how much awareness individuals may have about these processes, or how they play a role in decision making. More distant future events are considered using the process of prospection. Each of these components of prediction is of relevance to how people who have had breast cancer might predict their future pain.

Predicting pain in a clinical setting adds a number of complications in addition to those described above in predicting experimental pain. Clinical pain which comes to the attention of clinical psychologists is generally chronic in nature, it is experienced over a prolonged period of time and causes great distress to the individual.

Sometimes healthy individuals and those with chronic pain make accurate predictions, and sometimes they do not. While accurate predictions help individuals to avoid the costs of unexpected pain (Taylor, 1995), inaccurate predictions can also be protective as they allow the individual to retain a positive outlook. This is not a new concept; it has been outlined in literature for over 50 years. The Larkin poem below suggests that having a poor perspective, whether it is backwards or forwards in time, is adaptive and protects us from emotional pain. This is certainly

relevant in patients with longstanding pain, whose memories of life without pain may induce emotional pain and a sense of loss, and whose predictions of pain in the future might feel intolerable.

"Truly, though our element is time,
We are not suited to the long perspectives
Open at each instant of our lives.
They link us to our losses: worse,
They show us what we have as it once was,
Blindingly undiminished, just as though
By acting differently, we could have kept it so."

(Larkin, 1964)

Considering the impact of pain on quality of life, it is important to consider how individuals manage their pain and its impact. One way of reducing the impact of pain on quality of life is to predict pain levels and vary activities accordingly. The literature suggests that while some individuals accurately predict pain, others tend to overpredict or underpredict pain (Arntz & Hopmans, 1998; Arntz & Peters, 1995; Arntz, van Eck, & Heijmans, 1990; Finan et al., 2008; Rachman & Eyrl, 1989). The term 'overprediction' is used when an individual experiences less pain than they expected. Conversely, 'underprediction' refers to a situation where an individual experiences more pain than they expected to.

Pain prediction is affected by a number of factors such as personal characteristics, mental health, anxiety and fear (Arntz, van Eck, & Heijmans, 1990; Rachman & Arntz, 1991), optimism and pessimism (Finan et al., 2008; Morton et al., 2009; Scheier, Carver, & Bridges, 1994), past pain experience (Arntz, van Eck, de Jong, & van den Hout, 1990), current context (Goubert, Crombez, & Lysens, 2005) and how the individual understands their pain.

It is important for an individual to be able to accurately predict pain. An overprediction of pain is more common (Rachman & Arntz, 1991) and is associated with social costs such as unnecessarily reducing activity. The research literature shows that 'overprediction' is rarely revised, despite repeated disconfirmations (Arntz, van Eck, & Heijmans, 1990). An underprediction of pain is less common and is much more costly. An underprediction of pain may lead to increased pain intensity, increased avoidance and increased disruption (Arntz & Hopmans, 1998; Arntz, 1996). Individuals expect predictions to be correct, so pain which is worse than predicted is therefore unexpected. Unexpected pain is likely to be perceived as more threatening and aversive because it communicates novel danger (Arntz & Hopmans, 1998; Rachman & Arntz, 1991). It is perhaps these salient qualities that lead to underpredictions to be adjusted more quickly than overpredictions, although it is still a slow process for an individual to do so (Finan et al., 2008; Rachman & Arntz, 1991).

Recent studies have begun to explore the 'active ingredients' of the prediction. One possible factor is optimism. Optimistic individuals would be expected to predict more positive

futures while more pessimistic individuals would be expected to predict more negative futures. Optimism has been found to be associated with reduced pain after myocardial infarction (Scheier & Carver, 1992). Additionally, Finan et al. (2008) found that in patients with rheumatoid arthritis those with lower pessimism, as determined by the Life Orientation Test – Revised (Scheier et al., 1994), tended to under-predict their pain. Some research has found that under-prediction is associated with optimism and positive affect; both of which may aid adaptation and increase resilience (Finan et al., 2008). Other research however has found that under-prediction was associated with maintenance of chronic pain because individuals may engage in excessive activity (Arntz & Peters, 1995) and experience unexpected pain, which is more disruptive (Arntz & Hopmans, 1998). Therefore it appears that optimism has an important role in both pain perception and prediction in clinical samples.

Brown and colleagues (2009) asked participants to rate how emotionally distressing they thought taking part in the laser pain experiment might be. They were then asked to rate their confidence in the prediction – how likely they thought it would come true – on a 0-10 scale. Confidence was correlated with right anterior insula activity in both pain anticipation and perception, and confidence was also correlated with the degree to which anticipatory cues (being told whether the pain was low, medium or high prior to experiencing it) affected the pain experience. This study also found that confidence in the belief had more impact on pain anticipation and perception than the belief itself (Brown et al., 2009).

The study described above occurred in a controlled rather than a naturalistic setting (Finan et al., 2008). Studies which use clinical samples show how great the impact of confidence in predictions can be. If an individual is confident that they can predict their pain, they may feel as if they are in control of their pain. Chronic pain patients with higher perceived control over their illness have fewer stress-related hospital visits, more hope and less interference from their illness than those who perceive their illness to be uncertain: uncertainty makes coping difficult (Johnson, Zautra, & Davis, 2006).

Chronic pain has been shown to be associated with reduced grey matter density when these patients are compared to both healthy controls and those who have recovered from chronic pain (Baliki et al., 2012). This links to findings by Arntz et al (1990) who found that past pain experience influences pain prediction. This could explain the differences between the three groups in the study by Baliki et al (2012): for the healthy controls, there may be limited past pain experiences; for the recovered group these memories may be distant; for the chronic pain group these past experiences may in fact be very recent and therefore more salient or more easily accessible. It is possible that the changes in grey matter combined with a greater quantity and level of detail to be recalled (i.e. more recent and greater number of pain experiences) results in reduced performance of chronic pain patients when asked to make predictions about their future pain. This is not consistent with the breast cancer patient population, who tend to be younger (Office for National Statistics, 2013b) and therefore may have fewer previous pain experiences.

Despite fewer previous pain experiences they show increased pain compared with other cancers (van den Beuken-van Everdingen et al., 2007) and increased pain sensitisation throughout the body (Gärtner et al., 2009). Additionally, pain is not a common symptom of breast cancer (Cancer Research UK, 2014b) and patients sometimes report that their first painful experience in relation to their cancer is during treatment.

The timeframe of prediction is also important to consider. In research studies, this prediction is often short term, for example predicting pain in the next task (Goubert et al., 2005), next few hours (Buck & Morley, 2006), next day (Finan et al., 2008) or next few weeks (Rachman & Arntz, 1991). If a cancer patient sees their healthcare team every three months, or every year in the case of post-mastectomy patients, the interaction in this appointment may be affected by the individual's prediction of their pain for many months, until the next appointment. Although some research investigates memory of pain after a number of months has elapsed (e.g. Arntz, van Eck, & Heijmans, 1990), no research has asked participants to predict pain so far in advance.

In patients with active cancer around a third of predictions made about their pain in the next few hours were accurate (36.9%); another third were inaccurate, with roughly equal proportions of overprediction (13.3%) and underprediction (15.5%), and the remaining third of predictions were in the 'don't know' category (Buck & Morley, 2006). This shows that even over such a short time scale, pain was unpredictable for these individuals. A search of research literature did not reveal any published studies examining cancer survivors' predictions of their own pain.

It is important to consider the role of pain prediction in a clinical setting when patients attend medical appointments. In addition to past experience of pain influencing doctor-patient interactions and subsequent pain treatment, predictions of future experiences also have an important role, and if these predictions are not accurate then pain management may be adversely affected.

In summary, the psychological processes involved in emotion, memory, attention and prediction all affect the pain experience. These processes may differ in breast cancer survivors when compared to individuals with active cancer, other cancer types or pain from other causes. It is therefore vital that these processes are taken into consideration when pain in breast cancer survivors is measured and monitored. There is an absence of evidence around pain prediction in breast cancer survivors and therefore short-term pain prediction will be explored in the current study.

Assessment of pain

The measurement of any type of pain is notoriously difficult. Pain is a subjective experience which cannot be measured objectively, and instead patient report must be used (Brennan, 2004). One dilemma faced by those wishing to measure pain is choosing which aspect of the pain to

focus upon. As described above, pain is much more than a sensory experience and all of the other aspects – emotion, interference and cognition – are all worthy of measurement as all provide opportunities both to understand pain experiences and to offer intervention. Once the focus has been identified, the next decision is to identify a suitable tool. Some measures of chronic pain put aside issues of pain intensity or quality and instead focus simply on its presence or absence, and use the ratio of pain free days as a measure of progress (e.g. Kroenke et al., 2010).

Tools used to capture the experience of pain

Experimentally induced acute pain is typically measured and defined by its input, such as the wattage of the laser (Morton, El-Deredy, Watson, & Jones, 2010) or volume of capsaicin (Witting, Svensson, Gottrup, Arendt-Nielsen, & Jensen, 2000), whereas clinical pain can only be measured and defined by its output. For example, while some use self-report (Wolff, 1983), others use observation of behaviour (Sarafino, 2008) or physiological measures such as galvanic skin response or brain activity recorded by electrodes on the scalp. These are all non-specific proxy measures of the pain experience which can be problematic as they are not measuring the pain response uniquely; the increased activity recorded may instead reflect stress. These observational methodologies neglect acute pain which does not occur in a healthcare setting. Other research has used lay observer reports, such as reports from spouses, of overt pain behaviours to measure pain. Observer reports are problematic due to concerns over consistency and reliability, as well as practical issues. It is unlikely that such reports could be used systematically over time in recurrent acute pain because the observer may not be present.

There are a number of self-report tools available to monitor pain in a clinical setting. Not all of these tools are suitable for cancer patients or survivors, and not all would be suitable for longer term use in communicating pain experiences to healthcare professionals as they are too burdensome to interpret (Brennan, 2004). This is of particular importance in survivors of breast cancer whose pain may be managed within a number of different systems and settings such as primary care, specialist breast care services and specialist pain services.

Pain measures vary in their content and function; some are unidimensional (such as a Visual Analogue Scale; VAS) and others are multidimensional (such as the McGill Pain Questionnaire; Melzack, 1975). Some tools, such as pain diaries, combine these questionnaires and scales and repeat them at specified times to build a picture of the pain experience over time.

Scales are used throughout healthcare to rate mood, anxiety and fatigue as well as pain. There are a number of pain scales available and each vary in terms of scale properties (interval, ordinal or ratio), number of items and reliability (McDowell, 2006). Pain scales feature a line with regularly spaced markers, sometimes labelled with numbers. As these markers are evenly spaced, it is often assumed that the data can be treated as having ratio properties, although evidence of this is scarce (Williams, Davies, & Chadury, 2000). Instead pain scales may represent ordinal or

even nominal data, but this categorisation cannot be determined unless more is understood about how people use them.

Pain scales are used in many ways in research, such as measuring the effectiveness of analgesia in cancer patients. In one study for example, a scale was used to capture both pain and discomfort, where 0 = 'no discomfort-no pain' and 10 = 'worst discomfort-worst pain' and the authors deemed the treatment to be a success if pain was reduced by one or more point on the scale (Storto et al., 2006). However, there are a number of limitations of this approach. A one-point decrease was assumed to be equivalent for each person and for each point on the scale, and pain and discomfort are also assumed to correlate highly, which may not always be the case.

Pain diaries go one step further than these individual scaling or questionnaire tools. By incorporating both questions from such questionnaires about the intensity and quality of the pain together with questions about activity for example, the impact of the pain on daily life and what they have done to manage their pain, a more complete and temporal understanding of pain can be achieved. Diaries are an example of ecological momentary assessment, that is, data collected in real-time in the person's natural environment (Shiffman, Stone, & Hufford, 2008). There are two broad options to determine when a diary is completed. The majority of studies use time-based monitoring, whereby diaries are completed at set times regardless of current symptoms. Event-based monitoring requires the individual to complete a diary if a particular event has occurred, such as a panic attack or pain event. If there are relatively few events, this can be a more efficient process than regular diaries, but if there are many events then event-based monitoring can become burdensome. Additionally, it can be difficult to ascertain the level of missing data in event-based data collection (Shiffman et al., 2008).

Although it may appear that such diaries simply ask questions, some posit that dairies are an intervention in themselves. This has been found on a broad level in CBT for anxiety and depression, as well as more specifically in the use of pain diaries in patients with active cancer and their carers (Schumacher et al., 2002).

Methods used to capture the experience of pain

Measures for describing pain can be broadly categorised as verbal, numerical or analogue. Verbal descriptors are included in the McGill pain questionnaire for example, where individuals are asked to select words to describe their current pain in terms of its temporal, spatial and thermal qualities for example (Melzack, 1975). Other measures focus on intensity and use labels such as 'mild', 'moderate' or 'severe' (McDowell, 2006). When using numerical methods, individuals are asked to rate their symptom, such as pain, on a predetermined scale such as 0-10 or 0-100. This scale may be presented verbally or a visual scale with increments may be provided. If there are no numbers on the scale, it is described as a visual analogue scale. Sometimes these methods are combined, and a pain scale may range from 0-10 with verbal anchors at either end, such as in

the Brief Pain Inventory. Alternatively, a range of words such as 'no pain', 'some pain', 'a lot of pain' may be assigned values of 0, 1, 2 and so on, which are then used in numerical analyses.

Context of pain measurement

The context within which monitoring takes place is important. Studies have shown that completion of pain ratings can be affected by the context, such as whether the measure is completed in the presence of a GP, psychiatrist, psychologist or surgeon (Kremer, Block, & Hampton Atkinson Jr, 1983).

Pain scales have been criticised on the basis that they require the individual to judge their average pain for a given time period, which may be too difficult to do meaningfully (De Conno et al., 1994). This can be overcome by asking individuals to rate their *worst* pain in the given time period rather than their *average* pain as this is more specific and refers to a discrete experience rather than an interpolated one. In this example it was the instructions which were receiving criticism rather than the scale itself. Scales are versatile in that the instructions can vary considerably and may ask the person to focus on pain intensity or the interference from pain; the pain rated may be the least, worst or average; the timescale can vary from pain in the last month, week or 24 hours and progress to current and also future pain predictions.

When the instructions vary and the tool records pain experienced over a different time period, this in turn affects how frequently the pain can be measured. For example, a measure which asks about pain experienced over the last week could only be completed a maximum of once per week to avoid overlapping data which may not be consistent. However, a scale asking about current pain can be completed much more frequently. The purpose of this current study is to obtain information about an individual's pain at a frequency which will assist their healthcare professionals to manage that pain more effectively.

One study used a semi-structured interview to examine how chronic pain patients used pain scales, and found that scales were used idiosyncratically and inconsistently, but with interest and engagement. It was also of interest to note that although the scales were described as a way to rate 'how bad their pain is', the patients in this study used interference, social desirability, affect and physical limitation to decide where to place their pain experiences on the scale (Williams et al., 2000). This study used chronic pain patients, and it is not known whether the broad range of responses reflected the range of clinical presentations and whether there might be a clearer method or consensus within a narrower patient group. Research within cancer patients suggests that responses can be reliably classified into three severity levels (mild, moderate and severe) based on the degree of interference from pain, and that this relationship is non-linear (Serlin, Mendoza, Nakamura, Edwards, & Cleeland, 1995).

In summary, pain is a subjective experience which requires self-report. Research with clinical populations has shown that the key components of pain for patients are intensity, quality

and emotion, so when considering pain management, all of these should feature in pain monitoring.

Study designs used to capture the pain experience

Many chronic pain studies compare the aggregated pain experiences of individuals in certain groups, such as those with and without chronic lower back pain (e.g. Arntz & Peters, 1995). However, a group approach such as this can mask individual differences and a case series approach may be more suited to chronic pain research, whereby the number of individuals and therefore the variation between them is reduced. In a case study patients can be recruited in a specific clinic at a specific time point in their treatment journey, which further reduces the 'noise' in the data when compared with block recruitment which provides a cross section of the patient population. This case study method still uses a clinical population with all of its comorbidities, just like in a group study, but the reduced variation and individual approach arguably enables the data to be analysed in more depth and for more valid conclusions to be drawn.

Comorbidities of chronic pain, whether due to cancer survivorship or other causes, include low mood, fatigue and cognitive difficulties. These are of particular relevance to this study because the monitoring regime requires some degree of effort, attention and concentration. This suggests two hypotheses: is there a true single phenomenon (pain) which could be accurately measured if the correct tools were available, or is pain a malleable experience which will be affected by any attempt to monitor it? The first stance is perhaps naïve and unrealistic, although it is propagated by discussions in research methodology of topics such as demand characteristics and ethnography. It is acknowledged that the research or researcher can affect people's behaviour and elicit certain characteristics which influence the results, and ethnography, an approach whereby the researcher is covertly embedded within the group of participants, aims to overcome such issues.

The second alternative, that pain is a malleable experience, is infinitely more likely. In this scenario, monitoring affects pain. This could happen on a number of levels. For example, the relationship with the researchers can lead to demand characteristics and social desirability. Regular monitoring may impose an increased sense of structure on the participant, and this daily structure could perhaps aid medication regimes for example, which would in turn influence their pain. Monitoring may also affect pain via internal processes. For example, participants might try to recall their past pain ratings and compare them with their current pain. They might also experience cognitive dissonance, which can be distressing, for example if they hold the general belief that their pain is tolerable but then complete a number of diaries with high pain and interference ratings.

Therefore, monitoring of pain can raise ethical issues for two reasons. First, individuals who begin to monitor their pain may find that they subsequently experience more pain and this impacts negatively on their quality of life. Second, participants may find that pain monitoring

reduces their pain or increases their quality of life, and we must ensure that other individuals are given this opportunity to benefit. It is therefore important that people's experiences of monitoring their pain, as well as the monitoring itself, is captured in an effort to understand any potential impacts of such monitoring.

Electronic healthcare technologies

The majority of these measurement and monitoring options, including pain diaries, could be aided by the use of technology. Technology provides opportunities for monitoring to be quicker and more accurate for the individual and increase convenience for both the individual and the other recipients of the information (researchers or clinicians). Previous studies have called for the use of technology in assisting the capture of pain and pain predictions (e.g. Finan et al., 2008).

In wider society the use of electronic technology is increasing every year. With this increased usage comes increased expectations in terms of what hospital systems are capable of, and what level of technology should be available to patients. In reality integrating new developments into the NHS is a long and costly process which is also politically charged. It is not known to what extent the NHS utilises new technologies on a local level to help improve patient care. The current study has been carried out in Leeds, Yorkshire. In nearby Sheffield, renal patients can access an online system which stores their blood test results, reducing the need for additional telephone calls or clinic visits for results which do not need action. This system is well established in the department and is designed to be an ongoing part of the service. In other areas, technology has been used on a project by project basis, such as in Leeds where during the project patients could view microscopic coloured images of their tumour cells.

While enthusiasm from medical professionals and the media is vital to help develop these tools, there is a risk that normalising these tools as part of routine care can lead to unrealistic expectations when patients attend the clinic.

The increasing use of healthcare monitoring tools was the focus of the BBC Horizon programme in August 2013. This programme showed how a smartphone can process, store and display physiological measurements taken by other devices such as a small handheld blood pressure monitor, which is the size of a credit card and requires the patient to hold it with their thumbs. This immediately transmits blood pressure readings to the smartphone (via wireless technology, Bluetooth) and displays them on the screen. Many believe that mobile health, dubbed mHealth, offers the potential to provide convenient, cost-effective collaborative healthcare with improved outcomes (Steinhubl, Muse, & Topol, 2013).

These developments are interesting and exciting for many reasons. First, technology is driving clinical practice, and formal research is lacking, contributing further to the debate over whether evidence-based practice or practice-based evidence is best for patients. So far the discussions around the impacts of healthcare technology are confined to opinion pieces rather than in empirical research. Second, there is a risk that the psychological impact of such monitoring

has been ignored. It is not known whether such intense monitoring increases or decreases health anxieties or whether the monitoring affects the patient's relationship with their clinician. It is also not known whether the clinicians feel better equipped, or deskilled or how patients feel about the increasing presence of technology in their medical care. There is concern that although the technologies are shared, knowledge of how they are applied is lacking (Cassel & Saunders, 2014).

A third important feature of these technologies which are available to monitor health is that they are all measuring objective physical states. Heart rate, blood sugar and calorie burn can (arguably) be calculated with some accuracy. This is not true for pain. There is no peripheral physiological marker which can be detected by equipment. Pain is a very personal experience with many interdependent components. Therefore any physiological markers of pain (such as increased skin conductance) must be supplemented with self-report in order to be monitored effectively and thoroughly.

Electronic pain monitoring

In addition to considering the measurement of pain, it is also important to consider the mode in which the data will be collected. Over time, available modes for self-report data collection in pain research have progressed from pen and paper, to electronic, to internet-based electronic collection and more recently to mobile internet-based platforms. Of these four modes, only the first three are well documented in the literature. The use of the latter two formats in clinical settings healthcare is increasing, and developments are increasingly reported in the media (e.g. Toronto hospital for sick children, 2012). A brief search on iTunes shows an abundance of software applications (apps) for smart phones or tablet PCs which can be used by patients to monitor pain. It is not yet clear how effective these apps are in a clinical setting, in terms of who sees the data, who uses these apps and whether the use of apps influences clinical pain management. Research has shown that patients found using healthcare technology was a positive experience (Akesson, Saveman, & Nilsson, 2007; Hassol et al., 2004); these studies utilised mixed methodologies, including both online surveys and focus groups, therefore reducing possible bias or sample skew when exploring opinions of online or electronic healthcare aids.

Due to the discrepancy between use of technology in research and clinical settings, and because the use of apps in pain monitoring has not been sufficiently researched yet, the present study will use tools derived from established measures together with an established desktop online survey program to collect data (Q-tool).

In summary, there are a number of established paper-based self-report measures to measure pain. These measures have also been used in electronic and online formats. There is much research comparing validity and reliability of paper and electronic recording methods (Buchanan, 2003), including in the pain literature (Jamison et al., 2001; Jamison, Raymond, Slawsby, McHugo, & Baird, 2006; Marceau, Link, Jamison, & Carolan, 2007). From these studies it appears that electronic recording of pain (either basic or internet based) is as reliable and valid

as traditional pen and paper recording and reduced missing data. Studies report that participants preferred using technology to pen and paper methods. The researchers preferred it too, as it enabled them to monitor engagement in real time and in some studies (e.g. McClellan et al., 2009) missing data prompted a telephone call to the participant. In the clinical environment although patients still report positive experiences (Hassol et al., 2004), staff have reported mixed experiences. While some welcome the opportunity for a collaborative approach with their patients (Tann, Platts, Welch, & Allen, 2003), others reported negative experiences, questioning the purpose or benefit of healthcare technologies they have been asked to use with their patients (Darbyshire, 2004). Therefore the impact of using technology in general will be considered both when interpreting the results and reflecting upon the recruitment and design of the study. However, the use of technology instead of pen and paper is not itself a focus of this research because the same platform will be used throughout data collection and no comparison can be made between different formats.

Summary

This introduction has demonstrated that there are a growing number of individuals surviving breast cancer. As this number increases, we are learning more about the issues they face in the months and years after treatment has ended. One such issue is pain, which is a complex phenomenon affected by emotion and memory. The challenges of measurement, monitoring and prediction of pain were outlined.

A number of gaps in the literature have been identified. First it is not known to what extent pain is present in breast cancer survivors; research focuses on individuals with a current diagnosis of breast cancer and often those undergoing treatments such as radiotherapy or chemotherapy. Additionally, little is known of the qualitative dimensions of pain in breast cancer survivors, how individuals manage it and how they talk to their medical teams about it. There is a paucity of research into multiple pains in this population. While it is known that multiple pains in chronic pain patients are common, less is known about multiple pains in breast cancer, especially survivors. Linked with this, although pain may be monitored regularly at clinic appointments, these appointments can be up to a year apart for cancer survivors and the complexities in pain and memory suggest that this annual verbal report is not sufficient to gain a meaningful understanding of an individual's pain. There is a gap in the research regarding the frequency with which monitoring should occur. There are numerous studies using pain diaries but none have been identified which use such diaries to explore pain in breast cancer survivors. Such diaries often include a pain scale but how these are used on an individual basis is rarely explored alongside such ratings, and has not been explored in breast cancer survivors. Finally, there is a lack of research into pain prediction in breast cancer patients, particularly survivors, and how this might influence management of pain in this population.

Therefore, in an effort to inform decision making when implementing a clinical pain monitoring system to improve pain management, this research uses a mixed methods approach and aims to compare two different pain and pain prediction monitoring schedules in a discrete population of cancer patients: those who are post-mastectomy and are currently cancer-free. The two monitoring schedules are event-driven and time driven. In event driven monitoring, individuals complete a pain diary if and when they experience a predefined pain event. In the time driven monitoring, individuals complete diaries on a regular basis, every 12 hours, regardless of pain levels. The monitoring must be accurate, timely, relevant and not too burdensome. Additionally the monitoring must gather information which could feasibly be shared with healthcare professionals to assist them to manage the pain as effectively as possible. Crucially, all pains are included, regardless of whether they predate or are seen as unrelated to the cancer. This wide remit is very different to other research and was an attempt to focus on the individual, not the pain, and invite a broader sample of participants than might normally be eligible for research, where comorbidities are often exclusion criteria. An experimental case study design will be used to compare different schedules of monitoring in an effort to capture variation within individuals. The qualitative component aims to capture the experiences of participants who have monitored and predicted their pain, including a specific understanding of the use of the pain scales. This stage provides a crucial opportunity to validate the quantitative results with the individual participants and give them an opportunity to expand upon their earlier answers during the monitoring phase. Although qualitative methodologies are common in understanding the experiences of participants, it is a methodology which is often neglected in the literature which focuses on measurement and monitoring.

Method

This research aims to compare event-driven pain monitoring and regular pain monitoring in people who have had breast cancer in terms of their pain ratings, pan predictions and completion rate of the pain diaries (aim one). It also aims to explore how individuals understand their pain in terms of how they define a pain 'event', their experience of making predictions and their use of pain scales (aim two).

Design

This study in part aimed to compare event driven and time driven pain monitoring. A group design was considered but was rejected based on two factors. First, it was felt that not enough participants could be recruited in the given timescale to yield sufficient statistical power, and second that a group design would not be in keeping with the knowledge of the variance in the pain experience between individuals. Therefore this study used a replicated n = 1 design. This single case design is particularly well suited to pain research when there is so much variation between individuals (Onghena & Edgington, 2005). Each monitoring schedule (event 'A' or regular 'B') lasted for 2 days and was used three times for each individual, meaning that there were six stages lasting a total of 12 days. On event days, participants were required to complete the pain diary if they experienced a pain event. Each individual identified criteria for a pain event at the start of the study. On regular days, participants were required to complete the diary once in the morning and once in the evening, preferably 12 hours apart.

There were 20 possible sequences of these six stages, but six were not suitable due to the number of consecutive repeats (e.g. AAABBB). Once these undesirable options were excluded, 14 possible sequences remained and therefore just 14 participants were required (see Table 1). This design has a number of advantages. First, even with just 14 participants there is sufficient statistical power. Second, the increased number of changes between the two conditions (event sampling and regular sampling) provides further opportunity to analyse the impact of these two sampling strategies. Similarly, the accuracy of pain prediction can be analysed in more detail according to the strategy used.

Table 1: Single case experimental design possible assignments

No.	*Sequence*	*Comment*	*No.*	*Sequence*	*Comment*
1	AAABBB	Undesirable	11	BBBAAA	Undesirable
2	AABABB		12	BBABAA	
3	AABBAB		13	BBAABA	
4	AABBBA	Undesirable	14	BBAAAB	Undesirable
5	ABAABB		15	BABBAA	
6	ABABAB		16	BABABA	
7	ABABBA		17	BABAAB	
8	ABBAAB		18	BAABBA	
9	ABBABA		19	BAABAB	
10	ABBBAA	Undesirable	20	BAAABB	Undesirable

This method of using randomisation tests to aggregate the single case studies relies on participants completing sufficient numbers of both event and regular diaries in each phase. This study design is data driven and therefore the analysis began soon after data collection. This allowed regular review of the data as the study progressed. The study also aimed to investigate predicting pain, which was included in both event and regular conditions, and scaling pain, which was a separate task after the diaries had been completed.

Participants

Participants were recruited from the mastectomy clinic after their annual check-up appointment and at the time of recruitment were at least two years post-surgery.

Table 2: Inclusion & exclusion criteria

Exclusion criteria	*Inclusion criteria*
Participants must not be: • unconscious or confused • terminally ill • unable to provide informed consent • in the opinion of the researcher, unable to understand and complete the survey (due to cognitive impairment for example)	Participants must: • be aged at least 18 years • be female • have a previous diagnosis of breast cancer • currently have pain • have a good level of spoken and written English • be able to provide informed consent to participate • have access to a computer connected to the internet at home • be able to complete the measures online

Recruitment

Individuals were asked to take part if they were currently cancer-free and still under the care of the breast care team at Leeds Cancer Centre (St James's University Hospital, Leeds) and experienced pain. Recruitment was carried out on a rolling basis.

At the time of recruitment there was an ongoing audit conducted by breast care research nurses in the breast cancer clinic as part of recent changes to the patient pathway. As part of this audit, patients were routinely being given a short paper questionnaire during their clinic visit. This questionnaire asked about surgery, pain and medication (Appendix C). There was a section at the bottom of this audit form for patients to consent to be contacted about opportunities to take part in research. Nurses identified and contacted patients who met the inclusion criteria for this study and who had also said they would be interested in opportunities to take part in research. During the telephone call the potential participants were given brief details of the study and were asked if they would like an information sheet. Those who expressed an interest and were sent an information sheet were asked for verbal consent for the researcher to contact them via telephone

a week later to arrange an enrolment meeting at their home. Participants were told that they were free to withdraw at any time, without giving a reason, and that their care would be unaffected.

Recruitment in this way, in waves, can mean that recruitment takes longer, but is in keeping with the nature of hospital clinics. As each patient completes the audit form at their clinic appointment, each person is approached at a similar point in their treatment journey. This would not have been the case if postal recruitment was used for example.

Measures

Standardised

A number of measures were used in this study. The following measures were completed at baseline, during the enrolment meeting, and at the end of the study after the pain diaries had been completed:

Mood

Mood was measured using the using the positive and negative affect scale (PANAS; McDowell, 2006; Watson, Clark, & Tellegen, 1988) The PANAS produces two scores, one for positive emotions and one for negative emotions. Answers range from 'Very slightly or not at all', scoring 1, to 'Extremely', scoring 5. There are 10 questions contributing to each score and therefore the range of scores for each is 10-50 (Watson, Clark, & Tellegen, 1988).

The PANAS was selected as it covers a broad range of emotional experiences rather than focussing on depression or anxiety for example. The focus of the current study was to understand pain in this population, and therefore a broad exploration of affect was more appropriate than a focus on specific diagnoses such as anxiety or depression. The PANAS has been shown to be reliable and valid in both clinical (Dyck, Jolly, & Kramer, 1994) and non-clinical samples (Crawford & Henry, 2004), and has been used in other pain diary studies (e.g. Buck & Morley, 2006).

Quality of life

General quality of life was measured using the EQ-5D (Euroquol Group, 2009). EQ-5D scores should not be aggregated and are instead presented as a series of five scores, one for each question, ranging from 1 to 5 (Euroquol Group, 2009). Therefore scores range from 11111 (no problems) to 55555 (the most severe problems). The numbers are presented in the order of the questions and therefore correspond to mobility, self-care, usual activities, pain/discomfort and anxiety/depression. The final question of rating health on a 0-100 scale is simply presented as a standalone figure and has been shown separately in the results tables.

There are a number of quality of life measures available, including some which have been developed for use in oncology. However, it was felt that a generic quality of life measure would be more suitable for the current study for a number of reasons. First, although there are cancer-

related quality of life measures including those developed for survivors, there is a lack of credible measures for individuals in the early years of survivorship (Pearce, Sanson-Fisher, & Campbell, 2008), and participants in the current study are part of this group. Second, as mentioned previously, health services are changing and increasing numbers of cancer survivors will be referred back to primary care services for their annual reviews. This means that as they are no longer in oncology services they will be reviewed in a generic manner with generic tools. If cancer survivors are to be cared for in a similar way to other people with chronic long term health conditions, their needs must be contextualised within this wider remit. The EQ-5D was selected as the generic quality of life measure for its ease of completion, reliability, validity and ubiquity. In addition, the combination of categorical and continuous measures provides a thorough snapshot of current quality of life. Given the concerns raised earlier around relying on recall to report pain, it was felt that a quality of life measure which requires minimal recall would be preferable. The EQ-5D asks about health today, not over the past 4 weeks for example. This also suits the current study design where the quality of life measure could feasibly be repeated within a 4 week time period and the two results would include overlapping data.

Optimism

Optimism was measured using the LOT-R (Scheier et al., 1994).Lot-R scores are generated from six of the ten questions (four are filler questions), with three of these being negatively scored to account for the question wording (Scheier et al., 1994). Answers ranged from 'I agree a lot', scoring 4, to 'I disagree a lot', scoring 0. Therefore Lot-R scores range from 0 to 24, with higher scores denoting greater optimism.

The LOT-R was selected as it has been shown to be a reliable and valid measure of optimism (Scheier et al., 1994), a trait which has been shown to impact upon pain prediction and pain ratings (Morton, Brown, Watson, El-Deredy, & Jones, 2010; Morton et al., 2009).

Customised

Additionally, participants completed pain diaries during the study. There were two pain diaries, one for each monitoring type (event and regular). These diaries were very similar to each other. They were based on both the IMPACCT diary and the pain diary used by Buck & Morley (2006), which have been constructed using questions from established tools. The diaries were also consistent with the literature which suggests that use of a single pain measure should be avoided in order to increase accuracy (Broderick, Stone, Calvanese, Schwartz, & Turk, 2006). The diaries included questions about current pain (measured on a pain scale), how much pain is interfering with daily activities (0-10 scale), how they have coped with their pain (open question) and what they expect their pain to be like tomorrow (four options: 'more intense than today', 'less intense than today', 'the same as today', 'don't know').

1. Pain diaries

The regular and event pain diaries were very similar, with the only difference being an additional question in the event diary asking whether any pain events had been missed (indicated with * in the table). Table 3 shows the origin of each question in the diary and whether it is present in the IMPACCT study diary.

Table 3: Pain diary construction

Question	*Answer options*	*Origin*	*Present in IMPACCT diary?*
Have you experienced any other pain events since you last completed this survey, apart from the one you are about to tell us about?*	Yes (please briefly state why) No	New	No
Please rate your pain by selecting the one number that best describes your pain at its worst in the last 12 hours.	0-10 pain scale**	Serlin et al., 1995	Yes
Please rate your pain by selecting the one number that tells how much pain you have right now.	0-10 pain scale**	Serlin et al., 1995	Yes
Has your pain changed in the last 12 hours?	Yes No (skip next question)	Adapted from Buck & Morley, 2006	Yes
Has the location of your pain changed?	Yes (please describe) No	New	Yes
Has anything other than the location changed?	Freetext	New	Yes
Please rate how much pain has interfered with your daily activities in the last 12 hours	0-10 pain scale***	Adapted from Serlin et al., 1995	Yes
Have you done anything additional (to your usual pain medication) to control your pain?	Yes (please describe) No	Adapted from Buck & Morley, 2006	Yes
Based on all the things you did to cope, or deal with your pain, how much control do you feel you had over the pain? Please circle the appropriate number. Remember,	0-6 Likert scale 0= no control 3=some control 6=complete control	Buck & Morley, 2006	Yes

Question	*Answer options*	*Origin*	*Present in IMPACCT diary?*
you can circle any number along the scale.			
Based on all the things you did to cope, or deal with your pain, how much were you able to decrease it? Please circle the appropriate number. Remember, you can circle any number along the scale.	0-6 Likert scale 0= no decrease 3=some decrease 6=complete decrease	Buck & Morley, 2006	Yes
Based on all the things you do to cope or deal with your pain, how much control do you expect to have over it in the next 12 hours? Please circle the appropriate number. Remember, you can circle any number along the line.	0-6 Likert scale 0= no control 3=some control 6=complete control	Buck & Morley, 2006	No
How intense do you expect your pain to be tomorrow?	The same as today Less intense than today More intense than today Don't know	Buck & Morley, 2006	No
Please use the box below to provide comments on anything you would like us to know	Freetext	N/A	Yes

** denotes present in event diary only*

*** included two anchors: 0=no pain and 10=pain as bad as you can imagine*

**** included two anchors: 0=no interference and 10=unable to carry out usual activities*

The diaries used in the present study were based on the IMPACCT diaries but as Table 3 shows, some additional questions were used to meet the aims of the study. As one concern about event diaries is an unknown completion rate, the extra question sought to ascertain the degree of missing data. The two other additional questions were used to explore the prediction of pain, which is not part of the IMPACCT study.

The diaries were entered into Q-tool, which required detailed development in order to achieve a satisfactory appearance and functionality, including routing respondents away from irrelevant questions. The diaries were piloted by the researcher for one week and some minor adjustments made to appearance.

Data from the pain diaries were analysed using IBM Statistics Package for Social Sciences (SPSS), R software (for randomisation tests) and Microsoft Excel.

2. Scaling task

Near the end of the study, immediately following the interview, participants were asked to complete a brief scaling task, as shown in Figure 1. The task involved asking participants to place small paper labels (around 2.5cm^2) onto an A4 printed scale. The scale ranged from 0 to 10 with each number around two centimetres apart. It is worth noting that during the diary phase, these 0-10 scales were presented with two anchors: 0 had 'no pain' and 10 had 'pain as bad as you can imagine'. The use of these anchors during the diary phase was not referred to during this scaling task and the pain scale in this task did not contain any anchors. The scaling task had two parts. In the first part, participants were asked to place six labels on the scale which are consistent with the labels used in the IMPACCT study, shown in Table 4. In the second stage, participants were given the choice of a further 29 words which could also be used to describe their pain, taken from previous research (Morley & Pallin, 1995; Morley, 1989). Participants were instructed to pick up any labels which contained words which they may use to describe their pain (if any), and place them on the scale. In both parts of the task, words were presented in a random order. Participants were also asked if there were any other words not included in the options which they use to describe their pain, and where it would be placed on the scale. Participants were asked to clarify which number they had placed the labels on, and whether the label covered a range or an individual point on the scale. The labels are shown in Table 4.

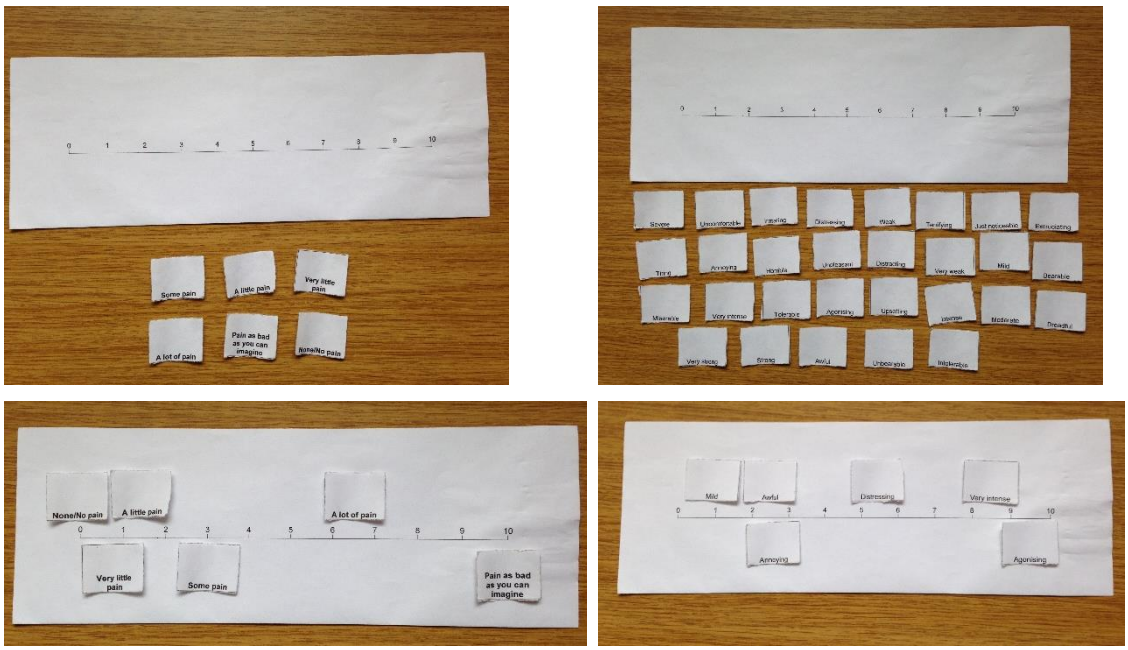

Figure 1: Photographs of pain scale presentation and example completion of IMPACCT labels (left) and intensity and affect labels (right)

Table 4: Scaling task pain labels

IMPACCT labels	*Intensity labels*		*Affect labels*	
None / no pain	Excruciating [1,2]	Strong [1]	Awful [1]	Irritating [1,2]
Very little pain	Intense [1,2]	Very strong [1]	Agonising [1,2]	Miserable [1,2]
A little pain	Just noticeable [1]	Very intense [1]	Annoying [1,2]	Terrifying [2]
Some pain	Mild [1,2]	Very weak [1]	Bearable [1,2]	Tiring [2]
A lot of pain	Moderate [1]	Weak [1]	Distracting [1,2]	Tolerable [1]
Pain as bad as you can imagine	Severe [1]		Distressing [2]	Unbearable [1]
			Dreadful [2]	Uncomfortable [1,2]
			Horrible [2]	Unpleasant [1,2]
			Intolerable [1,2]	Upsetting [2]

[1] Morley (1989)

[2] Morley & Pallin (1995)

3. Interviews

The second aim of this study was to explore individuals' views of their pain in terms of how they found taking part in the study and what they thought about making pain predictions. To explore this, qualitative data were collected. Following the completion of the pain diaries, participants took part in an interview. This interview lasted between 25 and 45 minutes and covered three main areas: reflections on taking part in the research, consistency of their definition of a pain event, and reflections on their pain predictions. This was a semi structured interview (for interview schedule see Appendix H). Semi structured interviews are a widely used method in psychological research and allow the researcher to conduct an interview which is driven by the research questions yet gives participants space to talk (Willig, 2001). These interviews took place in participants' homes to increase convenience for the participant. Interviews were audio recorded to overcome difficulties with note taking, namely reduction in data, difficulty in building rapport and distraction. Interviews were transcribed by either the researcher or an external transcriber.

Interviews were analysed using thematic analysis, which is a widely used and 'theoretically flexible' approach in psychological research (Braun & Clarke, 2006; Clarke & Braun, 2013). Data were coded manually at the utterance level – the smallest meaningful component - using NVivo software before being aggregated across individuals into categories and then themes (Morse, 2008). Codes, categories and themes can be found in Appendix I.

Procedure

A week after the potential participants had received the information sheet from the nurse, the researcher contacted them via telephone to arrange an enrolment meeting at their home to begin the study. In the enrolment meeting the participant was asked to complete the consent form, and discuss any queries about taking part. Participants were then asked questions about their pain to help them define a pain event. Participants were given a support booklet to keep, and during the enrolment meeting their definition of a pain event was written down in the space provided in the booklet. The booklet (Appendix G) also included contact details for the researcher (university email address and university departmental administration office telephone number), breast care nurses (telephone number) and the Patient Advice and Liaison Service (PALS).

The researcher then introduced them to the online program, Q-tool, which was used during the study to record all data from the mood and quality of life measures and the pain diaries. The baseline measures of the mood and quality of life measures were completed with the researcher present. This allowed the researcher to ensure that their technology was adequate and that they were capable of using the software. This project uses Q-tool for all diary data. As this relies on an internet collection, participants had to be able to connect to the internet every day during the study.

After this meeting the participant was asked to complete pain diaries over a two week period using Q-tool. Participants received an email each morning informing them what to do each day and encouraging them to contact the researcher if there were any issues. The email also contained a link to the Q-tool site for ease of access. Q-tool is a secure web based tool purpose-built to enable generation of online surveys and was used to collect baseline measures, pain diaries and end of study measures. It allowed individuals to log on with their own username and password and their homepage lists available surveys (in this case diaries). It was considered more sophisticated than other options considered, such as Bristol Online Surveys, as Q-tool allowed the researcher to construct studies with various 'arms' and allocate participants to each. The ability to stipulate opening and closing dates and times for each diary meant that the researcher could set up the 12 day structure for each individual in its entirety in advance.

Ethical approval

This study was carried out in accordance with all relevant guidelines such as those from the British Psychological Society, Health Professions Council, University of Leeds and the NHS research ethics service (Department of Health, 2001; Health Professions Council, 2008; The British Psychological Society, 2009, 2010; University of Leeds, 2008; World Medical Association, 2008). Ethical approval was granted by the Leeds East NHS research ethics service in October 2013 (Appendix A) and research and development approval was granted in April 2014 (Appendix B). Two amendments were also submitted to the ethics panel, the first in January 2014 to amend the recruitment pathway and the second in May 2014 to allow an external transcriber to be used.

All participants were provided with information about the study and were given the opportunity to ask questions before providing written consent. It was planned that capacity would be assessed by the researcher as required. All study materials were kept in accordance with the Data Protection Act. Participants were allocated an anonymous identification number and all study materials were kept confidentially. Only the researcher and supervisors had access to research data.

There were a number of possible ethical issues in this study. First, patients could have felt obliged to take part. This effect was minimised by using the common approach of avoiding a direct face-to-face invitation by the researcher to take part and instead potential participants were approached by research nurses in the team delivering their care. Second, the research took place over a number of weeks and may have been a burden on a person's time and energy. Participants were made aware that they could withdraw from the study at any time with no consequences and their usual care would not be affected. Thirdly, some research has shown that attending to pain during monitoring can increase perception of pain (Brennan, 2004). However, this is not true for everybody, and will be explored in the analyses of both the pain diaries and interviews. However, participants were advised that if an increase in pain occurred and they were concerned, they should contact their medical team. It was not expected that participation would have any significant or lasting effects on the wellbeing of those who took part.

Results

This section will detail the participants and their mood and quality of life responses. Results will be presented for each individual in turn before the aggregated results are presented. The aggregated results include the thematic analysis which was conducted using nine interviews (one participant did not complete the interview).

Participants

All participants were female, married, and spoke English as their first language. Nine participants were of White British ethnicity and one was of Black British ethnicity. A summary of the ages, treatments and medications for each participant is shown in Table 5. Participants were allocated pseudonyms in alphabetical order in order of recruitment.

The recruitment pathway is shown in Figure 2. The data-driven design meant that the data were regularly reviewed during the study. At the halfway point when seven individuals had completed the study, it became apparent that the number of event diaries completed was very small, and for some individuals none were completed. It was therefore estimated that many more participants (around 30) would need to be recruited before fourteen individuals completed the study with sufficient numbers of both regular and event diaries, and those who did not complete sufficient diaries would subsequently be excluded, which it was felt would be unethical and unfair. Recruitment was a gradual process with an average of two participants recruited per month. It was therefore estimated that recruitment of the additional participants would take around eight months, which would be far beyond the available time for this thesis. The lack of event diaries meant that it was not possible to carry out the randomisation tests as planned and the data could therefore not be aggregated. As a result, it was decided that the full 14 participants were no longer required as this number had been determined by the randomisation tests. Ongoing review of the diary and interview data showed that ten individuals would provide sufficient data, variety and saturation. Therefore ten participants completed the study over a period of five months using the first ten of the 14 identified desirable randomisation patterns.

Table 5: Summary of participants

Pseudonym	*Age*	*Surgeries*	*Other treatments*	*Current hormonal therapy*	*Current analgesics*
Angela	68	1. Mastectomy and latissimus dorsi flap reconstruction	None	Tamoxifen (previously anastrazole)	Naproxen
Belinda	53	1. Lumpectomy, axillary node clearance and sentinel lymph node biopsy (SNB) 2. Axillary node clearance	Supraclavicular fossa (SCF) radiotherapy	Letrozole	Paracetamol and ibuprofen
Carol	63	1. SNB and lumpectomy 2. Axillary clearance	Radiotherapy	Anastrazole	Paracetamol and ibuprofen
Diane	39	1. Wide local excision (WLE) and axillary clearance	SCF radiotherapy and chemotherapy	Not known	Not known
Elizabeth	51	1. WLE and axillary clearance 2. SNB	Radiotherapy and chemotherapy	Tamoxifen (previously Herceptin)	Not known
Faith	62	1. WLE and SNB Mastectomy	Radiotherapy with boost and chemotherapy	Not known	Not known
Gina	53	1. WLE and SNB	Radiotherapy and chemotherapy	Herceptin (previously anastrazole and tamoxifen)	Not known
Helen	55	1. WLE and axillary clearance	Chemotherapy	Tamoxifen (anastrazole)	Not known
Isobel	50	1. WLE and SNB 2. Mastectomy and axillary clearance 3. TRAM flap reconstruction	Chemotherapy	Tamoxifen	Not known
Julie	57	1. WLE and SNB	Radiotherapy	Letrozole (previously anastrazole and tamoxifen)	Not known

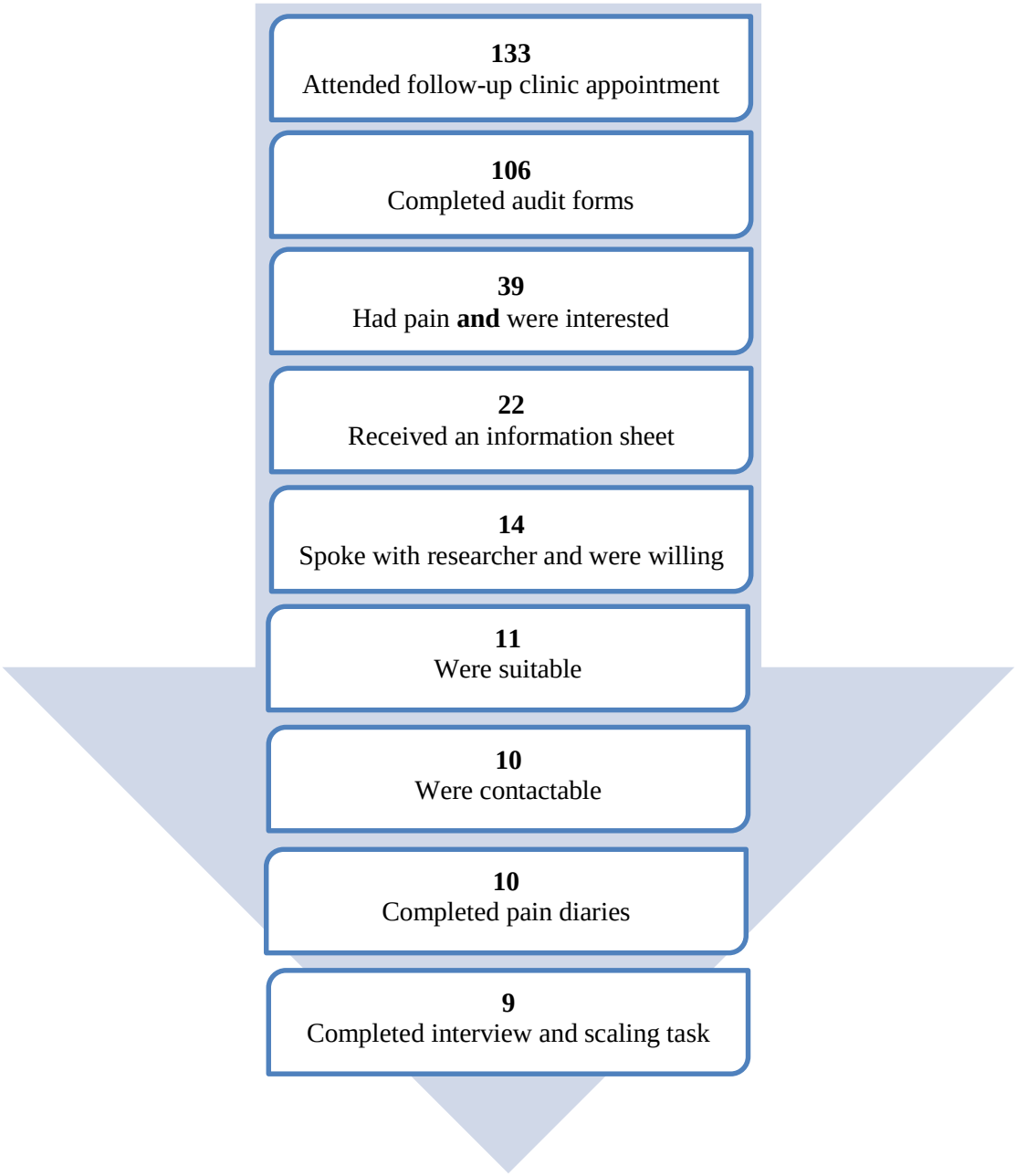

Figure 2: Recruitment pathway

Following this decision it was also necessary to review the analysis of the diary data. It was decided that a predominantly individual visual analysis would be most appropriate as a means of consistently understanding and displaying the results from each individual. The detailed analyses for each individual are shown below. Detailed definitions of each participant's pain events can be found in Appendix F on page 123. To aid understanding, interview responses will be used to supplement diary data but a full thematic analysis of all the interviews will be provided separately later in this section. Figure 3 shows a fictitious display of diary data and has been annotated for clarity. The x-axis shows the study day, ranging from 0 to 12. The y-axis shows the pain rating given using a 0-10 pain scale in each diary. Event days and regular days have been distinguished by the use of blue bars for event days (see box E). In this example, day 3 is an event day. The

figure shows that three diaries were completed on that day. In one diary, current pain was rated as five out of ten, in another it was rated as four out of ten and in another it was rated as three out of ten, although the order in which the diaries were completed is not shown. In all three diaries the pain in the last 12 hours was rated consistently as two out of ten, which has been plotted on day 2, the previous day (see box D). In the first diary, they indicated that their pain would remain the same, but in the next two diaries indicated that they thought it would increase (see boxes B and C).

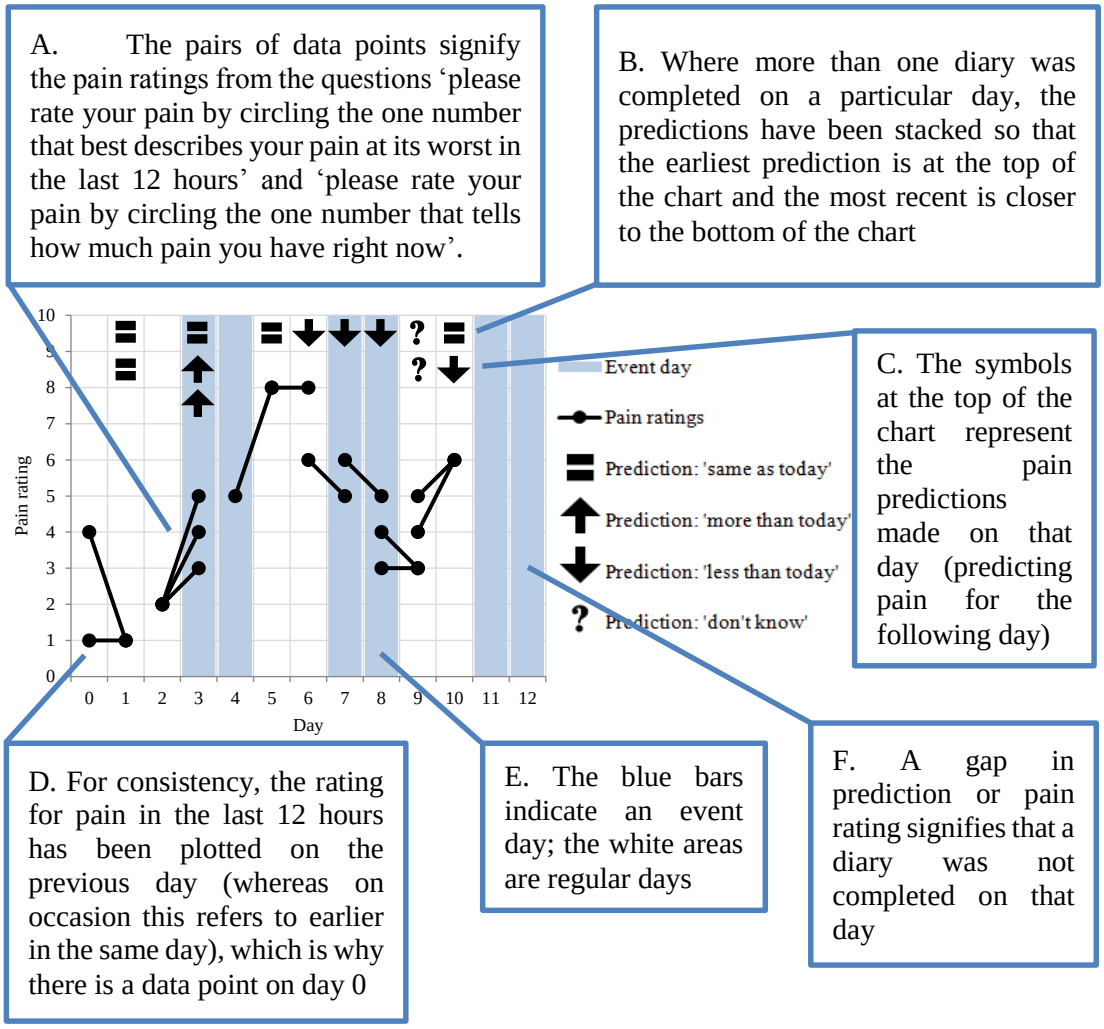

Figure 3: Example pain diary summary chart

Analysis of individual cases

Results are presented person by person in keeping with the holistic approach of the case series design and allows different parts of the study to be considered for each individual in turn.

Angela

1. Pain diaries

In total Angela completed 11 diaries, of which four were event diaries, four were morning diaries and three were evening diaries. Event diaries were completed between 7pm and midnight,

morning diaries between 1pm and 5pm and evening diaries between 8pm and 11pm. The smallest gap between completion of morning and evening diaries was four hours and the largest was ten hours.

Table 6: Summary of diaries completed by Angela

Phase	*1*		*2*		*3*		*4*		*5*		*6*	
Type	Event		Event		Regular		Event		Regular		Regular	
Day	1	2	3	4	5	6	7	8	9	10	11	12
Diaries completed	1	1	1	1	0	2	0	0	2	1	2	0

Table 6 shows that at the start of the study, Angela recorded one pain event per day. When asked 'Have you experienced any other pain events since you last completed a pain diary?' Angela always answered no, suggesting that all pain events were recorded. As shown in Table 7, Angela's pain ratings varied from zero to seven out of 10, with this range captured by both event and regular diaries. Of the six regular diary days, Angela completed both diaries on three of these. On two days she did not complete any diaries. This was due to a technical error whereby in forwarding the daily email, [1] had been added to the end of the link. This did not prevent the participant from navigating to the webpage but it meant that any login details were rejected as incorrect. On the second day the cause of the problem was detected and rectified, but Angela was unable to complete diaries due to fatigue following the physiotherapy session.

Table 7: Angela's pain scale scores for past and current pain for each diary type

	Pain at its worst in last 12 hours			*Pain right now*		
	Minimum	*Maximum*	*Average*	*Minimum*	*Maximum*	*Average*
Event	0	7	2.25	0	4	1.50
Morning	0	7	2.50	0	7	2.50
Evening	0	3	2.00	0	3	2.00

Figure 4 below summarises Angela's pain ratings over the course of the study. With the exception of the first day, Angela consistently reported that her previous pain was identical to her current pain. On the first day of the study Angela indicated that she thought her pain would be the same the following day, when in fact it decreased. However, in each subsequent diary she chose 'don't know'. From the interviews it was apparent that this was a genuine answer and although she did not know what her pain would be like, this did not distress her and she still felt that she would be able to control it and carry on with her normal activities.

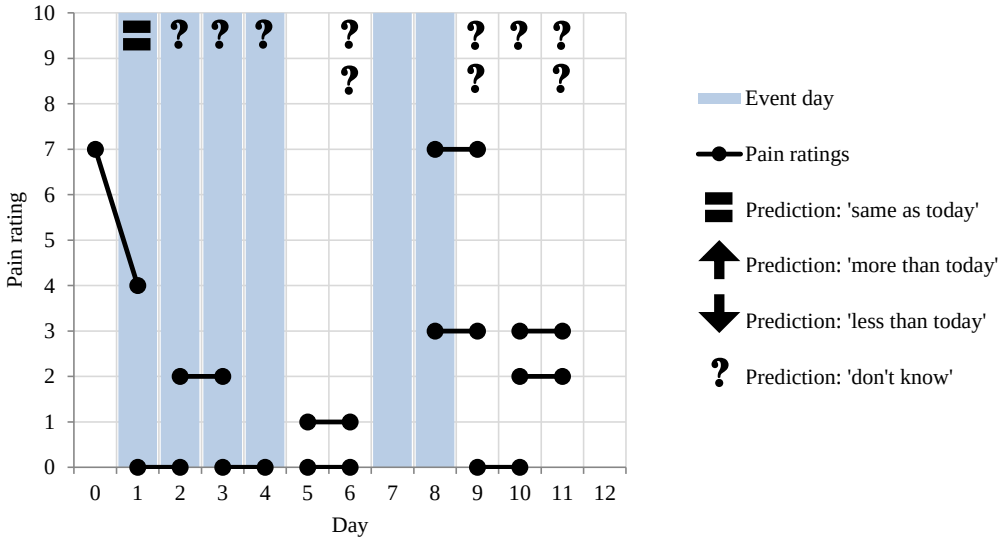

Figure 4: Angela's pain ratings and predictions over 12 days

In nine of her 11 diaries Angela said that the pain had changed in the last 12 hours. However, it is not clear what had changed about her pain, as she stated that the location had not changed but did not state what else had changed. From her pain ratings it does not appear that the intensity had changed as her ratings were consistent. At the beginning of the study in her second diary Angela used the freetext comments box at the end of the diary to say that she would use shorthand to state how many prescription painkillers she had taken e.g. X1 for one tablet, X2 for two tablets and so on. In total she stated how many tablets she had taken in eight diaries. On two occasions she also stated why she had taken more than one, which was due to increased activity levels such as gardening and a challenging physiotherapy session. When asked how much the pain had interfered with daily activities (0-10 scale; 10=unable to carry on any activities), Angela mostly said that it had not. Her answers ranged from 0 to 7 with an average of 1.7. Table 8 shows that Angela's responses for the control questions were remarkably consistent and she almost always felt that she had control over her pain, and expected this to continue. On one occasion she was less able to decrease the pain (3 = 'some decrease'), which was due to a prolonged gardening session which led her to take three painkillers, the most she took during the study.

Table 8: Angela's scores for the control questions for each diary type

	How much control do you feel you had over the pain 0 = no control 6 = complete control			*How much were you able to decrease the pain 0 = no decrease 6 = complete decrease*			*How much control do you expect to have over the next 12 hours 0 = no control 6 = complete control*		
	Min	*Max*	*Avg*	*Min*	*Max*	*Avg*	*Min*	*Max*	*Avg*
Event	5	6	5.75	5	6	5.75	5	6	5.75
Morning	6	6	6.00	3	6	5.25	3	6	5.25
Evening	6	6	6.00	6	6	6.00	6	6	6.00

Table 9 below shows that for Angela, current and past pain were significantly correlated, and both of these were significantly correlated with interference. Current feelings of control did not correlate significantly with any other ratings. However, current pain and interference both correlated with ability to decrease the pain and future control. Ability to decrease pain and future control were perfectly correlated.

Table 9: Correlations of Angela's scores for pain, interference and control

	pain right now	*interference from pain*	*control over this pain*	*ability to decrease*	*control in next 12 hours*
worst pain in last 12 hours	.944**	.869**	.035	-.576	-.576
pain right now	-	.957**	.000	-.741**	-.741**
interference from pain		-	.261	-.694*	-.694*
control over this pain			-	.228	.228
ability to decrease				-	1.000**

* denotes significance at $p<.05$

** denotes significance at $p<.01$

2. Scaling task

When given the choice of additional labels, Angela chose 'bearable' and 'uncomfortable'. She initially placed 'bearable' between two and three, but after a discussion with her husband changed this label to cover a broader range of zero to six. 'Uncomfortable' covered between eight and nine, which fills the gap between the two upper IMPACCT labels. Additionally, Angela said that she also uses the word 'hurting' to describe her pain and placed this between four and five, which also bridges a gap between two IMPACCT labels.

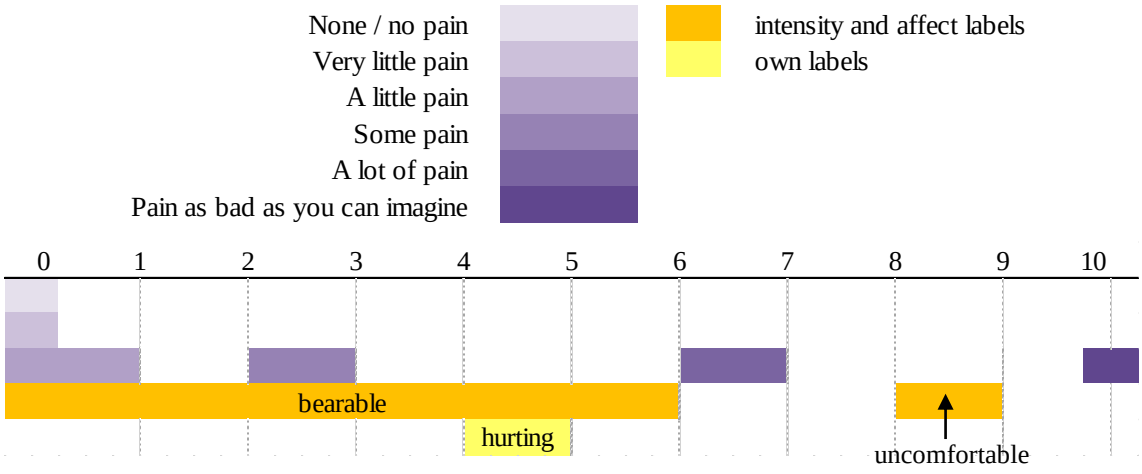

Figure 5: Angela's pain scale

Belinda

1. Pain diaries

In total Belinda completed eight diaries, of which four were morning diaries, three were evening diaries and one was an event diary. The event diary was completed around 6pm, morning diaries between 9am and 7pm and evening diaries between 9pm and 10pm. The smallest gap between completion of morning and evening diaries was three hours and the largest was eight hours.

Table 10: Summary of diaries completed by Belinda

Phase	*1*		*2*		*3*		*4*		*5*		*6*	
Type	Event		Event		Regular		Regular		Event		Regular	
Day	1	2	3	4	5	6	7	8	9	10	11	12
Diaries completed	0	0	0	0	2	0	2	1	1	0	0	2

Table 10 shows that at the start of the study, Belinda did not record any pain events, and only recorded one pain event in the study overall. As shown in Table 11, Belinda's pain varied from one to seven out of 10, with the seven recorded on an event day. The highest pain rating recorded on a regular day was four. Of the six regular diary days, Belinda completed both diaries on three of these. On two days she did not complete any diaries. This was in part due to the same technical error experienced by Angela (as they took part in the study at the same time), and on one day Belinda did not complete any diaries as she spent the day at the hospital having routine scans and appointments.

Table 11: Belinda's pain scale scores for past and current pain for each diary type

	Pain at its worst in last 12 hours			*Pain right now*		
	Minimum	*Maximum*	*Average*	*Minimum*	*Maximum*	*Average*
Event	7	7	7.00	6	6	6.00
Morning	1	3	2.00	1	4	2.00
Evening	1	4	2.33	1	4	2.00

Figure 6 below summarises Belinda's pain ratings over the course of the study. Belinda's ratings of her current and previous pain in each diary were very similar; they were either the same or only one point different. Belinda mostly predicted that her pain would decrease or stay the same. It is possible to comment on five of her predictions as these were followed by completed diaries. When Belinda predicted her pain would increase, it decreased, and when she predicted it would decrease, it increased.

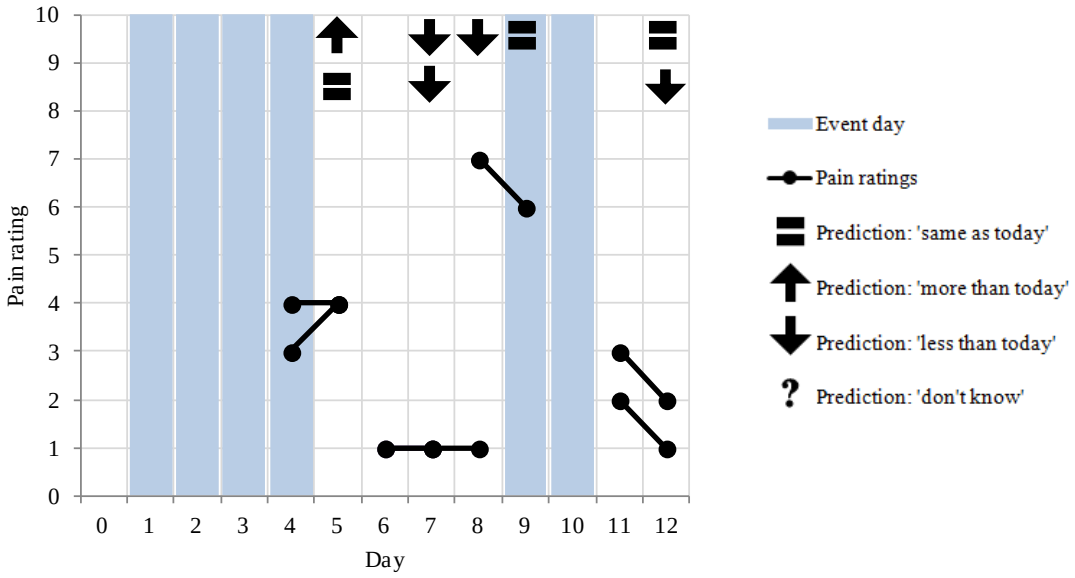

Figure 6: Belinda's pain ratings and predictions over 12 days

In two of her eight diaries Belinda said that the pain had changed in the last 12 hours. Similar to Angela, she did not state what had changed about her pain as she stated that the location had not changed, but from her pain ratings it appears that it is the intensity which had changed, first by increasing to seven and second by decreasing to two. Belinda did not use the comments or free text boxes at any time during the study. When asked how much the pain had interfered with daily activities, Belinda mostly said that it had not. Her answers ranged from 1 to 8 with an average of 3.0. Table 12 shows that Belinda's responses for these questions covered most of the range of possible responses, on some occasions feeling in control and on other occasions less so. Overall for each diary the answers for these questions were similar, with the answers only being one point apart for six diaries and two points apart for two diaries. On these two occasions it was the expectation of future control which had the highest rating. Belinda stated that she had not done anything extra to control her pain during the study.

Table 12: Belinda's scores for the control questions for each diary type

	How much control do you feel you had over the pain 0 = no control 6 = complete control			*How much were you able to decrease the pain 0 = no decrease 6 = complete decrease*			*How much control do you expect to have over the next 12 hours 0 = no control 6 = complete control*		
	Min	*Max*	*Avg*	*Min*	*Max*	*Avg*	*Min*	*Max*	*Avg*
Event	1	1	1.00	2	2	2.00	3	3	3.00
Morning	2	5	3.50	3	4	3.25	3	5	4.25
Evening	4	5	4.30	3	4	3.67	3	5	4.33

A number of Belinda's answers were correlated. Current and past pain were significantly correlated, and both of these were significantly correlated with interference. These three were

significantly correlated with current levels of control. Ability to decrease the pain was significantly correlated with current pain, interference and current control, but not past pain. Future control was correlated with all except past pain and prediction. Prediction was correlated with current pain only. Predictions were coded so that 'same' = 0, 'more intense' = 1 and 'less intense' = -1, with 'don't know' left blank.

Table 13: Correlations of Belinda's scores for pain, interference and control

	pain right now	*interference from pain*	*control over this pain*	*ability to decrease*	*control in next 12 hours*	*prediction code*
worst pain in last 12 hours	.939**	.902**	-.738*	-.640	-.685	.585
pain right now	-	.930**	-.786*	-.734*	-.860**	.747*
interference from pain		-	-.930**	-.761*	-.784*	.643
control over this pain			-	.714*	.764*	-.611
ability to decrease				-	.764*	-.339
control in next 12 hours					-	-.702

* denotes significance at $p<.05$

** denotes significance at $p<.01$

2. Scaling task

When given the choice of additional labels, Belinda chose 'miserable', 'distracting', 'uncomfortable', 'agonising' and 'very intense'. She did not add any additional labels.

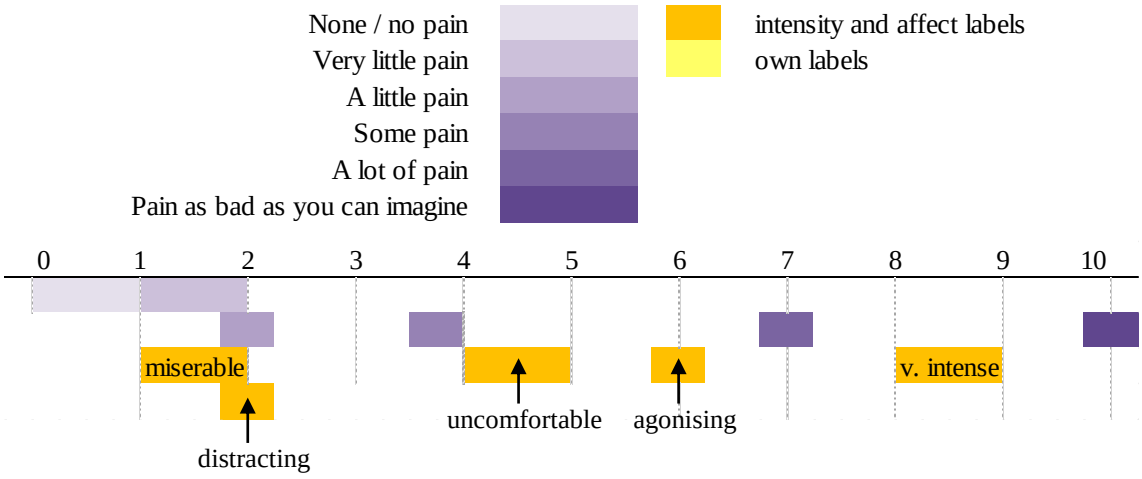

Figure 7: Belinda's pain scale

Carol

1. Pain diaries

In total Carol completed ten diaries, of which five were morning diaries, four were evening diaries and one was an event diary. The event diary was completed around 8am, morning diaries between 8am and 3pm and evening diaries around 10pm, with the exception of one day where an evening diary was completed at 9am by mistake. The smallest gap between completion of morning and evening diaries was 12 hours and the largest was 14 hours.

Table 14: Summary of diaries completed by Carol

Phase	*1*		*2*		*3*		*4*		*5*		*6*	
Type	Event		Regular		Event		Event		Regular		Regular	
Day	1	2	3	4	5	6	7	8	9	10	11	12
Diaries completed	1	0	2	1	0	0	0	0	2	1	1	2

Table 14 shows that at the start of the study, Carol recorded the only pain event of the study. This was on the first day of the study and through email correspondence and the end of study interview it appeared that Carol had become unsure of the instructions and had completed the diary when she did not have pain. As shown in Table 15, Carol's pain ratings during the study varied from zero to two out of 10, with little different between the diary types. However, Carol did consistently rate past pain as higher than current pain, with the exception of one diary where she rated them the same. Of the six regular diary days, Carol completed both diaries on three of these and one diary on the other three days.

Table 15: Carol's pain scale scores for past and current pain for each diary type

	Pain at its worst in last 12 hours			*Pain right now*		
	Minimum	*Maximum*	*Average*	*Minimum*	*Maximum*	*Average*
Event	1	1	1.00	0	0	0.00
Morning	1	2	1.20	0	1	0.20
Evening	2	2	2.00	0	1	0.25

Figure 8 below summarises Carol's pain ratings over the course of the study. In each diary Carol predicted that her pain would be the same the following day. These predictions were broadly correct in that her current pain was most often rated at zero, and it was mainly the pain in the last 12 hours which fluctuated up to a rating of two.

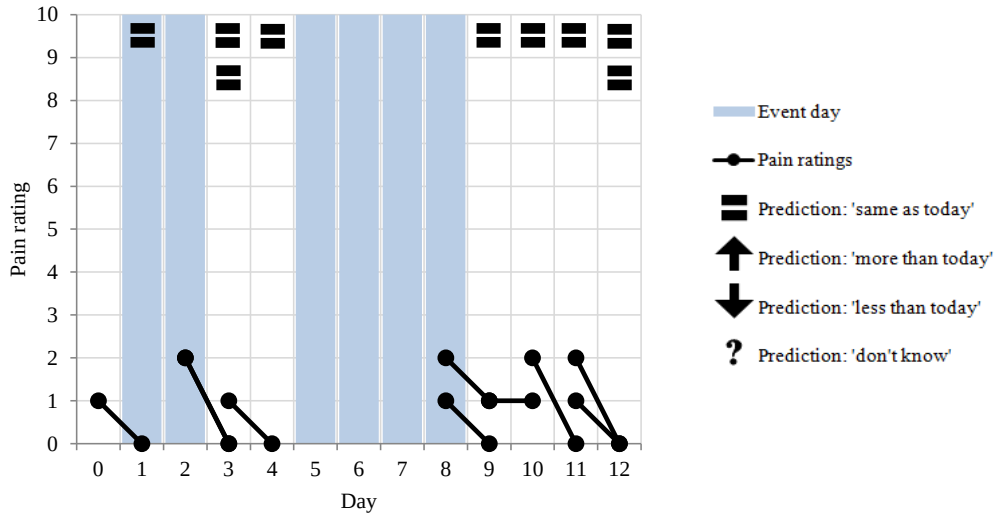

Figure 8: Carol's pain ratings and predictions over 12 days

In nine of her ten diaries Carol said that the pain had changed in the last 12 hours. The location had not changed, but sleeping had changed her pain. It is not known how sleeping affected her pain; it could have been a reduction in intensity, a lack of awareness or simply being less active. When asked how much the pain had interfered with daily activities, Carol said that it had not, always answering zero. Table 16 shows that Carol's responses for these questions covered most of the range of possible responses and varied much more than the pain ratings themselves. Overall Carol reported feeling more in control and able to decrease the pain in the morning compared to the evening. Carol stated that she had not done anything extra to control her pain during the study.

Table 16: Carol's scores for the control questions for each diary type

	How much control do you feel you had over the pain 0 = no control 6 = complete control			*How much were you able to decrease the pain 0 = no decrease 6 = complete decrease*			*How much control do you expect to have over the next 12 hours 0 = no control 6 = complete control*		
	Min	*Max*	*Avg*	*Min*	*Max*	*Avg*	*Min*	*Max*	*Avg*
Event	4	4	4.00	5	5	5.00	5	5	5.00
Morning	3	5	4.40	2	6	3.40	3	6	4.20
Evening	3	5	3.50	2	4	3.25	3	3	3.00

None of Carol's scores were significantly correlated, and a number were unable to be analysed as they were constant.

Table 17: Correlations of Carol's scores for pain, interference and control

	pain right now	*control over this pain*	*ability to decrease*	*control in next 12 hours*
worst pain in last 12 hours	.000	-.224	-.229	-.371
pain right now	-	-.559	.172	-.371
control over this pain		-	-.513	.519
ability to decrease			-	.043

* denotes significance at $p<.05$

** denotes significance at $p<.01$

2. Scaling task

In the scaling task Carol chose 'tolerable', 'uncomfortable' and 'irritating'. She considered choosing 'bearable' but said this meant the same as 'tolerable' for her so she did not select it. Carol did not add any additional labels.

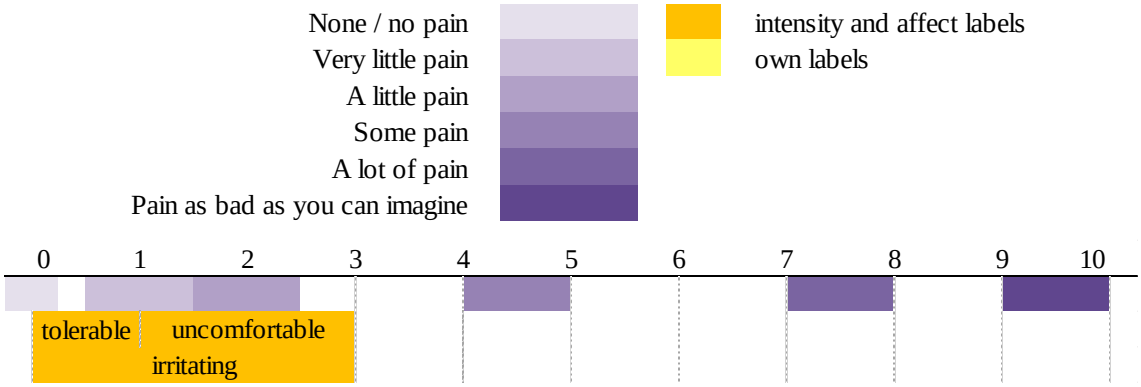

Figure 9: Carol's pain scale

Diane

1. Pain diaries

In total Diane completed four diaries, of which three were morning diaries and one was an event diary. The event diary was completed around 5pm and morning diaries between 10am and 6pm.

Table 18: Summary of diaries completed by Diane

Phase	*1*		*2*		*3*		*4*		*5*		*6*	
Type	Event		Regular		Event		Regular		Event		Regular	
Day	1	2	3	4	5	6	7	8	9	10	11	12
Diaries completed	1	0	1	1	0	0	0	0	0	0	0	1

Table 18 shows that at the start of the study, Diane recorded the only pain event of the study. As shown in Table 19, Diane's pain ratings varied from zero to five out of 10, with the five recorded on an event day. The highest pain rating recorded on a regular day was three.

Table 19: Diane's pain scale scores for past and current pain for each diary type

	Pain at its worst in last 12 hours			*Pain right now*		
	Minimum	*Maximum*	*Average*	*Minimum*	*Maximum*	*Average*
Event	5	5	5.00	2	2	2.00
Morning	1	3	2.00	0	1	0.33
Evening	-	-	-	-	-	-

Figure 10 below summarises Diane's pain ratings over the course of the study. Diane rated past pain as higher than current pain in three of the diaries, and in the other diary she rated them the same. As Diane did not participate in the interview (she rearranged the interview a number of times and then disengaged) it is not known why she only completed four diaries or how she found predicting her pain. Only one of the four predictions can be tested for accuracy. Her prediction on day three was accurate in that her pain rating increased from zero to one.

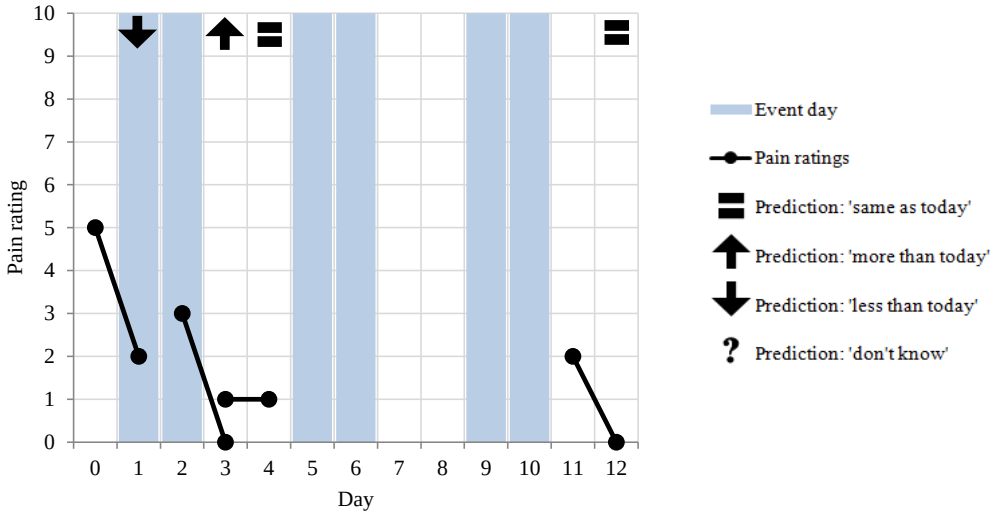

Figure 10: Diane's pain ratings and predictions over 12 days

In all of her diaries Diane said that the pain had changed in the last 12 hours, but only once stated that the change was a reduction due to analgesia. Diane said that her pain had not interfered with daily activities, always answering zero. Table 20 shows that Diane always answered that she felt she had control over the pain, even when she was unable to decrease it. Although she was always optimistic about controlling her pain, she did also predict on one day that the pain would increase. Diane stated that she had not done anything extra to control her pain during the study.

Table 20: Diane's scores for the control questions for each diary type

	How much control do you feel you had over the pain 0 = no control 6 = complete control			*How much were you able to decrease the pain 0 = no decrease 6 = complete decrease*			*How much control do you expect to have over the next 12 hours 0 = no control 6 = complete control*		
	Min	*Max*	*Avg*	*Min*	*Max*	*Avg*	*Min*	*Max*	*Avg*
Event	6	6	6.00	5	5	5.00	6	6	6.00
Morning	6	6	6.00	0	0	0.00	6	6	6.00
Evening	-	-	-	-	-	-	-	-	-

It was only possible to correlate current pain, pain in last 12 hours, ability to decrease pain and prediction code as the other scores were constant. There were no significant correlations in these four variables.

Table 21: Correlations of Diane's scores for pain, interference and control

	pain right now	*ability to decrease*	*prediction code*
worst pain in last 12 hours	.561	.878	-.478
pain right now	-	.870	-.853
ability to decrease		-	-.816

* denotes significance at $p<.05$

** denotes significance at $p<.01$

2. Scaling task

As Diane did not participate in the interview she did not complete the scaling task.

Elizabeth

1. Pain diaries

In total Elizabeth completed five diaries, of which three were morning diaries and two were evening diaries. The morning diaries were completed between 1pm and 11pm and evening diaries between 10pm and 11pm. When completed on the same day, the morning and evening diaries were completed around 10 minutes apart. However, from looking at the pain ratings and from the interview it appears that Elizabeth filled in the morning diaries according to how she felt that morning, not how she felt at the time of completion.

Table 22: Summary of diaries completed by Elizabeth

Phase	*1*		*2*		*3*		*4*		*5*		*6*	
Type	Event		Regular		Event		Regular		Regular		Event	
Day	1	2	3	4	5	6	7	8	9	10	11	12
Diaries completed	0	0	2	0	0	0	0	2	0	1	0	0

Table 22 shows that Elizabeth did not complete any pain event diaries during the study. As shown in Table 23, Elizabeth's pain varied from one to five out of 10. Of the six regular diary days, Elizabeth completed both diaries on two of these. On one day she completed one diary and on three days she did not complete any diaries. This was in part due to her busy work schedule and associated with this was irregular computer access. Elizabeth tried to complete the diaries on her smartphone but found this very difficult as the diaries were not designed for such a small screen. In the interview Elizabeth said that she had experienced pain events during the study but these either occurred on regular days or on days when she was not able to complete the event diaries.

Table 23: Elizabeth's pain scale scores for past and current pain for each diary type

	Pain at its worst in last 12 hours			*Pain right now*		
	Minimum	*Maximum*	*Average*	*Minimum*	*Maximum*	*Average*
Event	-	-	-	-	-	-
Morning	2	5	3.33	2	4	2.66
Evening	3	4	3.50	0	0	0.00

Figure 11 below summarises Elizabeth's pain ratings over the course of the study. Elizabeth rated past pain as higher than current pain in four of the diaries, and in the other diary she rated them the same. Her predictions varied throughout the study and were different in the morning and evening diaries on the same day. In the diaries Elizabeth attributed the decrease in pain on day three to completing some physiotherapy exercises. It was not possible to determine the accuracy of her pain predictions as none were immediately followed by another diary.

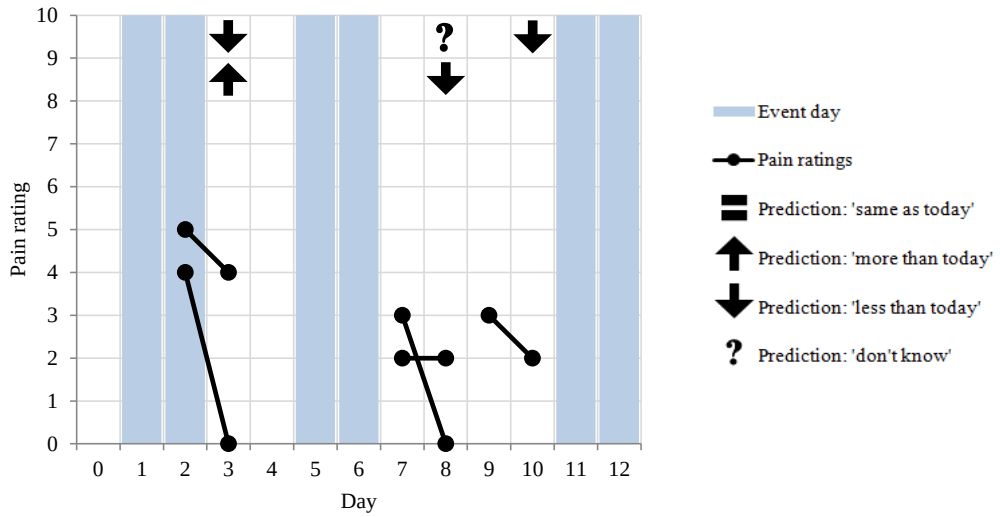

Figure 11: Elizabeth's pain ratings and predictions over 12 days

In three of her five diaries Elizabeth said that the pain had changed in the last 12 hours, but did not state in what way the pain had changed. In her interview Elizabeth described how pain from a recent hip operation was at its worst after a period of sitting and decreased upon gentle

movement, changing from stiffness to an ache, so perhaps this was the change she was referring to in the diaries. When asked how much the pain had interfered with daily activities, Elizabeth mostly said that it had. Her answers ranged from 2 to 8 with an average of 4.6. Table 24 shows that Elizabeth's responses for the control questions averaged around the midpoint of the scale. Overall for each diary the answers for these questions were similar, with the answers only being one point apart for five diaries and identical for one diary. Elizabeth stated that on one occasion she had taken part in physiotherapy to help control her pain during the study.

Table 24: Elizabeth's scores for the control questions for each diary type

	How much control do you feel you had over the pain 0 = no control 6 = complete control			*How much were you able to decrease the pain 0 = no decrease 6 = complete decrease*			*How much control do you expect to have over the next 12 hours 0 = no control 6 = complete control*		
	Min	*Max*	*Avg*	*Min*	*Max*	*Avg*	*Min*	*Max*	*Avg*
Event	-	-	-	-	-	-	-	-	-
Morning	3	3	3.00	2	4	3.00	3	4	3.33
Evening	3	3	3.00	2	2	2.00	3	3	3.00

The only significant correlation in Elizabeth's scores was between interference and pain in the last 12 hours, which was significant at the $p<.01$ level.

Table 25: Correlations of Elizabeth's scores for pain, interference and control

	pain right now	*interference from pain*	*ability to decrease*	*control in next 12 hours*	*prediction code*
worst pain in last 12 hours	.367	.981**	.686	.784	.174
pain right now	-	.491	.869	.802	-.522
interference from pain		-	.791	.868	-.088
ability to decrease			-	.875	-.522
control in next 12 hours				-	-.333

* denotes significance at $p<.05$

** denotes significance at $p<.01$

2. Scaling task

When given the choice of additional labels, Elizabeth chose eight labels: 'irritating', 'uncomfortable', 'annoying', 'miserable', 'bearable', 'tiring', 'awful' and 'horrible'. She did not add any of her own labels.

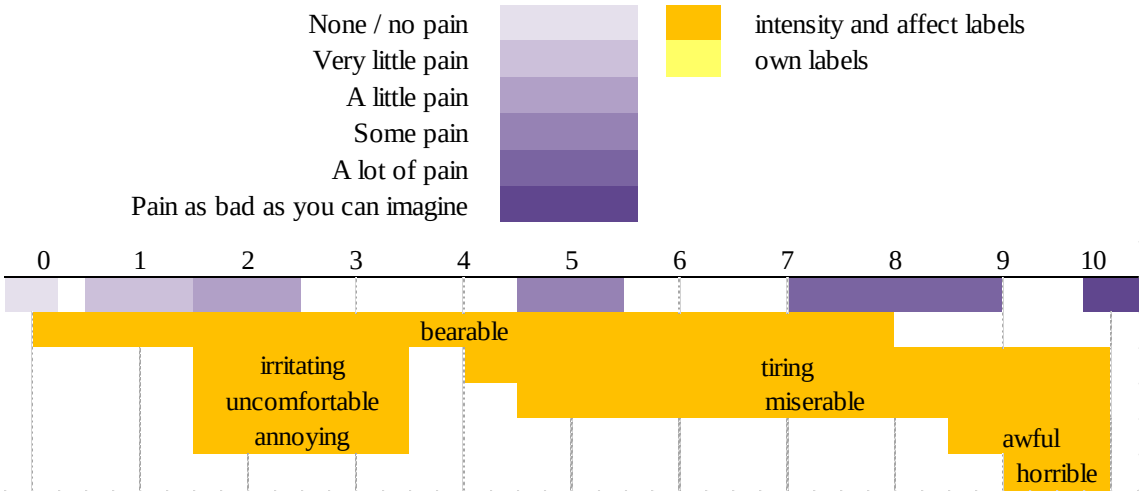

Figure 12: Elizabeth's pain scale

Faith

1. Pain diaries

In total Faith completed 11 diaries, of which six were morning diaries, three were evening diaries and two were event diaries. The morning diaries were completed between 8am and 2pm, evening diaries between 9pm and 10pm and the event diaries around 11am. The smallest gap between completion of morning and evening diaries was ten hours and the largest was 12 hours.

Table 26: Summary of diaries completed by Faith

Phase	*1*		*2*		*3*		*4*		*5*		*6*	
Type	Event		Regular		Regular		Event		Event		Regular	
Day	1	2	3	4	5	6	7	8	9	10	11	12
Diaries completed	1	1	2	1	2	1	0	0	0	0	2	1

Table 26 shows that at the start of the study Faith recorded two pain events and did not record any more during the study. As shown in Table 27, Faith's pain ratings varied from zero to five out of 10, with ratings of four and five recorded across the diary types. Of the six regular diary days, Faith completed at least one diary every day. Faith did have problems with her laptop on one of the event days but this was fixed the same day. On days four and six there were problems with the system in that the evening diaries were not listed as 'available', resulting in two missed evening diaries. This problem was then resolved by reloading her remaining diaries.

Table 27: Faith's pain scale scores for past and current pain for each diary type

	Pain at its worst in last 12 hours			*Pain right now*		
	Minimum	*Maximum*	*Average*	*Minimum*	*Maximum*	*Average*
Event	0	4	2.00	0	1	0.50
Morning	3	5	4.16	1	5	3.00
Evening	3	4	3.66	2	5	3.33

Figure 13 below summarises Faith's pain ratings over the course of the study. Faith's prediction in each diary was 'don't know', stating in the freetext box that there is no pattern to her pain. In seven diaries Faith rated past pain as higher than current pain; in three diaries she rated them the same and in one diary she rated her current pain higher than her past pain. In each diary Faith said she did not know what her pain would be like the following day so it is not possible to determine the accuracy of her predictions.

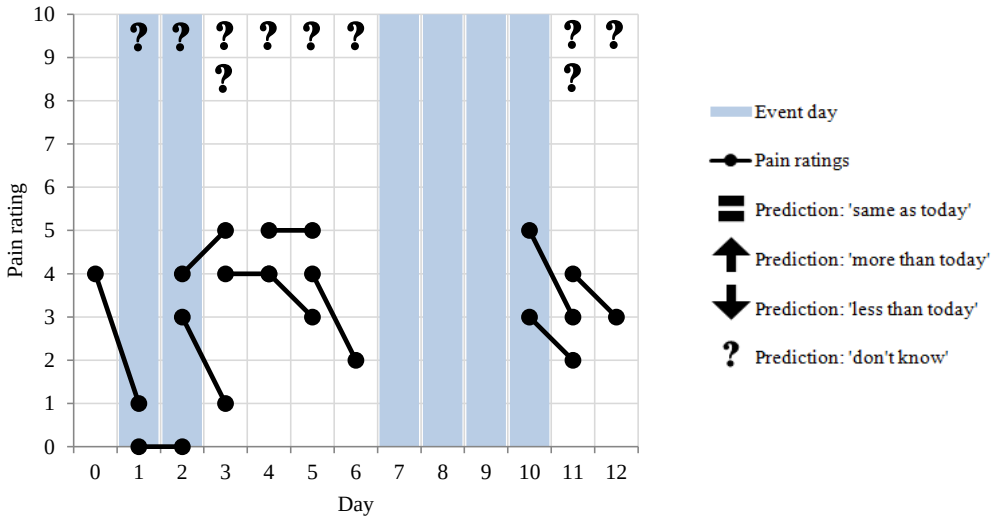

Figure 13: Faith's pain ratings and predictions over 12 days

In two of her 11 diaries Faith said that the pain had changed in the last 12 hours; in one diary the location had changed and in the other the intensity had changed. On two occasions Faith used paracetamol tablets and ibuprofen gel to treat her pain. When asked how much the pain had interfered with daily activities, Faith mostly said that it had not. Her answers ranged from 0 to 5 with an average of 3.0. Table 28 shows that Faith's responses for the control questions were almost identical for each diary, suggesting that her ability to decrease the pain is closely linked with both current and future perceptions of control.

Table 28: Faith's scores for the control questions for each diary type

	How much control do you feel you had over the pain 0 = no control 6 = complete control			*How much were you able to decrease the pain 0 = no decrease 6 = complete decrease*			*How much control do you expect to have over the next 12 hours 0 = no control 6 = complete control*		
	Min	*Max*	*Avg*	*Min*	*Max*	*Avg*	*Min*	*Max*	*Avg*
Event	0	3	1.50	0	3	1.50	0	3	1.50
Morning	2	4	2.33	2	4	2.33	2	4	2.33
Evening	2	3	2.33	2	3	2.33	1	3	2.00

Faith's current and past pain ratings were significantly correlated, and both of these were significantly correlated with interference. Current control, future control and ability to decrease pain were all similarly highly correlated at $p>.01$.

Table 29: Correlations of Faith's scores for pain, interference and control

	pain right now	*interference from pain*	*control over this pain*	*ability to decrease*	*control in next 12 hours*
worst pain in last 12 hours	.701*	.766**	.503	.503	.447
pain right now	-	.823**	.045	.045	-.096
interference from pain		-	.304	.304	.143
control over this pain			-	1.000**	.958**
ability to decrease				-	.958**

* denotes significance at $p<.05$; ** denotes significance at $p<.01$

2. Scaling task

In the scaling task Faith chose six additional labels, namely 'weak', 'uncomfortable', 'upsetting', 'distressing', 'strong' and 'intense'. Faith did not add any of her own words. Faith was the only participant to place the IMPACCT labels in a different order, and the reason for this is unknown.

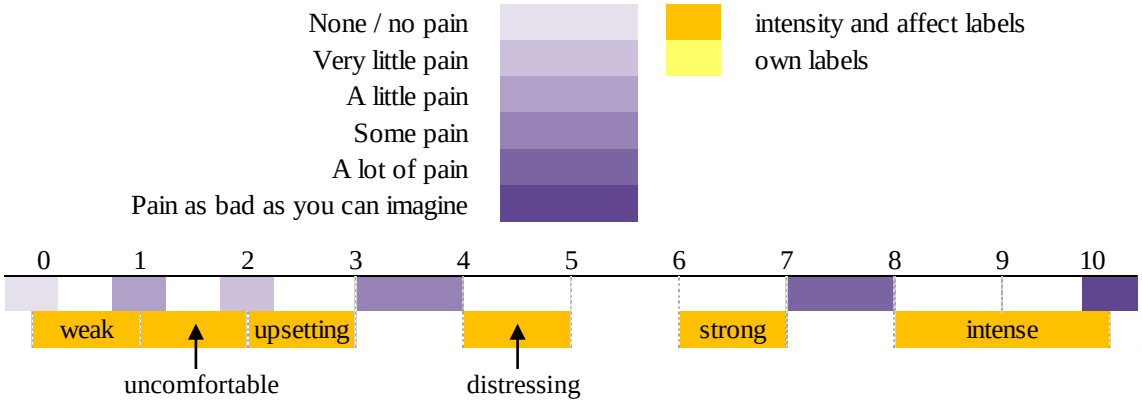

Figure 14: Faith's pain scale

Gina

1. Pain diaries

In total Gina completed 17 diaries, of which nine were event diaries, five were morning diaries and three were evening diaries. The event diaries were completed between 11am and 9pm, morning diaries between 9am and 9pm and evening diaries between 9pm and 11pm. The morning and evening diaries were completed around 12 hours apart.

Table 30: Summary of diaries completed by Gina

Phase	*1*		*2*		*3*		*4*		*5*		*6*	
Type	Event		Regular		Regular		Event		Regular		Event	
Day	1	2	3	4	5	6	7	8	9	10	11	12
Diaries completed	1	2	2	1	2	0	3	0	2	1	1	2

Table 30 shows, Gina recorded pain events throughout the study. As shown in Table 31, Gina's pain ratings varied from zero to seven out of 10, with both event and regular diaries capturing the upper ratings. Of the six regular diary days, Gina completed both diaries on three of these. On two days she completed one diary and on one day she did not complete any diaries, which was due to internet problems at her home.

Table 31: Gina's pain scale scores for past and current pain for each diary type

	Pain at its worst in last 12 hours			*Pain right now*		
	Minimum	*Maximum*	*Average*	*Minimum*	*Maximum*	*Average*
Event	4	7	5.55	3	6	4.88
Morning	0	5	3.40	0	5	2.80
Evening	6	7	6.33	3	6	4.33

Figure 15 below summarises Gina's pain ratings over the course of the study. In nine diaries Gina rated past pain as higher than current pain and in the other eight diaries she rated them the same. Gina either predicted that her pain would be the 'same' or 'more intense'. Five of her predictions can be considered accurate; it was not possible to determine the accuracy of seven predictions because a pain diary was not completed on the day after these predictions.

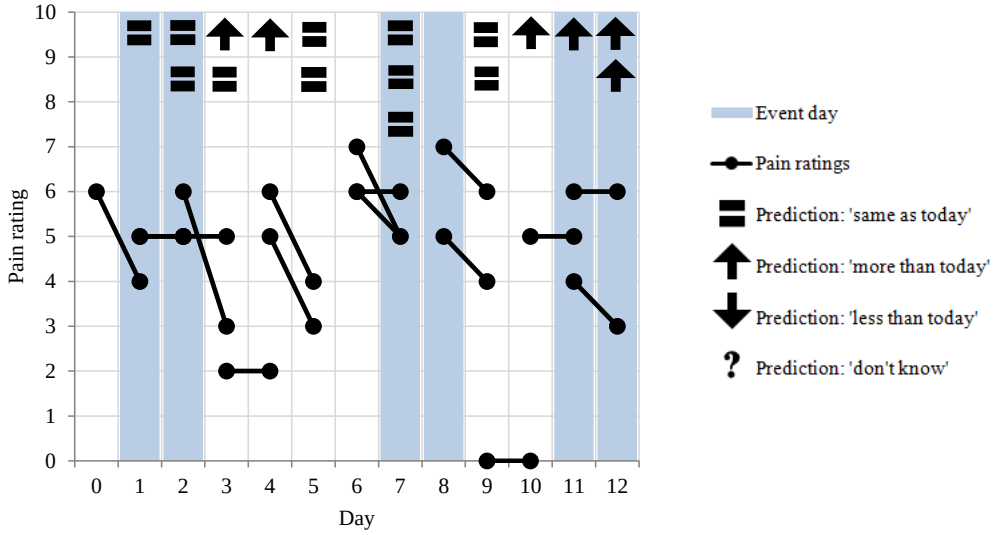

Figure 15: Gina's pain ratings and predictions over 12 days

In 13 of her 17 diaries Gina said that the pain had changed in the last 12 hours. 11 times this was a change in location, but it is not known what had changed on the other two occasions. The

changes in location were also associated with changes in the quality and frequency of the pain, as Gina described that pain in certain parts of her body was a shooting pain whereas in other parts it is not. When asked how much the pain had interfered with daily activities, Gina mostly said that it had not. Her answers ranged from 1 to 7 with an average of 3.35. Gina reported that she had not done anything extra to control her pain during the study. Table 32 shows that Gina did not feel that she had much control over her pain. In the interview she suggested two reasons for this; one being her reluctance to take any analgesia and another being her demanding job which required frequent travel, including walking, which she found made her joints sore. Gina consistently scored zero for all three questions in the regular diaries but gave more varied answers in the event diaries.

Table 32: Gina's scores for the control questions for each diary type

	How much control do you feel you had over the pain 0 = no control 6 = complete control			*How much were you able to decrease the pain 0 = no decrease 6 = complete decrease*			*How much control do you expect to have over the next 12 hours 0 = no control 6 = complete control*		
	Min	*Max*	*Avg*	*Min*	*Max*	*Avg*	*Min*	*Max*	*Avg*
Event	0	3	0.33	0	3	0.67	0	3	0.56
Morning	0	0	0.00	0	0	0.00	0	0	0.00
Evening	0	0	0.00	0	0	0.00	0	0	0.00

Gina's current and past pain scores were significantly correlated, and both of these correlated with interference. Current control, future control and ability to decrease pain were all highly correlated at $p>.01$. Prediction was correlated with past pain and interference.

Table 33: Correlations of Gina's scores for pain, interference and control

	pain right now	*interference from pain*	*control over this pain*	*ability to decrease*	*control in next 12 hours*	*prediction code*
worst pain in last 12 hours	.787**	.588*	.144	.152	.113	-.620**
pain right now	-	.571*	-.042	.080	.042	-.301
interference from pain		-	.077	.229	.177	-.589*
control over this pain			-	.792**	.821**	-.185
ability to decrease				-	.960**	-.312
control in next 12 hours					-	-.264

* denotes significance at $p<.05$

** denotes significance at $p<.01$

2. Scaling task

In the scaling task Gina described ‘shooting pains’ as sixes and sevens and ‘ache’ as a five. When given the choice of additional labels, Gina chose ‘tolerable’, ‘uncomfortable’, ‘upsetting’, ‘miserable’, ‘distracting’, ‘tiring’, ‘unbearable’, ‘intense’, ‘intolerable’ and ‘excruciating’.

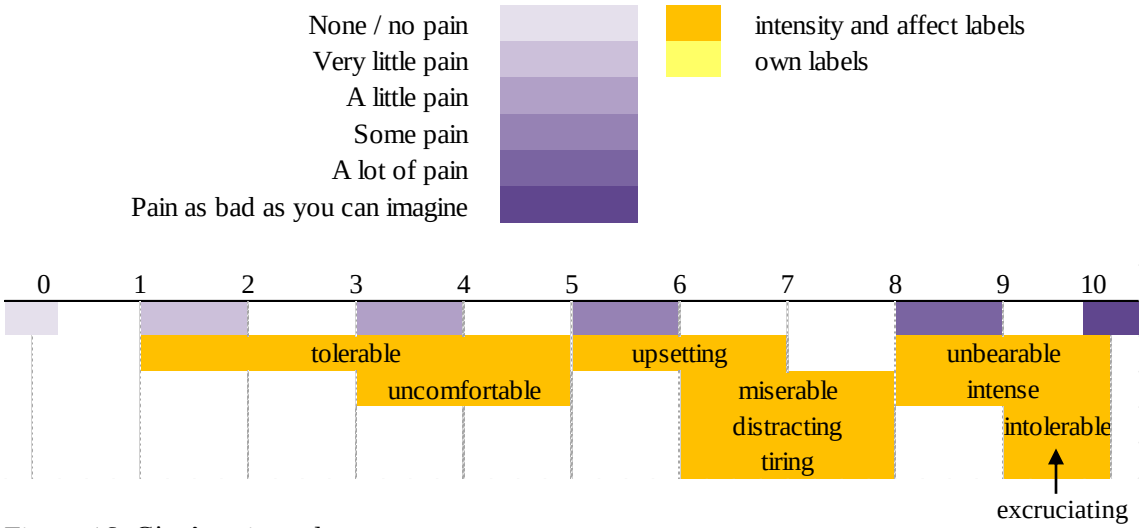

Figure 16: Gina’s pain scale

Helen

1. Pain diaries

In total Helen completed 14 diaries, of which seven were event diaries, four were morning diaries and three were evening diaries. The event diaries were completed between 8am and 8pm, morning diaries between 7am and 9am and evening diaries between 1pm and 8pm. The smallest gap between completion of morning and evening diaries was ten hours and the largest was 12 hours.

Table 34: Summary of diaries completed by Helen

Phase	*1*		*2*		*3*		*4*		*5*		*6*	
Type	Regular		Regular		Event		Regular		Event		Event	
Day	1	2	3	4	5	6	7	8	9	10	11	12
Diaries completed	2	2	2	0	1	0	1	0	2	1	1	2

Table 34 shows that Helen recorded pain events on five of the six event days. Of the six regular diary days, Helen completed both diaries on three of these. On one day she completed one diary and on two days she did not complete any diaries. Both during and after the study Helen reported some difficulties with using the diaries as she could not locate the ‘finish’ button at the end. As a result two of the 14 diaries did not contain any information because Q-tool only records content if the finish button is clicked. As shown in Table 35, Helen’s pain varied from three to five out of 10, with the fives recorded on an event day.

Table 35: Helen's pain scale scores for past and current pain for each diary type

	Pain at its worst in last 12 hours			*Pain right now*		
	Minimum	*Maximum*	*Average*	*Minimum*	*Maximum*	*Average*
Event	3	5	3.70	3	5	3.57
Morning	4	4	4.00	3	3	3.00
Evening	3	4	3.50	3	3	3.00

Figure 17 below summarises Helen's pain ratings over the course of the study. Helen's ratings of her current and previous pain were very similar; they were either the same or only one point different. She only made predictions that her pain would be the same, or that she did not know what her pain would be like. Of the five predictions that the pain would be the same, one of these was accurate in that her current pain remained the same, although her pain in the last 12 hours had increased slightly. It was not possible to determine the accuracy of the other predictions.

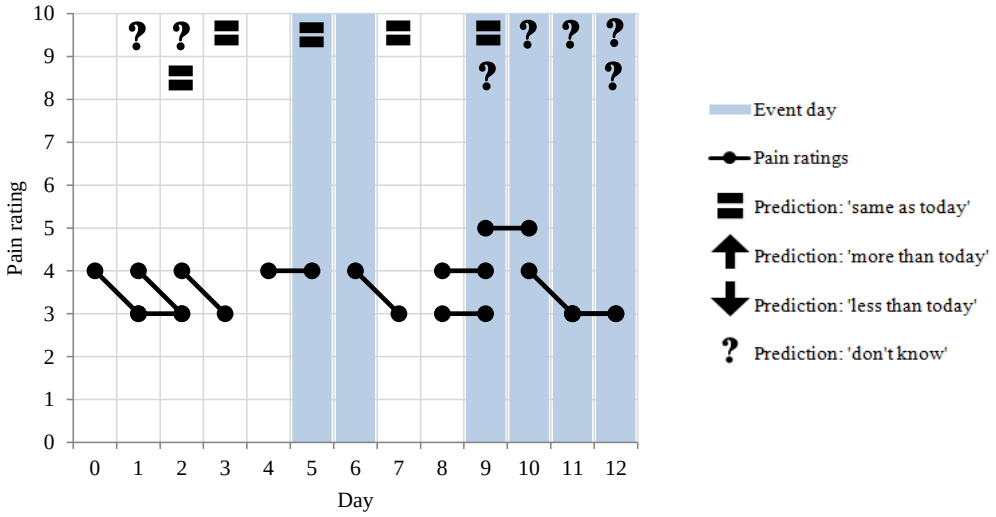

Figure 17: Helen's pain ratings and predictions over 12 days

In five diaries Helen said that the pain had changed in the last 12 hours, one of which was a change in location. When asked how much the pain had interfered with daily activities, Helen mostly said that it had not. Her answers ranged from 3 to 5 with an average of 3.75. However, in the interview she did talk about how her expectations of daily activity were low since being diagnosed and treated. Table 36 shows that Helen's responses for the control questions were all in the mid and lower range of the scale, with little differences between the diary types. Helen stated that she had not done anything extra to control her pain during the study.

Table 36: Helen's scores for the control questions for each diary type

	How much control do you feel you had over the pain 0 = no control 6 = complete control			*How much were you able to decrease the pain 0 = no decrease 6 = complete decrease*			*How much control do you expect to have over the next 12 hours 0 = no control 6 = complete control*		
	Min	*Max*	*Avg*	*Min*	*Max*	*Avg*	*Min*	*Max*	*Avg*
Event	2	3	2.14	1	2	1.86	2	2	2.00
Morning	2	3	2.67	0	3	1.67	2	3	2.67
Evening	3	3	3.00	2	3	2.50	2	3	2.50

Helen's current pain and past pain were significantly correlated, and both of these were significantly correlated with interference. No other variables were significantly correlated, although prediction was excluded as it was constant (zeros).

Table 37: Correlations of Helen's scores for pain, interference and control

	pain right now	*interference from pain*	*control over this pain*	*ability to decrease*	*control in next 12 hours*
worst pain in last 12 hours	.674*	.631*	.071	-.231	-.081
pain right now	-	.741**	-.181	-.117	-.309
interference from pain		-	.059	-.038	.200
control over this pain			-	.315	.293
ability to decrease				-	.063

* denotes significance at $p<.05$

** denotes significance at $p<.01$

2. Scaling task

When given the choice of additional labels, Helen chose 'upsetting', 'irritating', 'unpleasant', 'horrible', 'distracting', 'miserable', 'distressing', 'annoying', 'moderate', 'agonising', 'tiring', 'weak', 'uncomfortable', 'strong', 'very strong', 'intense' and 'awful'. It is worth noting that Helen described herself as tiring easily and feeling weak, rather than using tiring and weak to describe the pain itself. Helen used 'intense' and 'awful' to describe shooting pains. Helen added the word 'niggling' to describe dull pain that is always there and rated this as a five.

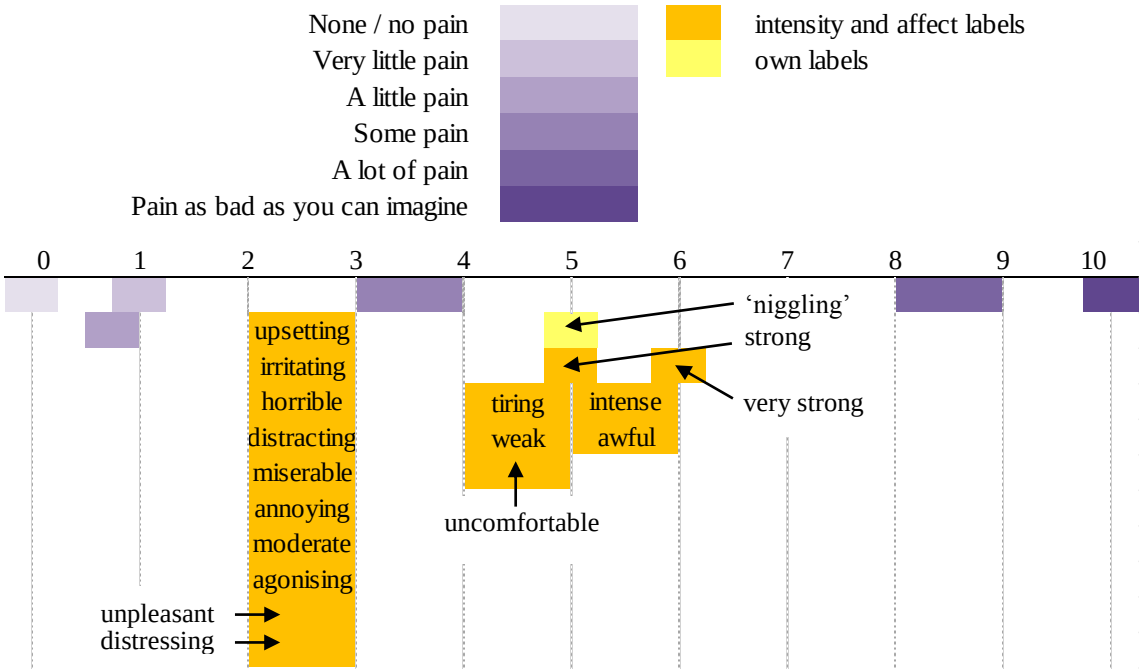

Figure 18: Helen's pain scale

Isobel

1. Pain diaries

In total Isobel completed 12 diaries; four of each type, although two of the event diaries were not submitted successfully and therefore did not contain any data. The event diaries were completed between 8am and 8pm, the morning diaries at either 9am or 4-7pm and evening diaries between 4pm and 10pm. The smallest gap between completion of morning and evening diaries was five minutes and the largest was 12 hours. In the interview Isobel stated that she completed the morning diaries as she felt that morning.

Table 38: Summary of diaries completed by Isobel

Phase	*1*		*2*		*3*		*4*		*5*		*6*	
Type	Regular		Regular		Event		Event		Regular		Event	
Day	1	2	3	4	5	6	7	8	9	10	11	12
Diaries completed	2	2	0	2	1	1	1	0	0	2	1	0

Table 38 shows that Isobel attempted to record four pain events during the study, also stating that she had experienced a pain event after completing a regular evening diary the previous day. Of the six regular diary days, Isobel completed both diaries on four of these and did not complete any diaries on the other two days. As shown in Table 39, Isobel's pain ratings were very similar throughout the study with little difference between the diary types.

Table 39: Isobel's pain scale scores for past and current pain for each diary type

	Pain at its worst in last 12 hours			*Pain right now*		
	Minimum	*Maximum*	*Average*	*Minimum*	*Maximum*	*Average*
Event	6	6	6.00	6	6	6.00
Morning	5	6	5.75	4	6	5.25
Evening	5	6	5.75	5	6	5.75

Figure 19 summarises Isobel's pain ratings over the course of the study. Isobel's ratings of her current and previous pain were very similar; they were either the same or only one point different. She mostly stated that her pain would be the same the following day, and was accurate in around half of these predictions; the others could not be determined. On two occasions she predicted that her pain would increase; on both occasions she did not complete a diary the following day so the accuracy cannot be determined.

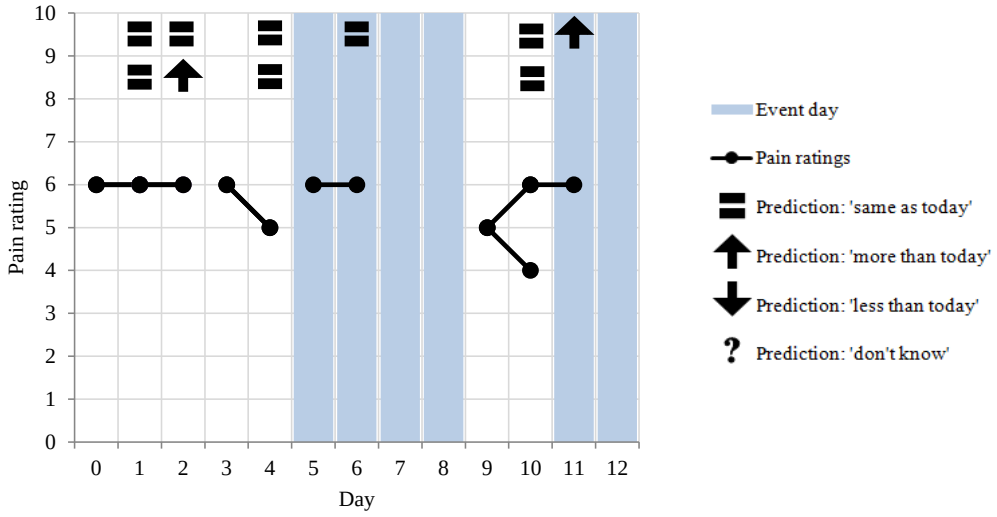

Figure 19: Isobel's pain ratings and predictions over 12 days

In four diaries Isobel said that the pain had changed in the last 12 hours. On one occasion she described an increase in intensity and on three occasions described a change in the quality of the pain, using words such as discomfort, stabbing and tightness. When asked how much the pain had interfered with daily activities, Isobel mostly said that it had, with answers ranging from 4 to 6 with an average of 4.8. From the interview it appears that this interference included caring for grandchildren, driving and gardening. Table 40 shows that Isobel's responses were very similar, mostly around the midpoint, which was labelled '3 – some [control / decrease]'. Isobel stated that she had not done anything extra to control her pain during the study.

Table 40: Isobel's scores for the control questions for each diary type

	How much control do you feel you had over the pain 0 = no control 6 = complete control			*How much were you able to decrease the pain 0 = no decrease 6 = complete decrease*			*How much control do you expect to have over the next 12 hours 0 = no control 6 = complete control*		
	Min	*Max*	*Avg*	*Min*	*Max*	*Avg*	*Min*	*Max*	*Avg*
Event	3	3	3.00	3	3	3.00	3	3	3.00
Morning	3	3	3.00	2	3	2.75	3	3	3.00
Evening	3	3	3.00	2	3	2.75	3	3	3.00

It was only possible to correlate current pain, past pain, interference, decrease in pain and prediction, and none of these were significantly correlated.

Table 41: Correlations of Isobel's scores for pain, interference and control

	pain right now	*interference from pain*	*ability to decrease*	*prediction code*
worst pain in last 12 hours	.452	.535	-.250	.250
pain right now	-	.443	.075	.302
interference from pain		-	-.134	.468
ability to decrease			-	.250

* denotes significance at $p<.05$

** denotes significance at $p<.01$

2. Scaling task

In the scaling task Isobel chose six labels which were 'annoying', 'awful', 'uncomfortable', 'distracting', 'miserable' and 'tolerable'. She did not choose any additional labels.

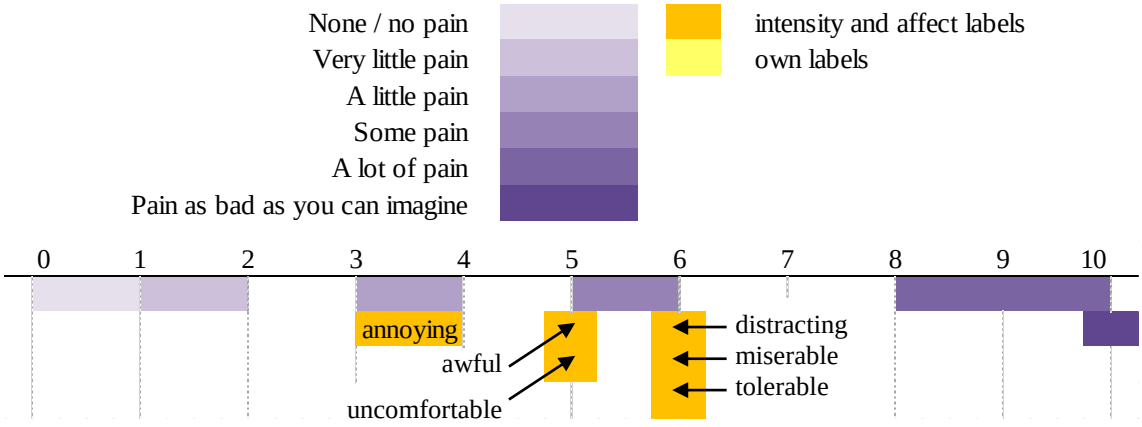

Figure 20: Isobel's pain scale

Julie

1. Pain diaries

In total Julie completed seven diaries, of which two were morning diaries, three were evening diaries and two were event diaries. The event diaries were completed around 10am, morning diaries around 7pm and evening diaries between 8am and 8pm. The gap between completion of morning and evening diaries was around 10 minutes. In the interview Julie stated that she completed the morning diaries as she felt that morning.

Table 42: Summary of diaries completed by Julie

Phase	*1*		*2*		*3*		*4*		*5*		*6*	
Type	Regular		Event		Regular		Regular		Event		Event	
Day	1	2	3	4	5	6	7	8	9	10	11	12
Diaries completed	2	0	1	0	1	0	0	2	1	0	0	0

Table 42 shows that during the study Julie recorded two pain events. In addition, she said she had experienced another pain event but had forgotten to complete a diary. Of the six regular diary days, Julie completed both diaries on two days, one diary on one day and no diaries on three days. As shown in Table 43, Julie's pain varied from one to four out of 10, with the full range recorded in regular diaries and mid-range ratings recorded in the event diaries.

Table 43: Julie's pain scale scores for past and current pain for each diary type

	Pain at its worst in last 12 hours			*Pain right now*		
	Minimum	*Maximum*	*Average*	*Minimum*	*Maximum*	*Average*
Event	2	3	2.50	2	2	2.00
Morning	3	3	3.00	1	2	1.50
Evening	3	4	3.67	2	3	2.33

Figure 21 below summarises Julie's pain ratings over the course of the study. Julie's ratings of her current and previous pain were similar; they were either the same or only one to two points different. Julie mostly predicted that her pain would be the same, even when she had taken painkillers or been more active than usual. Two of the 'same' predictions can be considered accurate but it is not possible to determine the accuracy of any other predictions. It is not known why she gave two different predictions at the end of the study.

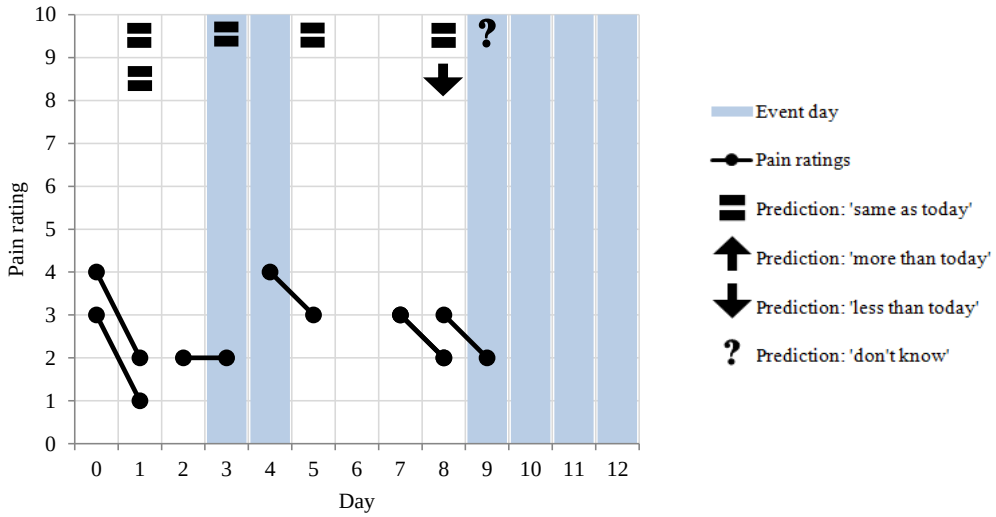

Figure 21: Julie's pain ratings and predictions over 12 days

In five of her seven diaries Julie said that the pain had changed in the last 12 hours. On one occasion she said that the location had changed and that she had experienced swelling, and on a second occasion stated that she had swelling again. These were the only two occasions where Julie did anything extra to control the pain, which was massage and 'tablets'. When asked how much the pain had interfered with daily activities (0-10 scale; 10=unable to carry on any activities), Julie mostly said that it had not. Her answers ranged from 1 to 3 with an average of 2.14. Table 44 shows that Julie's responses for the control questions covered the lower half of the scale, with answers ranging between one and three. Interestingly in the only diary where she stated she had taken painkillers was when she gave her lowest ratings for current and expected control.

Table 44: Julie's scores for the control questions for each diary type

	How much control do you feel you had over the pain 0 = no control 6 = complete control			*How much were you able to decrease the pain 0 = no decrease 6 = complete decrease*			*How much control do you expect to have over the next 12 hours 0 = no control 6 = complete control*		
	Min	*Max*	*Avg*	*Min*	*Max*	*Avg*	*Min*	*Max*	*Avg*
Event	3	3	3.00	3	3	3.00	3	3	3.00
Morning	1	3	2.00	2	3	2.50	2	3	2.50
Evening	1	2	1.67	2	2	2.00	1	3	2.00

For Julie, her current and past pain ratings were not significantly correlated. The only significant relationship was between current pain and degree of interference from pain.

Table 45: Correlations of Julie's scores for pain, interference and control

	pain right now	*interference from pain*	*control over this pain*	*ability to decrease*	*control in next 12 hours*	*predictio n code*
worst pain in last 12 hours	.418	.300	-.575	-.645	-.439	.108
pain right now	-	.837*	.321	-.540	.000	.000
interference from pain		-	.230	-.645	-.132	-.542
control over this pain			-	.198	.370	.000
ability to decrease				-	.679	.316
control in next 12 hours					-	.200

* denotes significance at $p<.05$

** denotes significance at $p<.01$

2. Scaling task

When given the choice of additional labels, Julie chose 'irritating', 'uncomfortable', 'annoying', 'tiring' and 'severe'. Additionally, Julie said that she also uses the phrase 'very uncomfortable' to describe her pain and placed this between eight and nine, which also bridges a gap between two IMPACCT labels. Her IMPACCT labels covered the full range of 0-10 whereas the additional labels covered 2-9 on the scale.

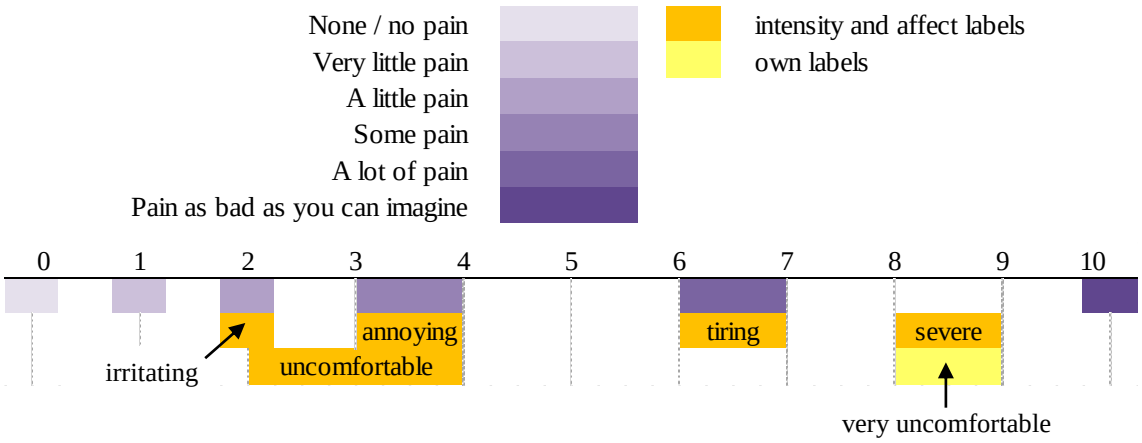

Figure 22: Julie's pain scale

Group level results

Mood and quality of life measures

Due to concerns about the possible negative impact of pain monitoring, the mood and quality of life measures were used to examine changes over time while the monitoring took place. Table 46 below shows that overall the mood and quality of life measures were stable over the course of the

study. Some measures showed a slight decrease, but given the high baseline scores this can be explained by regression to the mean in most cases.

Table 46: Summary of mood and quality of life scores

	Lot-R		*EQ-5D*		*EQ-5D scale*		*PANAS (positive)*		*PANAS (negative)*	
	B	*E*	*B*	*E*	*B*	*E*	*B*	*E*	*B*	*E*
Angela	24	24	12331	11131	50	69	48	45	10	11
Belinda	16	11	11111	12221	97	79	27	26	14	10
Carol	13	16	11111	11121	90	97	38	40	23	13
Diane	20	19	11332	11223	95	96	34	32	14	12
Elizabeth	9	10	32331	31331	40	40	32	42	15	14
Faith	13	12	11132	11333	90	48	26	16	17	28
Gina	21	15	31231	11121	50	50	36	22	14	19
Helen	12	9	31332	33333	41	40	19	9	27	30
Isobel	9	7	22332	22233	60	70	26	24	27	21
Julie	22	17	22322	21232	85	70	26	30	15	19

B=baseline; E=end of study

All participants were asked to complete the mood and quality of life measures at the start of the study (during the enrolment meeting) and again once all the diaries had been completed. Most participants completed the end of study measures immediately after the last diary, while others were prompted to complete the end of study measures at the end of study interview and completed them after the researcher had left. Paired samples t-tests showed that the difference between baseline and end of study measures was not significant for the 0-100 EQ-5D scale, positive PANAS scale or negative PANAS scale. The Lot-R approached significance $t(9) = 2.08$, $p=.067$.

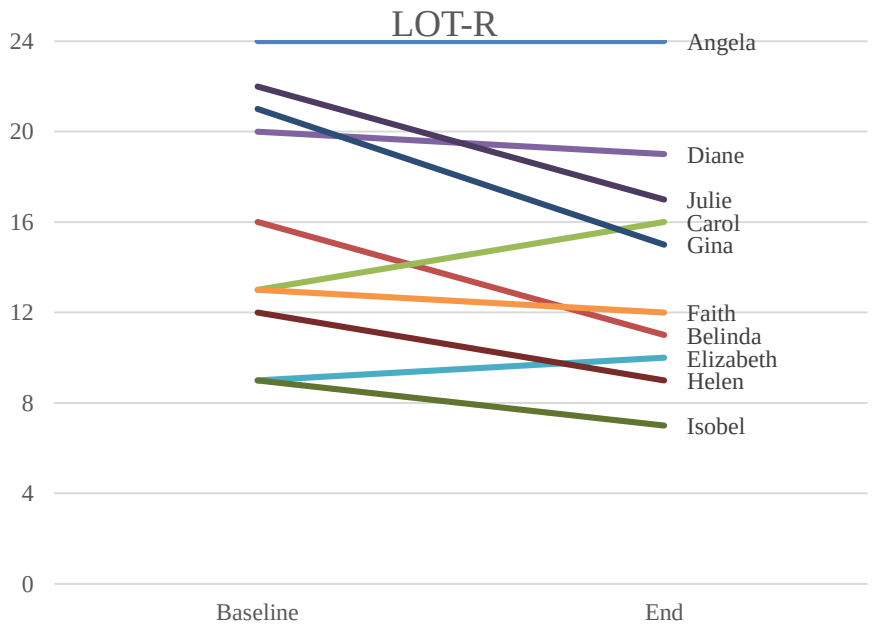

Figure 23: Baseline and end Lot-R scores

Overall two Lot-R scores increased, one stayed the same and the remaining seven decreased over the study period. The baseline LOT-R scores were significantly negatively correlated with the baseline PANAS negative score (r = -.71, p<.05), but not with any other baseline scores. The end of study Lot-R was not significantly correlated with any other end of study measures.

Overall four EQ-5D 0-100 scale ratings increased, two stayed the same and four decreased. The baseline score was not significantly correlated with any other baseline scores but the end of study score was significantly negatively correlated with the end of study negative PANAS score (r = -.64, p<.05).

There was much greater variation in positive scores over the study period and the negative scores were much more stable. Interestingly the positive and negative scores were not significantly correlated at baseline (r = -.58, p>.05), but were at the end of the study (r = -.83, p<.05).

Summary of pain diaries

Completion

A total of 99 diaries were submitted during the study, of which 95 were valid. 29 were event diaries, 39 were morning diaries and 27 were evening diaries. Of the four invalid diaries, two were event diaries, one was a morning diary and one was an evening diary. The average number of diaries attempted by each person was 9.7 (range 4-17; SD=3.95). Not all participants completed all types of diary. For example, one participant did not complete any evening diaries and one participant did not complete any event diaries (because they did not experience a pain event during the study). No diaries were completed by carer/spouse. On five occasions participants stated that they had experienced another pain event since last completing a diary, and on four occasions a reason was given. Twice participants indicated that the pain events happened on regular diary days; one participant forgot and one had the pain event when they were in bed late at night. The average time taken to complete the diaries was 52 minutes, however this has been distorted by a small number of occasions where participants said they had left diaries half-finished sometimes until the next day. The quickest diary completion was 59 seconds and the slowest was 25 hours and 44 minutes. 70 of the 95 valid diaries were completed in under 5 minutes, a further 13 in 5-10 minutes and six in 11-30 minutes. The remaining six diaries had much longer completion times of 90 or more minutes.

Pain ratings

The continuous variables from the pain diaries (pain right now, pain in the last 12 hours, how much pain has interfered, how much control they had over the pain, how much they were able to decrease the pain and how much control they expect to have over the next 12 hours) met all assumptions for parametric data in that data were normally distributed, there was homogeneity of variance, data were continuous and independent (Field, 2009). Pain ratings for current pain and

pain the last 12 hours varied from zero to seven out of ten. Using an SPSS file where each individual had one record which summarised their diary data, a paired samples t-test showed that although the average pain ratings for each individual were slightly higher for the event diaries than the regular diaries, there was no significant difference for either pain right now ($t(8) = -.84$, $p>.05$) or pain at its worst in the last 12 hours ($t(8) = -.88$, $p>.05$). Similarly t-tests also showed that there were no significant differences between event or regular diaries for the average scores for how much the pain had interfered, how much control they had over the pain, how much they were able to decrease the pain and how much control they expect to have over the next 12 hours (all *p*s>05).

The ratings given for how much pain had interfered with daily activities varied greatly both within and between individuals. The variation between individuals may in part be explained by the significant negative correlations between the average interference score for each person with both end of study Lot-R scores ($r = -.75$, $p<.05$) and end of study EQ-5D 0-100 health rating ($r = -.78$, $p<.01$). There was more within-person consistency for the future control questions, and the average score also correlated with the mood and quality of life measures. Again, there was a significant correlation with the end of study EQ-5D 0-100 health rating ($r = .67$, $p<.05$), and with the end of study negative PANAS score ($r = -.75$, $p<.05$). These relationships suggest that people perceive less interference from their pain when they have a more optimistic outlook and also rate their health more highly. Additionally, people perceive that they have more control over their pain when they rate their health more highly and experience more positive affect.

Overall a number of different patterns were observed when comparing the pain ratings for each of the ten participants. Carol's pain diaries were the most consistent. She always predicted that her pain would be the same, and for the most part it was, ranging between 0 and 2. Past pain was either the same or higher than current pain. Helen's pain ratings were also consistent, but covered between three and five out of 10. Diane's pain ratings ranged from 0 to 5 and appeared to decrease over the course of the study, although she only completed four diaries. Elizabeth recorded the greatest decrease (four points) in past pain to current pain, which encompassed most of her range of reported pain (between 0 and 5 out of 10). Faith had the most variation in her responses over the course of the diary phase.

For all 10 participants, pain ratings increased and decreased many times during the study, with most diaries having either two peaks or a uniform shape. This shows that even over 12 days, pain fluctuated a great deal. Additionally, in only three of the 95 diaries was current pain reported to be higher than past pain; with each diary completed by different participants. Current pain was the same as past pain in 39 of the diaries and in the remaining 53 diaries current pain was rated as lower than past pain. From the pain diaries there did not appear to be any significant benefit or negative effect from taking part, although some participants did talk about managing their pain more proactively as a result of participation. However, these actions commenced between the diary phase and interview and were therefore not captured by the diaries.

Predicting pain

Of the 95 predictions made, the majority were 'the same as today' (44). There were 31 'don't know' predictions, 11 'more intense' predictions and nine 'less intense' predictions.

Table 47: Summary of pain predictions

Participant	*Less intense*	*Same*	*More intense*	*Don't know*	*Total*
Angela	0	1	0	11	12
Belinda	4	3	1	0	8
Carol	0	9	0	0	9
Diane	1	2	1	0	4
Elizabeth	3	0	1	1	5
Faith	0	0	0	11	11
Gina	0	11	6	0	17
Helen	0	5	0	7	12
Isobel	0	8	2	0	10
Julie	1	5	0	1	7
Total	**9**	**44**	**11**	**31**	**95**

When these predictions were coded so that 'same' = 0, 'more intense' = 1 and 'less intense' = -1, the relationship between prediction and other aspects of the diaries could be explored. There were no significant correlations between an individual's average prediction score and the other continuous variables. Due to a number of different factors, it was not possible to ascertain how accurate the predictions were for every diary for each participant. Unless they completed a diary the following day, the prediction could not be tested. Even if a diary was completed the following day, for example a morning diary, the accuracy of the prediction made the previous day could not be ascertained unless an evening diary had also been completed. As the prediction did not stipulate a timeframe other than 'tomorrow', pain experienced after diaries had been completed could have matched a prediction but not been recorded. In these cases if a diary was completed on the second day after the prediction, the pain in the last 12 hours was useful in determining the accuracy of the prediction but as it referred to the last 12 hours and not the previous day as a whole, it required some caution in interpretation. Therefore the accuracy comments above in the individual results sections are an overall impression rather than an absolute accuracy score. Participants' experiences of making pain predictions will be explored further in the thematic analysis.

Summary of scaling task

The scaling task was completed at the end of the interview at the very end of the study. All but one participant completed the interview part of the study, therefore a total of nine individuals completed the scaling task. Table 48 shows that the IMPACCT scaling words were used similarly by all participants. All participants used all the labels, and all but one placed them in the same order. Additionally, most participants clustered the labels at each end of scale and had a portion of the pain scale with no labels. A number of participants overlapped some of the labels, particularly at the lower end of the scale. The middle labels mostly had greater ranges than the

labels at either end. In watching the participants complete the task it was apparent that people used different strategies. While some people placed the two extreme markers on the scale first and then the middle labels, others started from 0 or 10 and worked along, and a small number just picked up the labels one by one and placed them on the scale (as they were presented in a random order at the start of the task). There did not appear to be any relationship between method of labelling and the location of the labels.

Table 48: Overall ratings of IMPACCT scaling words

IMPACCT labels	*Average rank*	*Range of averages*	*Range of individual ratings*
None / no pain	0.06	0.0 - 0.5	0-1
Very little pain	1.17	0.0 - 2.0	0-2
A little pain	1.92	0.5 - 3.5	0-4
Some pain	4.14	2.5 - 5.5	2-6
A lot of pain	7.67	6.5 - 9.0	6-10
Pain as bad as you can imagine	9.94	9.5 - 10.0	9-10

The averages in Table 48 were calculated by using the average of the range given by each participant and then combining these to show an overall average. For example, when Helen said that a little pain for her was between 0.5 and one, the average was taken as 0.75 and this was entered into the subsequent calculation to find the average rating for a little pain across all participants. The average rating has been plotted in Figure 24 and the error bars refer to the range of individual ratings given for that point. IMPACCT labels have been allocated a score from zero to five, which is consistent with how the IMPACCT team uses these labels in their calculations. The figure shows that the relationship between the label score and pain rating is not linear and instead appears to show a curved relationship, with a triple curve polynomial line providing a perfect fit.

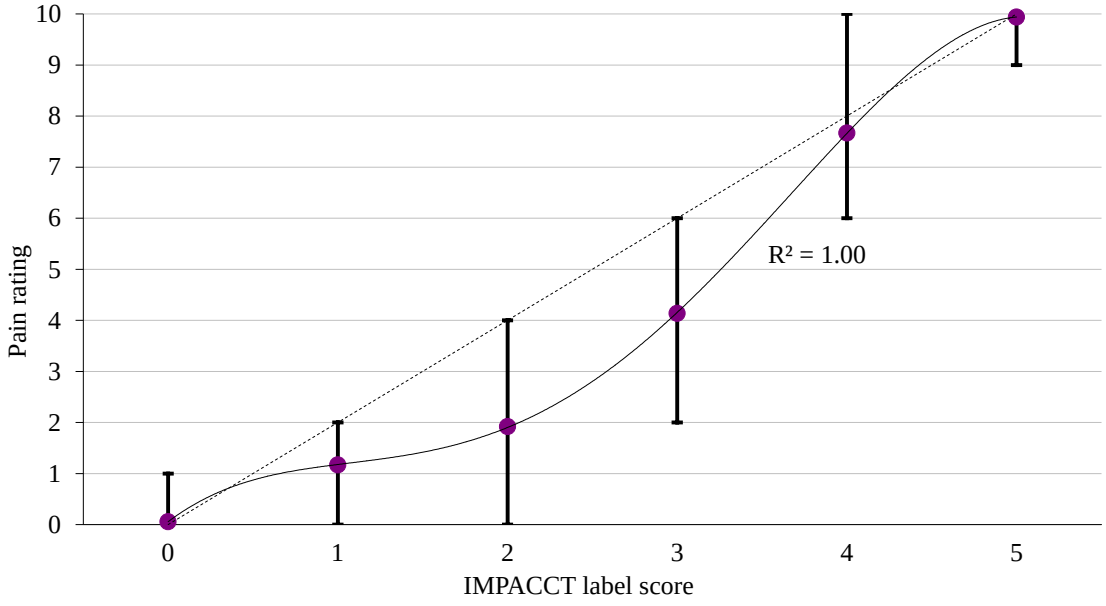

Figure 24: Graph of average ratings for IMPACCT labels

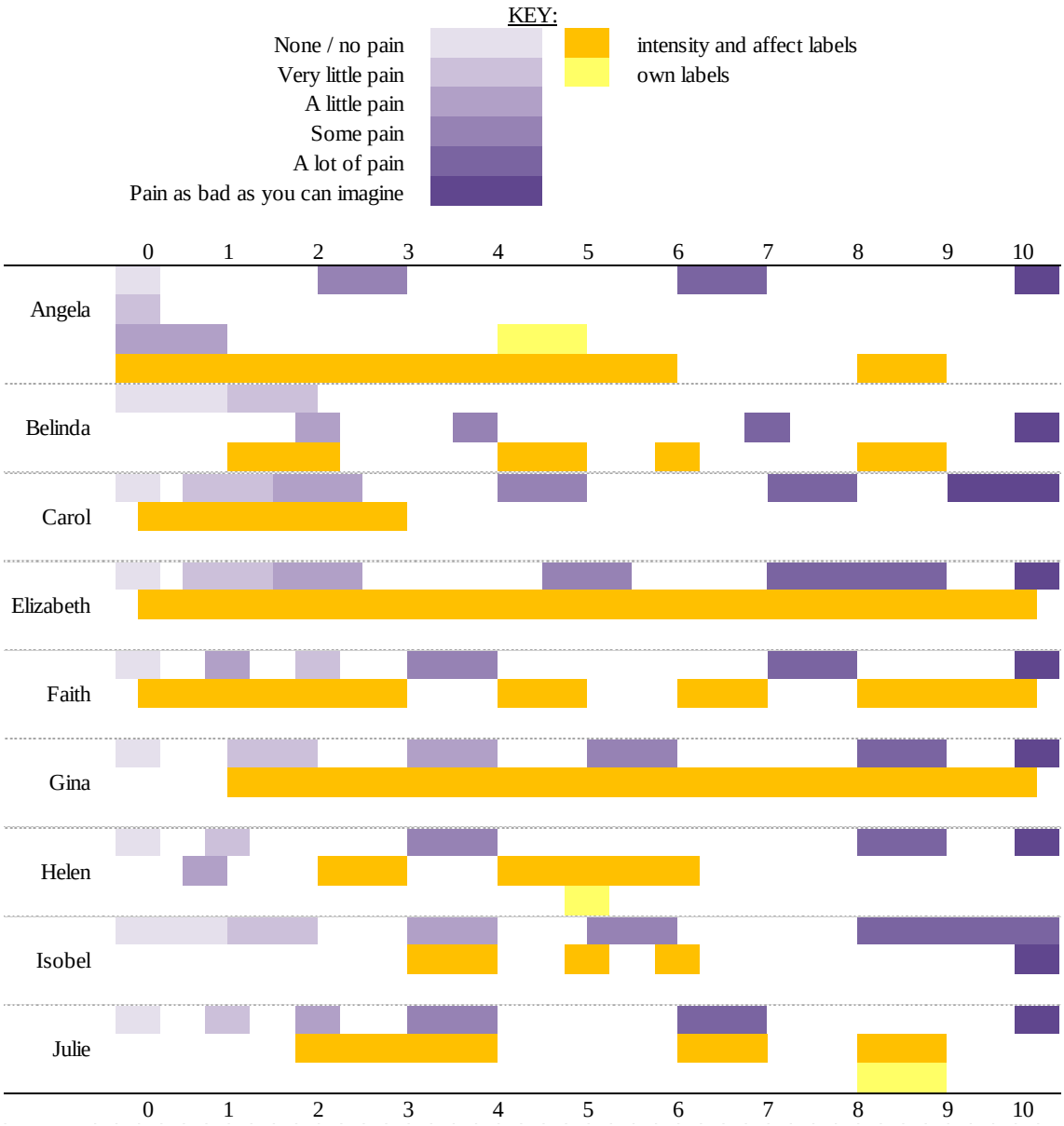

Figure 25: Visual display of use of IMPACCT labels and intensity and affect scaling words

Figure 25 displays all of the IMPACCT labels, intensity and affect labels and participants' own labels from the scaling task. It shows that only three participants added their own labels to the scale. On all three occasions these were added in gaps left by IMPACCT labels, but overlapped the intensity and affect labels. The figure also shows that while the zero and ten anchors for the IMPACCT labels were consistent across individuals, the intermediate labels varied. The parts of the scale covered by the intensity and affect labels show much less consistency between individuals.

Table 49 shows the average rank and range for each intensity and affect label. These have been calculated in the same way as the IMPACCT label summary above. This summary shows that 16 of the 18 affect labels were chosen at least once, whereas only eight of the 11 intensity words were chosen at least once. The most popular word was 'uncomfortable', which was chosen by every participant. Overall the affect words had larger ranges than the intensity words, suggesting that there is more variance between individuals in how these words are used when compared with the use of intensity words. It is also worth noting that although the word 'weak' is listed here as an intensity word, one participant used it as an affective word in describing her own sense of weakness.

Table 49: Use of intensity and affect words in the scaling task

	Type	*Number of times selected*	*Average rank*	*Range of averages*	*Range of individual ratings*
Uncomfortable	Affect	9	3.94	1.5-8.5	1-9
Miserable	Affect	5	4.85	1.5-7.25	1-10
Annoying	Affect	4	3	2.5-3.5	1.5-4
Distracting	Affect	4	4.38	2-7	2-8
Irritating	Affect	4	2.13	1.5-2.5	0-3.5
Tiring	Affect	4	6.25	4.5-7	4-10
Awful	Affect	3	6.58	5-9.25	5-10
Tolerable	Affect	3	3.17	0.5-6	0-6
Upsetting	Affect	3	3.67	2.5-6	2-7
Agonising	Affect	2	4.25	2.5-6.0	2-6
Bearable	Affect	2	3.5	3-4	0-8
Distressing	Affect	2	3.5	2.5-4.5	2-5
Horrible	Affect	2	6	2.5-9.5	2-10
Intolerable	Affect	1	9.5	-	9-10
Unbearable	Affect	1	9	-	8-10
Unpleasant	Affect	1	2.5	-	2-3
Dreadful	Affect	0	-	-	-
Terrifying	Affect	0	-	-	-
Intense	Intensity	3	7.83	5.5-9	5-10
Strong	Intensity	2	5.75	5-6.5	5-7
Weak	Intensity	2	2.5	0.5-4.5	0-5
Excruciating	Intensity	1	9.5	-	9-10
Moderate	Intensity	1	2.5	-	2-3
Severe	Intensity	1	8.5	-	8-9
Very intense	Intensity	1	8.5	-	8-9
Very strong	Intensity	1	6	-	6-6
Just noticeable	Intensity	0	-	-	-
Mild	Intensity	0	-	-	-
Very weak	Intensity	0	-	-	-

Thematic analysis

Interview transcripts were split into meaningful units and coded by the author in NVivo 10 software, producing 291 codes. Meaningful units range from a word to a paragraph but always contain only one meaning. These codes were aggregated based on common meaning into 47 categories, and the raw data were re-read to check for homogeneity of qualitative meaning. During the re-reading of utterances some codes moved categories. Forty-six of these categories were then aggregated into 12 themes. The miscellaneous category was excluded from the themes as it contained either researcher speech, environmental noise or unrelated statements, all of which were deemed to be unrelated to the experiences of participants. Ten of these themes were then collapsed into three broad meta-themes. At this point the utterances within these meta-themes were scanned to confirm location. One theme, 'technological problems', was kept separate from the remaining themes and was not integrated into the meta-themes. 'Technological problems' contains categories that represent specific difficulties encountered with technology during the course of the diary study and this is qualitatively distinct from the other interview data. The themes which are relevant to the aims of the current study will be discussed.

The analysis was checked for quality and discussed at the coding stage and the theme creation stage with one supervisor, Dr Bridgette Bewick. A summary of the categories, themes and meta-themes is shown in Table 50. A full list of codes can be found in Appendix I.

Table 50: Structure of three meta-themes from thematic analysis

Meta-theme 1: Making sense of experiences

Making sense of experiences				
Community of cancer	**Personal experience of cancer**	**Complexity of changes in pain**	**Desire to understand pain**	**Scaling pain**
Gratitude for medical care	Complexities of decision making around cancer treatments	Fluctuations in pain	Impact of study on pain and understanding of pain	Cognitive element of scaling pain
Pervasiveness of cancer	Sharing details of own diagnosis of breast cancer	Complexities around taking analgesics	Mood, fatigue and pain are connected	How the pain scale is used
Feel better off than other people with cancer	Sharing details of own treatments	Discussing and comparing different pains	Perceived causes of pain	Reflections on scaling task
Wanting to connect with other cancer patients	Found treatments difficult	Proactive pain management	The cognitive element of pain prediction	
Curiosity about other participants			New pains are worrying	

Meta-theme 2: Uncertainties about the future

Uncertainties about the future		
Life looks different now	**Need for support**	**Future health**
Lasting side effects after treatment	Importance of others understanding me	Not sure what future health will be
Understanding own limitations	Others don't understand recovery	Feeling that mammograms are essential
Pain will always be there	Difficulties in accessing cancer support networks	
Managing rest and relaxation		

Meta-theme 3: Research is beneficial

Research is beneficial		
Positive experience of taking part	**Limitations of current study**	**Positive about research**
Mixed opinions about not being able to see previous diaries	Diaries didn't entirely reflect experience	Enthusiasm for research
Taking part in study was convenient	Practical barriers to participation	Desire to be a good participant
Felt benefits of taking part	Some parts of the study were confusing	
Diaries captured all relevant information		
Pain prediction was difficult but interesting		
Comparing event & regular diaries		

Separate theme

Technological problems
Adaptations required for this study
Difficulties with equipment or software
Difficulties with using equipment or software
Unsure of impact of technology problems

The first meta-theme, ‘making sense of experiences’, describes how participants continue to negotiate their experiences of pain and cancer. They described feeling part of a ‘community of cancer’, in which they compared themselves to others but also wanted to connect with them. Many expressed gratitude for the care they have received from St James’ University Hospital in Leeds. Within this meta-theme people also described their personal journey of cancer, including diagnosis and treatment. Of particular interest was the decision making process around treatments. Although this was most often described in pragmatic terms, there were still doubts about whether it was the right decision:

> *“[the nurse] said: 'You don't need to have radiotherapy and chemo; you don't have to have them both or you can just have one' but she said she*

recommended that you have both. Because it's like 80% surviving if you have both but, if you don't it's like a third if you don't, you know what I mean? Because I wasn't sure quite sure so I thought, oh I should have both, I'll go for it then" *(Helen)*

Three themes described their experiences with pain and how they are trying to understand it. All participants described an ongoing process of trying to understand their pain and how best to manage it; no participants felt that they had total control or understanding of their pain. There was a strong 'desire to understand pain', including how to predict it, which was described as a cognitive process often using past experiences as guidance:

"[When] I get up it's going to be painful because it's occurred lots and lots of times before" *(Carol)*

Although the scaling task was separate from the interview itself, many participants spontaneously discussed scaling pain in the interview, and also shared reflections and opinions during the task. Again, like predicting pain, participants described scaling pain in cognitive terms: in particular, participants commented on the pain scale anchors.

"Obviously you can't imagine pain that intense, I haven't had it that bad [laughs]" *(Helen)*

"I would say alright, 'what's the worst ever?' and compare everything else to that" *(Elizabeth)*

"Well I knew that was no pain [0] and this were high pain [10] and I thought well, it's more towards high than it is towards low, so that was why I put it where I put it" *(Isobel)*

The second meta-theme, 'uncertainties about the future', described how participants are still adjusting following their diagnosis and treatment, and consequently 'life looks different now'. They described negotiating a 'need for support', a need which is not always met either because there were difficulties in accessing support or a lack of understanding from others that that support was required, sometimes because they did not understand their prognosis.

"When people sort of say, you know, 'Have you been given the all clear?', I think, you never get the all clear" *(Gina)*

"I know, it's like when you're going through the treatment people don't realise what you're going through, you know what I mean?" (Helen)

"They understand at the time, even though there's nothing they can do, they understand you'll be feeling ill, but afterwards they don't have that same understanding that you're still going to feel quite rubbish most of the time." *(Isobel)*

Participants also described a process of finding out what they are capable of and how others are also involved in this process, either in having their own opinions or by reminding them of their new limitations. There was also discussion about future health and how they were unsure what it would be. Many participants said they were now on annual check-ups and one participant in particular was very positive about mammograms and screening.

The final meta-theme encapsulates three themes about how 'research is beneficial'. Participants described a 'positive experience of taking part', saying that it was convenient, interesting and beneficial.

> *"I mean it shows me how to – it has shown me how to deal with things a lot better and as I say I'm really glad I took part in it"* *(Belinda)*

> *"In fact [laughs] I used to get up in the morning with my cup of tea and straight on here [tablet PC]"* *(Carol)*

Participants also described limitations of the current study, although these were still communicated in a way consistent with 'research is beneficial', with some participants saying that although the 'diaries didn't entirely reflect their experiences', they were glad that it had been attempted and felt that it would be very difficult to truly capture their experiences. One participant said that 'some parts of the study were confusing', because the pain scale and quality of life scale from the EQ-5D were inconsistent, with the former having zero as a positive ('no pain') and the latter having 100 as a positive ('best health'). This led her to check her support booklet, as she expressed a 'desire to be a good participant' and wanted the study to be a success. Additionally, participants also shared a general enthusiasm for research, both within cancer and with other conditions.

As mentioned earlier, the theme of 'technological problems' was kept separate from the three main meta-themes as it is qualitatively different. Within this theme participants described difficulties with equipment or software (both Q-tool and web browsers) and occasionally difficulties in using them. Some of these technological problems were directly related to the study, for example Q-tool was unavailable, or when the email link did not work, whereas others were around the general use of computers by the participants. The diaries were developed in Q-tool for use with a standard sized monitor, but some participants were more comfortable using a tablet PC with a much smaller screen, and therefore experienced some difficulties in navigating through the diaries, although they were ultimately successful in navigating the diaries.

During the interviews a wide range of data were generated. The interview topic guide was consistent with the aims of the research, and included questions and prompts around the experience of monitoring their pain. In these interviews, participants were fully engaged in the discussion about pain monitoring and responded appropriately to the questions and prompts. The

participants often provided context around their answers and opinions and gave reasons for their beliefs, and in doing so discussed their wider experience of having cancer including diagnosis, treatment and beyond. A semi-structured interview allows the researcher to use their discretion during the interview and pursue relevant leads, however, in the main the researcher did not deviate much from the topic guide, other than to clarify meaning. Although the discussion was interesting and of value, it was not an aim of the current research to explore people's experiences of having breast cancer and it was not felt that it would be ethical or appropriate to pursue these discussions in detail. The way in which the participants explained how their experiences shaped their current beliefs was of great value in interpreting the results and shows the value of using a semi-structured qualitative methodology over alternatives such as structured interview or questionnaire. Although these latter methodologies may have generated similar results in terms of monitoring preference, using a pain event definition and predicting pain, the individual rationales behind these would not have been captured.

Another important aspect of the method employed here is that the interview took place after the diary component of the study. This meant that at the time of the interview, the minimum contact that the participants had had with the researcher was a telephone call, a home visit for the induction meeting, 12 daily study email and either email or telephone contact to arrange the interview. In some cases this was an efficient process and there were only four weeks between initial contact and interview. For others this period was much longer, for example due to holidays, illness or other life events. Therefore rapport and trust had been established over a period of weeks prior to the interview taking place which perhaps explains why participants were willing to talk about their thoughts, feelings and experiences within such a short interview.

Discussion

This study aimed to compare event-driven pain monitoring and regular pain monitoring in people who have had breast cancer. This comparison covered accuracy of predictions, completion rate and pain ratings. The study also aimed to explore how pain scales were used to rate pain, how these individuals view their pain 'events' and what their reflections were on making pain predictions. The results will be discussed in relation to the wider literature, followed by a discussion of the limitations of the current study and suggestions for future research.

Aim one: comparing event-driven and regular pain monitoring

Pain ratings

The pain diaries captured a range of pain ratings from zero to seven out of ten, with no observable difference in ratings between event and regular diaries. The intention was to use randomisation tests to systematically compare pain ratings from the two diaries for each individual, and subsequently combine these analyses, but this was not possible due to the variations in numbers of each type of diary completed.

The group level results showed that people perceived less interference from pain if they had a more optimistic outlook and also rated their health more highly, but due to the lack of variability amongst the scores of these measures within the sample it is not possible to determine whether the converse is also true, for example that people perceived more interference from pain if they were less optimistic and rated their health as lower. The results also showed that people felt they had more control over the pain when they rated their health more highly and scored higher on the measure of positive affect. This is unsurprising given the links between mood, quality of life and chronic pain found in the literature (Baliki et al., 2006; Kato et al., 2006). What was interesting was the presence of this understanding in the interview data. Not only were participants aware of their own links between fatigue, mood and pain, but also felt that more explicit mention of this in the study would have been beneficial.

The diaries provided space for respondents to detail briefly what they had done to cope with their pain. Responses were varied and included taking both prescribed and over the counter analgesics, physiotherapy, or massage. However, in the interviews people described other more psychological ways of coping with pain such as taking part in pleasurable activities and seeing friends and family. There are two possible reasons for this discrepancy. First, respondents may not have been aware that such activities constitute coping strategies; second, they may not have felt them to be relevant and instead only responded with more medical coping strategies.

Completion rates

As the study lasted 12 days, with six regular and six event days, full participation would be expected to result in at least the 12 regular diaries being completed, plus any event diaries. However, none of the participants completed all 12 regular diaries. Instead, they completed between three and nine regular diaries. The number of event diaries showed similar variation, with each person completing between none and nine. Eight of the ten participants completed more regular diaries than event diaries. Gina and Helen completed more event diaries than regular diaries and they also reported some of the highest pain levels in the study. It is therefore possible that event diaries may be more relevant to individuals who experience higher levels of pain, and this warrants further exploration.

Some participants emailed or telephoned the researcher to query login details or discuss technological problems, but others did not contact the researcher at all during the diary phase. It would have been reasonable to assume that the reduced completion and lack of contact was indicative of reduced engagement with the study. The end of study interview provided an opportunity to explore this hypothesis, which was subsequently rejected. There were numerous reasons why diaries were not completed, such as technological problems, work demands or lack of computer or internet access, none of which were due to a lack of engagement.

Predicting pain

The thematic analysis showed that although participants used cognitive strategies to help them predict pain, they found it to be a difficult task, although an interesting one. As already described, it was not always possible to determine whether the predictions made were accurate, partly due to methodological limitations and partly due to lack of subsequent diaries following the prediction. Some individuals gave varied predictions in their diaries, even when the diaries were only completed a few hours apart, whereas others gave more consistent predictions, such as ‘don’t know’. As with the rate of diary completion, the repeated use of ‘don’t know’ could have been interpreted as a lack of engagement with the requirement to predict pain, but the interview allowed this hypothesis to be tested and ultimately rejected. Instead, people genuinely struggled to predict their pain because they relied on cognitive strategies to predict pain, which were shown to be problematic when there is no pattern to their pain for example.

In the case of Angela, whose predictions were almost all ‘don’t know’, this not knowing was not distressing for her and instead reflected an acceptance of her new body and a patience in her recovery journey. On the other hand, Faith’s ‘don’t know’ predictions represented an anxiety about a lack of control over her pain, but an ability to predict long-term deterioration in pain over time. Faith’s long-term prediction (the year ahead) was not captured in the diaries and only became apparent in the interview. Carol’s predictions were all that the pain would be the same, and it mostly was. However, despite a relatively consistent low-level pain which she felt she could accurately predict, between the diary and interview she described seeking physiotherapy for the

first time since her treatments at the hospital. These three cases suggest that pain levels and consistency are not necessarily related to the acceptability of pain.

The research literature suggests that prediction is based on past pain experiences (Bubic et al., 2010), however, the interviews highlighted that often patients had not had any cancer-related pain prior to treatment. Therefore the multiple pains experienced by the participants after diagnosis were all new and all different. They reported that pains from radiotherapy, chemotherapy and surgery were all different, and they reported all of these changed differently over time. Therefore there was little prior information for participants to usefully base their predictions on. All participants took part in the study at least two years after their most recent surgery. All described how they thought healing was still occurring, pain was still changing and sometimes participants wondered whether further surgeries were required to alleviate discomfort.

The majority of predictions were that the pain the following day would be the 'same' (44 predictions), followed by 'don't know' (31 predictions), 'more intense than today' (11 predictions), and 'less intense than today' (9). When comparing pain at its worst in the last 12 hours with current pain, the majority of the diaries recorded that current pain was lower (53 diaries). Therefore there did not appear to be a relationship between recent pain experience and short-term future prediction of pain.

There are a number of possible hypotheses for the observation that in only three of the 95 diaries was current pain higher than past pain. First, participants may have waited until their pain had subsided to complete the diary, thus reducing the current pain rating. Second, participants may not have accurately recalled their past pain, and in an adaptive manner could have surmised that their current situation is optimal. Third, the act of completing the diary – sitting down and resting – may have reduced current pain, and the past, higher, pain ratings may have referred to periods of activity.

The second notion of biased recall is consistent with Larkin's idea (1964) that accurate perspectives 'link us to our losses' and therefore a revised or distorted view avoids the pain of loss. In the three diaries where current pain was highest, there is a loss compared to the previous 12 hours. For some the loss might be minimal, but for others it could be much greater: sleep, quality of life, functionality and wellbeing.

Aim two: Explore how individuals understood their pain

Defining a 'pain event'

For all of the participants defining a pain event was a novel task. Despite this, all participants were able to construct a definition with minimal prompting. Two participants, Angela and Diane, defined a pain event as pain which would require them to take analgesic medication. Carol defined a pain event as rating 7 out of 10 or more on a 0-10 pain scale. Four participants defined a pain event by the nature of the pain, saying that pain which was shooting, burning or stabbing would

constitute an event. Seven of the ten pain event definitions included the impact of the pain on their daily lives, such as pain which causes them to stop or amend their activity at the time of the pain.

Scaling pain

The scaling task was completed at the end of the interview and was the last part of the study for the participants. The placement of the IMPACCT words were consistent for the extreme poles, but varied considerably in between, with one participant even placing two labels in a different order. This is the first time that the IMPACCT labels have been explored in this way and it is hoped that the results will assist future design and analysis within the project. Of particular interest was the curvilinear line of best fit for the label ratings, which suggests that the 11 markers on the scale are not equidistant in people's minds. This provides further support for the notion that a pain scale is not a ratio scale and caution should be used when interpreting the results. The study by Storto et al. deemed analgesia to be a success if the pain scale rating reduced by one or more points. However, if the scale is curvilinear, a one point decrease at the extreme represents a much smaller change than a one point decrease at the midpoint and caution must be used when measuring outcomes in this way.

Participants also chose intensity and affect words and placed them on the same 0-10 scale. The words chosen varied greatly with just one label chosen by all nine participants: 'uncomfortable'. The list included some related labels, such as 'bearable' and 'unbearable', 'tolerable' and 'intolerable', 'strong' and 'very strong', 'intense' and 'very intense'. However, participants did not necessarily choose both words and often just chose one, which was unexpected. Additional words were chosen by three participants, who chose one word each. One chose 'niggling', a colloquial term for irritating, which she had also chosen but placed lower on the scale. One chose 'very uncomfortable', in addition to choosing 'uncomfortable' from the list. One participant simply chose 'hurting', which is a useful reminder that even with all the advanced research and focus on complexity, pain simply hurts. Overall these intensity and affect labels covered a much broader range than the IMPACCT labels, both in terms of each individual label and the overall amount of the scale covered once all labels had been used. For five of the nine participants the IMPACCT labels were mutually exclusive, the same is true for only one participant for the intensity and affect labels. Even when the range on the intensity and affects labels were smaller, they still filled the gaps left by the IMPACCT labels.

In both of these scaling tasks numerous approaches were taken by participants. While some portioned the scale into two and dealt with each part separately, others placed anchors first and then thought about the centre, others worked their way along from one end and others were guided by the labels, placing them on the scale one at a time. It does not appear that methodology impacted on the results in any way, but this may be worth exploring further and should be taken into account when providing instructions for such tasks.

This scaling task suggests that although it is possible for people to use predetermined intensity labels and place them on a pain scale, they do not do so consistently, even with such a small sample of just nine people. Additionally, such labels do not cover the entire 0-10 scale, with many points left bare, and for almost half of the participants the labels were not placed discretely on the scale. The current study also supports previous research by Williams et al. (2000) that found factors other than intensity influenced pain ratings, such as affect and physical limitation. Current pain may also affect such scaling tasks. For example, although Carol used the full range of the scale when assigning the IMPACCT labels, she only applied other labels to the lower half of the scale, which is where she rated her pain during the study. This raises questions about how stable the use of pain scales is over time as pain changes.

These scaling results also suggest that in this group of individuals the ongoing less intense pain impacts on people's wellbeing just as much, or in some cases more than, brief pains of a higher intensity. Intense shooting pains for example were described by participants as manageable because they are so short-lived and because they decrease in frequency over time as healing occurs. This may also explain the lack of relationship between pain intensity and interference; the scaling task results suggest that the lower levels of pain can interfere more due to their longevity both in terms of how long the pain lasts and over what period of their life they have experienced such pains.

This may help explain the reluctance of many of the participants to take analgesics. If the worst pain for them to live with is the constant background pain, then constant analgesics would be required, and it is this dependency which they described wanting to avoid. Given that both the literature and participants describe a relationship between mood, fatigue and pain, there may be an underlying belief that analgesia is not sufficient to lead to improvements if the other two issues – mood and fatigue – are not also addressed. Additionally, participants also expressed concern over side effects of analgesics including those that would contribute to fatigue or low mood, so again perhaps it is the connectedness of pain, mood and fatigue that has led them to reject a single approach to pain management.

Unanticipated findings

In addition to completing the two main aims of the research, other findings emerged which were not planned for but made an important contribution to the study.

For example, many participants talked of their 'pain threshold' either when defining their pain event or when completing the scaling task. The concept of a pain threshold was not within the scope of the current study as it is a broad and challenging topic for many reasons such as a lack of consistency of definition, questionable utility and strong lay narrative. However, the interviews showed that for a number of individuals it is an ever-present concept which had an impact on their pain ratings. For some, the pain threshold was synonymous with a pain event – the pain was over their 'threshold' – while for others reaching their threshold prompted

behavioural change such as resting and/or taking medication. Given that for some people their assessment of pain in relation to their pain threshold determined their medication consumption, the exploration around pain threshold might be of use when applying research findings to clinical practice.

Methodology

Strengths

This study used a mixed methods replicated single case design as a group design would not sufficiently capture people's individual experiences. Given the variability of pain experiences captured in this study both within and between individuals, it appears that the single case approach was the most appropriate methodology. It is particularly suitable to this population of people, those who are 2+ years post-treatment, who currently rarely feature in cancer pain research in their own right, and therefore little is known of the norms of such a group in regards to pain. The t-tests showed that there was no significant difference in the mood and quality of life measures completed at the start and end of the study, which supports the interview data that there were no detrimental effects of taking part in the study.

The pain diary responses provided an opportunity to compare the content of the regular and event diaries, where no difference was found. Additionally this study used the interview to gain a better understanding of the diary results, and this also showed that there was no preference for either event or regular diaries. Some jokingly referred to a preference for the one which required least completion, but for some participants this was the event diary, because they had so few pain events, whereas for others it was the regular diary, as they experienced a number of pain events. They reported that this preference might only emerge more strongly if the study was over a longer time period than 12 days.

This study combined a number of methods to explore pain ratings, interference, control, scaling pain and predicting pain, providing a rare opportunity to explore these aspects of pain within the same individuals. The results showed that individuals varied greatly in their responses to the various parts of the study, providing further support for the notion of single case research over group studies when exploring the idiosyncrasies of the pain experience.

It was not known whether each participant's pain event definition might evolve over the course of the study, but it was found to be consistent. One participant said that one pain event, a severe headache, might not have fitted her definition but she said that if it had occurred on an event day she would have used her own judgement and completed a diary anyway. It is not known whether this consistent use of the definition is due to the short time frame of the study, the clarity and specificity with which it was defined or that pain events are truly constant. Given that for all ten participants it was the first time they had encountered the idea of a 'pain event' and then gone through the process of defining one, it is somewhat surprising that it was so straightforward, but

does suggest that this might be an effective way to describe and monitor pain in a consistent and patient-centred manner.

The research literature sometimes divides pain into 'background pain' and 'breakthrough pain', the latter of which is often poorly defined (Haugen, Hjermstad, Hagen, Caraceni, & Kaasa, 2010), but is generally understood as a brief increase over and above background pain (The British Pain Society & Royal College of General Practitioners, 2004). While for some participants their pain events would fit with the various definitions described by Haugen et al., not all would, and not all pain events were 'brief'. However, the pain events in this study not only affected their quality of life but also their day to day lives and important decisions such as whether to continue in paid employment. Pain events also featured in the scaling task, influencing both the placement of the IMPACCT labels and the intensity and affect labels. This suggests that the notion of a 'pain event' may have more utility than merely defining 'breakthrough pain': exploring pain events has the potential to improve both pain research and clinical pain management.

This study differed from many published in the literature in that it did not focus on 'cancer pain', but instead on 'pain in people who have had cancer'. That is, the study included all pain, not just pain related to their cancer treatment. This approach was supported in both informal conversations during the enrolment meeting and in the interview, where participants described difficulty in understanding or interpreting pain: they did not always know whether a given pain was related to their cancer (or treatments) or not, and consistent with the research literature, many pains were interpreted as a sign that cancer had returned (Brummett, 2011). This suggests that attempts to distinguish between pains from cancer and pains from other causes is somewhat unrealistic. Although this study did not aim to be representative, there was a desire to capture the variability of pain experiences that might be observed in the whole population of post-treatment breast cancer survivors.

One participant excluded what she deemed to be 'irrelevant' pains from the study (e.g. old injuries), informing the researcher of this at the end of study interview. On one hand these 'irrelevant' pains appeared to be discrete in that they were limited to an isolated part of the body distal from parts of the body affected by breast cancer or its treatments. On the other hand they were not truly independent at all: the participant reported that these 'separate' pains from injury sometimes contributed to fatigue or medication decisions, thereby affecting the 'relevant' pains. Systemic analgesics consumed to help manage leg pain will also impact upon breast or arm pain. For the other participants pains from comorbidities, injuries or hormone therapies were all recorded in the diaries. In the interviews participants described how despite knowing the causes of other pains, such as injury or hormone therapy, these pains were associated with fear that the pain may instead be from cancer returning. When the rationale for including all pain was explained to the participants – that the aim was to understand the pain experiences of this group of people – many commented with relief that they were to be treated like a 'whole human being'.

Limitations

As described above, this study included all pains experienced by individuals who have had breast cancer, and did not distinguish between cancer-related pain, such as that from treatment, and other pain. While this is justified on a number of levels, it may have been beneficial to explore this distinction, or lack, of, more explicitly in the interviews. This would have allowed all individuals to consider the impact of the various pains on their lives and also explore whether they had different views or responses to pains which were perceived to have different causes with differing threat levels.

The present study used an established question to ask participants whether they thought their pain tomorrow would be 'more intense', 'less intense' or the 'same as today' (or 'don't know'). This is a general question which does not specify *which* aspects of the pain may be increased or decreased. While this gives the participant greater flexibility in answering the question, it may also be too vague. In this study, even though the majority of participants said that they were 'good' at predicting their pain, in many of the diaries the response to this prediction question was 'don't know'.

This study used an online tool to collect responses to the mood and quality of life measures and the pain diaries. Anecdotally concern was expressed over how accessible the study would be, but the online nature did not appear to present a significant barrier. Two individuals who received information sheets did not take part because they did not own a computer, and a third individual said she had a computer but did not use the internet. During these screening conversations with the researcher, some potential participants expressed anxiety about whether they would be capable of the study. In response the researcher reassured them that the study had been designed to be user-friendly and if they already did online shopping or communicated by email, they should have the required ability to take part. All participants said that they already used the internet in this way and were relieved that they would be able to take part. In the enrolment meeting the degree of guidance needed to complete the baseline measures varied greatly. Some participants sped through unassisted while others needed more guidance; the researcher was satisfied that all were competent at the end of the meeting. The support booklet was given at the enrolment meeting and the researcher regularly referred to specific parts of it when introducing Q-tool, in the hope that it would be easier to find what they needed in the booklet later. All participants reported that they found the booklet useful but most only referred to it for their login details.

There were numerous points of contact with each participant during the study. There was an initial telephone call, an enrolment meeting, telephone or email contact during the diary phase to answer any queries, and further telephone or email contact to arrange the interview. The only data collected were the pain event definition, diaries and interview, but other contacts provided useful insights. In future studies of this type consideration should be given to recording all interactions to ensure that these insights are not lost.

Wider implications

IMPACCT

This study was an adjunct to the Leeds IMPACCT research. Although IMPACCT and the current study recruited individuals at two different stages, namely advanced cancer or post-cancer, it is hoped that findings from the current study will be of use to the IMPACCT research. For example, some of the difficulties and solutions encountered with Q-tool will be of use, including both researcher and participant feedback. Additionally, the scaling task using the IMPACCT words revealed some unexpected results and might therefore need to be considered in both the methods and analyses in the IMPACCT research.

Survivorship

Although this study focussed on pain, participants spontaneously discussed their experiences of diagnosis and treatment, including the decisions around these, and the importance of support during and after these events. As more people with breast cancer survive, and people are diagnosed earlier, it appears that existing support networks must adapt to ensure that they are as inclusive as possible in order for people to feel supported in the years after their treatment has finished. This is of particular relevance when participants described their gratitude and faith in the hospital service, considering that this may be time limited in the future as annual check-ups move to primary care. As discussed in the Introduction, many of the resources and information available to members of the public is provided by cancer charities. Their focus is in reducing cancer deaths and therefore their efforts target prevention, detection and treatment, not life afterwards. Perhaps an unintentional consequence of this is that people who have survived cancer, who have 'beaten' it, become lost in public consciousness and there is no unified effort to identify or meet their needs.

Such annual check-ups for survivors of cancer require individuals to recall their past pain and predict their future pain. The current study and previous literature suggests that the main strategy for these processes is a cognitive one, which relies on being able to recall patterns in past pain experiences. The majority of participants said that their pain does not have a pattern and they could not confidently predict their pain. However, the majority of participants felt that their pain was sufficiently managed, and for the most part did not interfere with daily activities, and therefore in this group of participants short term prediction of pain may not be relevant. Longitudinal studies may identify a benefit of longer term pain prediction and monitoring in this population however, such as over a period of a year, which is more in keeping with the frequency of check-ups.

The current study is deemed to be a success in that patients were willing to take part and participants engaged well, with only one participant not completing the interview. Participants did not express any strong preference for event or regular diaries, and reported that they found

taking part to be a positive and beneficial experience. Some even re-evaluated their pain management and made significant changes, resulting in self-reported improved quality of life. It is proposed that the success of the study in terms of engagement and use of the diaries was due to 'common factors'. The participants received a personalised email every day from someone they had met in their own home who had taken time to explicitly discuss their pain. In the interviews participants said that they had no preference for the event or regular diaries, and instead it was the knowledge of what was expected of them that led them to feel comfortable and confident in completing the diaries.

It is proposed that the content or completion pattern of such diaries is as important as the relationship within which the monitoring takes place. This is of relevance when considering the discussions around online remote monitoring and efficiency. For example, a cancer centre which is short staffed may look to online remote recording to receive symptom information from patients in order to alleviate pressures on staff by reducing face to face clinic appointments. The present study suggests that it is the common factors – the home visit, named contact person and personalised daily contact which led to engagement with the online tool, all of which are perhaps not conducive to reduced staff time, but instead a *different* use of time. In short, online monitoring is not a 'quick fix' and cannot substitute the benefits of an effective working relationship between healthcare professional and patient, but could feasibly provide an enhanced service where that effective working relationship is already in place.

A number of studies and reviews have identified younger age and higher acute post-operative pain as risk factors for long term breast pain. The results of the current study suggest that at least some of the participants used past experiences of pain to make sense of their current pain, particularly in the scaling task. As we go through life we experience a number of painful events. Could it be therefore that younger women have had fewer pain experiences and it is therefore more likely that their breast pain is their worst pain? Could it also be true that for younger women pain has a greater level of interference in daily tasks? It is important that research considers these possibilities, for example by ascertaining participants' previous pain experiences (for example surgery, childbirth, tooth abscess, migraine, burns, amongst others).

Future developments

The present study asked participants whether they thought their pain tomorrow would be 'more intense', 'less intense' or the 'same as today' (or 'don't know'). This could be developed by asking participants to use the 0-10 scale to overtly predict either their worst pain tomorrow, and/or their average or overall pain tomorrow. Inclusion of a 'don't know' option would need careful consideration, as would an option to rate the confidence in their prediction, which has been used in some other studies. The use of a numeric prediction would provide more opportunity to assess the accuracy of people's pain predictions. In the current study, a prediction was treated as accurate if on the following day their pain ('pain right now' or 'worst pain in the last 12 hours') had

changed in the direction they had stated. If someone had rated their pain as 2 out of 10 and predicted that they would have more pain the following day, perhaps predicting 3 out of 10, but in fact they experienced 9 out of 10, is this prediction accurate? The direction is consistent with the prediction, but the magnitude is not. Other additional questions may be of use, namely asking participants to predict their pain both tomorrow and the day after; and to ask participants about their worst pain in both the last 12 and 24 hours. These two additional questions would provide greater opportunity for overlap and comparison.

The literature has identified that pain prediction is based on past pain experiences. Breast cancer itself rarely causes pain, and it was therefore assumed that these participants did not experience pain related to breast cancer until they began treatment, an assumption which was then confirmed in the interviews. However, this is unlikely to be the case for all other potential participants. It may be beneficial therefore to build on the current design and include a pre-diary interview where participants can describe their pain history in relation to their cancer and treatment but also other life experiences which may affect how they view their pain such as other surgeries, childbirth, or seeing loved ones experience cancer treatment.

The study design could also be developed to increase the likelihood of more consecutive diaries by having each phase last longer than two days. This means that even if someone does not experience any pain events during the study there is still opportunity to allow more detailed and robust analysis of pain predictions.

In the present study it was only possible to correlate mood and quality of life ratings with overall summary data for each person. As some participants suggested in the interviews that their pain ratings and predictions were affected by mood and fatigue, and that they would also tolerate longer diaries, it might be beneficial to add a mood rating and brief details on daily activity and fatigue to each diary. This would allow the degree of variation in mood within individuals to be investigated alongside its relationship to variation in pain levels.

Similarly, this study did not investigate catastrophizing which has been shown to have a strong relationship with pain and predicting pain. It was felt that it was not possible to explore catastrophizing within the scope of the current study although it would have fitted well into this mixed methods design.

Participants varied greatly in their responses to the scaling task, showing that they all used the pain scale very differently, and not necessarily consistently. For example on some days people might have completed their pain scale based on intensity while on other days based on mood or interference. It might therefore be useful to ask participants to label their current pain rating using both numbers and one of the labels in the scaling task. This would allow a further analysis of prediction and interference based on not just the current pain rating but the nature of the current pain.

There are a number of possible avenues for future work following on from the results of the current study. For example, one participant suggested carrying out the scaling task at the

beginning of the study as she 'hated' 0-10 scales, partly due to difficult past experiences where she had felt corrected on her ratings by a doctor, but reported that she found the scaling task helpful in understanding how she wants to use the scale. Similarly the scaling task could be developed by including a free recall task asking people to describe their pain, then ask them to rate those words, then carry out scaling task as it is presented here.

The interview aimed to explore participants' experiences of taking part in the study. For most of the participants this led to a broader discussion of the existential impact of cancer. One participant suggested exploring survivorship in more detail and what quality of life is like after multiple surgeries and taking part in clinical trials, which some of these participants had. Another participant suggested exploring people's views about mortality – both patients and doctors – and how this is talked about. She was aware that she was an 'early survivor' and that there is a lack of information both in terms of figures and exploring attitudes and beliefs around this changing landscape in cancer care. She described how statements from doctors such as 'I fully expect you to live 10 years' were difficult to interpret, and did not feel that the doctor themselves had an informed view of the future for her personally or for her cohort.

Similarly it would be beneficial to explore identity in more detail in relation to pain after cancer. The thematic analysis showed that participants reported that their pain felt more manageable when they knew more about it, and also expressed a desire to know about other participants and other patients whom they met during treatment. Cancer and particularly breast cancer is associated with a strong female 'fighter' identity, but is this still the case when all treatments are completed? What about when their care is back with their GP rather than in a specialist cancer centre? Interestingly many participants never said the word 'cancer' during their interview. A thematic analysis is not normally concerned with specific vocabulary, but other methodologies such as discourse analysis could reveal new insights into how identity is constructed in this group of people. Some now view cancer as a chronic condition, something to be lived with, and it would be interesting to explore this in more detail. If someone has been cancer free for many years but still experiences pain from their past treatments, would they still identify as a cancer patient, or as a chronic pain patient? How might this identity be linked to the services in which their needs are addressed?

In conclusion, there are a number of possible future developments. Many of these have been highlighted by the participants themselves, often unprompted, further supporting the importance of engaging current and past patients when planning research.

Summary

Pain is present in at least half of the individuals diagnosed with breast cancer, but less is known about the prevalence, type or levels of pain experienced by individuals in the years after their treatments have finished. This study used a mixed methods case series design which aimed to investigate the levels and type of pain, but not the prevalence, as the sample was small. The pain diaries and interviews revealed a longstanding complex relationship with pain which individuals are still negotiating.

This study has shown that it is difficult for people to accurately predict their pain over a short time frame, which is of importance in clinical practice where patients may be expected to predict their pain until their next appointment. Perhaps most importantly for clinical practice this study has shown that individuals are willing and capable to monitor their pain and its impact using an online tool, even when they did not initially feel confident in doing so. This study did not identify any negative consequences of pain monitoring, as participants found the process interesting and useful, with some making proactive changes to their lifestyle and pain management as a result of the study.

In summary, this study shows that effective pain management in individuals years after breast cancer surgery is still difficult to achieve, but online pain diaries provide a useful first step in monitoring and discussing pain and its management.

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Appendices

Appendix A: Ethical approval

NHS
Health Research Authority
NRES Committee Yorkshire & The Humber - Leeds East

North East REC Centre
Room 002
TEDCO Business Centre
Viking Industrial Park
Rolling Mill Road
Jarrow
NE32 3DT

Telephone: 0191 4283545

18 October 2013

Miss Stephanie Andrews
Psychologist in Clinical Training
Leeds Teaching Hospitals
Leeds Institute of Health Sciences
Charles Thackrah Building, 101 Clarendon Road
University of Leeds
LS2 9LJ

Dear Miss Andrews

Study title: **Understanding pain in people with breast cancer**
REC reference: **13/YH/0288**
IRAS project ID: **128206**

Thank you for your letter of 13 October 2013, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Vice Chair.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the REC Manager Hayley Jeffries, nrescommittee.yorkandhumber-leedseast@nhs.net

Confirmation of ethical opinion
On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

A Research Ethics Committee established by the Health Research Authority

Appendix B: Research & development approval

Claire Thompson
Reissued

20/03/2014

Miss Stephanie Andrews
Leeds Teaching Hospitals
Leeds Institute of Health Sciences
Charles Thackrah Building, 101 Clarendon Road
University of Leeds
LS2 9LJ

Dear Miss Stephanie Andrews

Re: NHS Permission at LTHT for: Understanding pain in people who have had breast cancer
LTHT R&D Number: MO13/10964
EuDRACT:
REC: 13/YH/0288

I confirm that *NHS Permission for research* has been granted for this project at The Leeds Teaching Hospitals NHS Trust (LTHT). NHS Permission is granted based on the information provided in the documents listed below. All amendments (including changes to the research team) must be submitted in accordance with guidance in IRAS. Any change to the status of the project must be notified to the R&D Department.

Permission is granted on the understanding that the study is conducted in accordance with the *Research Governance Framework for Health and Social Care*, ICH GCP (if applicable) and NHS Trust policies and procedures available at http://www.leedsth.nhs.uk/academic/research-development/

This permission is granted only on the understanding that you comply with the requirements of the *Framework* as listed in the attached sheet "Conditions of Approval".

If you have any queries about this approval please do not hesitate to contact the R&D Department on telephone 0113 392 2878.

Indemnity Arrangements

The Leeds Teaching Hospitals NHS Trust participates in the NHS risk pooling scheme administered by the NHS Litigation Authority 'Clinical Negligence Scheme for NHS Trusts' for: (i) medical professional and/or medical malpractice liability; and

Appendix C: Breast care clinic audit

The Leeds Teaching Hospitals NHS
NHS Trust

Breast Care Unit
Chancellor Wing
St James's University Hospital
Beckett Street
Leeds
West Yorkshire
LS9 7TF
Tel: 0113 2068628
Fax: 0113 2068281

Unit No:

Q1. What type of surgery did you have? (please tick all that apply)

- ☐ Wide Local Excision/lumpectomy
- ☐ Sentinel Lymph Node Biopsy
- ☐ Second Wide Local Excision/lumpectomy
- ☐ Axillary node clearance
- ☐ Mastectomy
- ☐ Reconstruction

  Which type: .....

  Was the reconstruction done at the same time as your Cancer surgery or at a later date? .....

Q2. Did you have any other treatments? (please tick all that apply)

- ☐ Tablets (please state which one).....
- ☐ Radiotherapy
- ☐ Chemotherapy
- ☐ Herceptin
- ☐ Other (please specify).....

Q3. Do you have any on-going pain?

- ☐ Yes
- ☐ No

Q4. If yes, where is the pain?

- ☐ Breast area
- ☐ Armpit/arm
- ☐ Other (please specify where).....

Q5.Do you take any painkillers for this specific pain? If yes, what do you take and how often?

- ☐ No
- ☐ Yes
- ☐ Type of Painkillers taken and how often.....

Q6. Have you ever been given any information/advice on pain and how useful was the information you were given?

- ☐ Extremely useful
- ☐ Very useful
- ☐ Moderately useful
- ☐ Slightly useful
- ☐ Not at all useful

Q7. It is possible we may do a future study on long term pain issues. Would you be interested in helping with such a study?

- ☐ Yes
- ☐ No

Q8. If yes, would you be happy for a Breast Nurse to contact you?

- ☐ Yes
- ☐ No

Thank you very much for taking the time to complete this survey.
If you have any questions, please feel free to ask a member of staff or contact Sue Hartup (Breast Care Research Nurse) on 0113 2068628

Appendix D: Participant information sheet

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Understanding pain in people who have had breast cancer

Participant Information Sheet

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is taking place and what it would involve for you. We will go through this information sheet with you and answer any questions you may have. Please talk to others about the study if you wish. Please ask if there is anything that is not clear.

What is the purpose of the study?

There are many different ways for someone to monitor their pain. This study will look at two different ways of monitoring pain. We are also looking at how people predict how much pain they will have each day.

Why have I been invited to take part?

You have been invited to take part because you are a patient in the Leeds Cancer Centre at St James's University Hospital, Leeds, you have previously been diagnosed with breast cancer and you experience pain.

Do I have to take part?

It is up to you to decide to take part in the study. If you agree to take part, we will ask you to sign a consent form, and you will get a copy of this. You are free to withdraw at any time without giving a reason. This would not affect the standard of care you receive. Although you have expressed an interest in the study, we cannot guarantee that you will be eligible to take part. This will be discussed with you when you meet with the researcher.

What will happen to me if I take part?

Taking part in the study will not affect your normal treatment. We would like to recruit up to 20 people for this study. First of all your nurse will tell you about the study during a telephone call. She will ask if you are interested in taking part, and if you are, the researcher will call you to answer any questions about the study and arrange an enrolment meeting with you, which will most likely be at your home, or at St James' if you prefer. This meeting will last no longer than one hour. In this meeting we will:

- ask you some questions about your pain
- introduce you to the online program which you will use during the study
- complete some quality of life and mood questionnaires using the online program
- answer any questions you might have about the study or the program

IRAS Project ID: 13/YH/0288 (126206) Version 5 June 2014

After this meeting you will be asked to record your pain over a two week period. There are two different ways to record your pain, and you will receive an email each morning explaining what you need to do each day. Each day you will be asked how much pain you have, how much it is interfering with your daily life, and what you think your pain will be like tomorrow. In one type of monitoring we will ask you to complete your online pain ratings once in the morning and once in the evening. In the second type of monitoring we will ask you to complete your online pain ratings only if you experience a pain event, which we will have discussed in the enrolment meeting. On the last day you will be asked to complete the same mood and quality of life questionnaires which you completed in the enrolment meeting.

After these two weeks are finished, you will meet with the researcher again to take part in a short interview lasting 30-45 minutes to ask you about how you found recording your pain for those two weeks. This interview would normally take place in your home, or at St James' if you prefer. The interview will be recorded on a secure digital audio recording device and this recording will be treated confidentially and will be deleted after the study has finished. The interview will be transcribed by an individual familiar with transcribing sensitive recordings who has signed a confidentiality agreement. After the interview, your participation in the study will be complete and you will not be asked to do anything else for this study.

Do I need any special equipment?

To take part in this study you will need a computer or laptop with an internet connection. All of your pain ratings will be recorded using a secure website which uses your normal browser (e.g. Internet Explorer or Firefox). No new software or hardware will be added to your computer.

Expenses & payments

There is no financial reimbursement for taking part in this study. The study has been designed so that there is little or no expense incurred by participants.

What are the possible disadvantages and risks of taking part?

Some people find that focussing on their pain in a study of his type may increase their pain, but this is rare. If you are concerned about your pain at any time during the study, or if you become distressed, please contact your specialist nurse in the medical team at St James's Hospital.

What are the possible benefits of taking part?

There are no direct benefits to taking part in this study, but the information we get from this study will help improve understanding of how to monitor pain in breast cancer patients.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this by contacting the Patient Advice and Liaison Service (PALS).

Will my taking part in the study be kept confidential?

Yes, unless there are exceptional circumstances when the researcher identifies concerns about your safety or the safety of others around you. If this situation arises the researcher will consult supervisors where possible before sharing any information. We will follow ethical and legal practice and all information about you will be handled in confidence. All information will be stored securely and anonymously in accordance with the Data Protection Act. The information you give will only be used in this study, and not for anything else. The only people who will see the information are the chief investigator and two supervisors. Information will be kept securely for three years after the study has finished, and then the information will be disposed of securely.

What will happen if I don't want to carry on with the study?

If at any point during the study you decide you don't want to carry on taking part, you can withdraw from the study without having to give a reason. All the information already collected will be retained in the study.

What will happen to the results of the research study?

The results will be written up as part of the researcher's Doctorate in Clinical Psychology qualification. The results will also be submitted for publication in a peer-reviewed journal. If you would like a copy of the results, please let the researcher know and a summary will be emailed to you when the study has been completed. You will not be identified in any publication.

Who is organising and funding the research?

This study is being carried out with the University of Leeds and the Leeds Teaching Hospitals NHS Trust.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the Leeds East Research Ethics Committee.

Appendix E: Consent form

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Understanding pain in people who have had breast cancer

Consent Form

Researcher: Stephanie Andrews

Please read each statement and write your initials in the box.

1. I confirm that I have read and understand the information sheet dated..... (version.....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I agree that the interview will be recorded on a secure digital audio recording device and I understand that this recording will be treated confidentially and will be deleted after the study has finished. ☐
3. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐
4. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐
5. I agree to take part in the above study. ☐

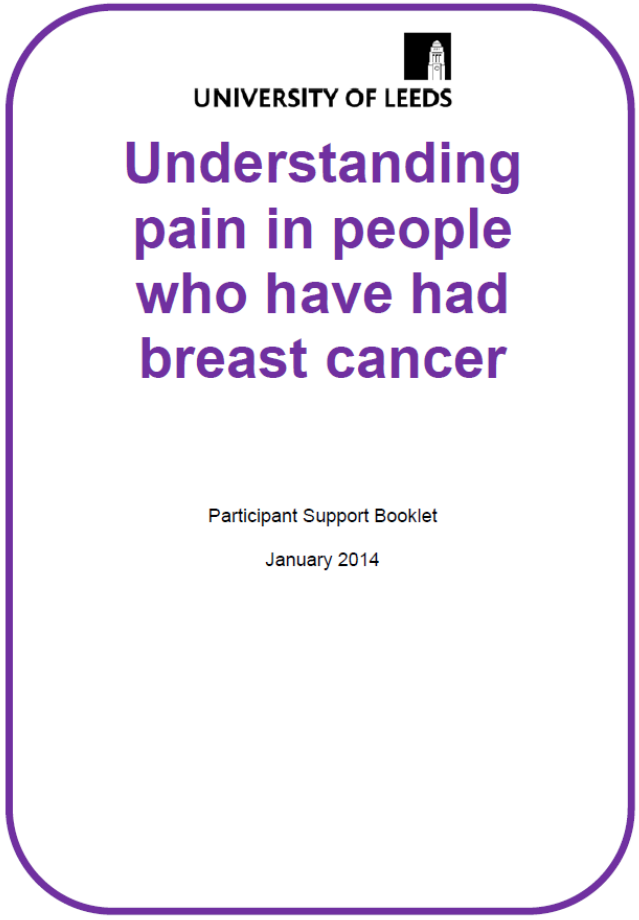
Participant name	Participant signature	Date
Researcher name	Researcher signature	Date

IRAS Project ID: 13/YH/0288 (126206) Version 2 January 2014

Appendix F: Pain event definitions

Participant	*Definition or criteria*
Angela	• Take prescribed pain medication
Belinda	• May have to stop current activity, or
	• Continue with current activity in an amended way
Carol	• 7/10 or more
	• May have to stop/pause current activity and rest
Diane	• Range of movement is reduced
	• Take paracetamol
Elizabeth	• Have to stop or amend current activity
Faith	• Have to stop and rest
Gina	• Stabbing or shooting pains which cause a sharp intake of breath
Helen	• Shooting pains in chest or arm
	• Cramping in hand
	• Have to stop and rest
Isobel	• Stabbing pain in chest
	• Pain in joints which prevents usual activities
Julie	• Shooting pain
	• Burning pain

Appendix G: Participant support booklet



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Understanding pain in people who have had breast cancer

Participant Support Booklet

January 2014

Understanding pain in people who have had breast cancer

Thankyou for agreeing to take part in this study. This booklet should help you with any queries you may have during your participation in the study.

This booklet contains:

My 'pain event'

Useful numbers

Stephanie Andrews

Chief Investigator

Psychologist in Clinical Training

University of Leeds & Leeds Teaching Hospitals NHS trust

Tel: 0113 343 2732 (please leave a message with the admin staff and I will get back to you)

Email: umshan@leeds.ac.uk

Bexley Wing

St James' University Hospital

Leeds Teaching Hospitals

Tel: 0113 243 3144

Patient Advice and Liaison Service

Patient Experience Team

St James's University Hospital

Trust Headquarters

Beckett Street, Leeds

LS9 7TF

Tel: 0113 206 6261

Email: patient.relations@leedsth.nhs.uk

What you need to do

Taking part in the study will not affect your normal treatment. In today's meeting we will:

- ask you some questions about your pain
- introduce you to the online program which you will use during the study
- complete some quality of life and mood questionnaires using the online program
- answer any questions you might have about the study or the program

After this meeting you will be asked to record your pain over a two week period. There are two different ways to record your pain. In both types you will be asked how much pain you have, how much it is affecting your daily life, and what you think your pain will be like tomorrow. In one type of monitoring we will ask you to complete your online pain ratings once in the morning and once in the evening (about 12 hours apart). In the second type of monitoring we will ask you to complete your online pain ratings only if you experience a pain event, which we will have discussed in the enrolment meeting. You can write your definition of a pain event in this booklet to remind you. You will switch between the two types of recording over the two weeks.

You will receive an email each morning explaining what you need to do each day, and the correct questions will be there waiting for you so you don't need to worry about completing the correct questionnaire. On the last day you will also be asked to complete the same mood and quality of life questionnaires which you completed in the enrolment meeting.

After these two weeks are finished, you will meet with the researcher again to take part in a short interview lasting 30-45 minutes to ask you about how you found recording your pain for those two weeks. This interview would normally take place in your home, or at St James' if you prefer. The interview will be recorded on a secure digital audio recording device and this recording will be treated confidentially and will be deleted after the study has finished. After the interview, your participation in the study will be complete and you will not be asked to do anything else for this study.

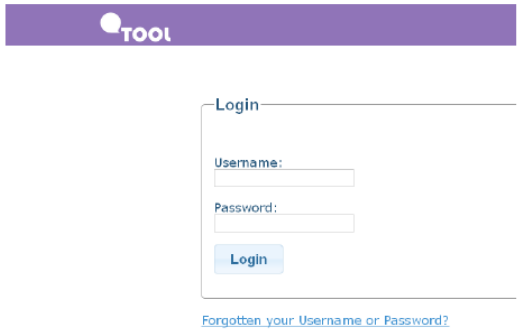
How to record your pain ratings

To take part in this study you will need a computer or laptop with an internet connection. All of your pain ratings will be recorded using a secure website which uses your normal browser (e.g. Internet Explorer or Firefox). No new software or hardware will be added to your computer.

Each morning you will receive an email to let you know whether you will be recording your pain in the morning and evening, or only when you experience a pain event. This email will have a link to the secure webpage.

The address of the webpage is https://qtool.leeds.ac.uk/account/participantlogon/xlab

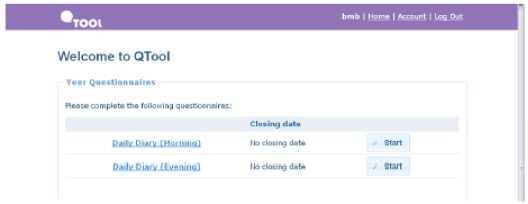
When you type in the address (or click on the link in the email) you will see this page:



You will need to log in using the username and password which were given to you at the enrolment meeting. If you like, you can write them on this picture so that you can remember them.

If you forget your username or password, please email umshan@leeds.ac.uk as soon as possible and we will help you.

Once you are logged in, you will see a page that looks something like this. It will list any questionnaires which you can complete. Please note that this page will look different on different days, depending on whether you are monitoring your pain in the morning and evening or when you experience a pain event. The correct questionnaire will be there waiting for you, so there is no need to worry about filling in the wrong one.



As you go through the questionnaires, there will be a progress bar at the top of the page showing you where you are in the questionnaire, which looks like this:

You will need to complete the questionnaire in one sitting – you cannot log out and return to it later. Please ensure that you complete the questionnaire and press submit on the last page.

Understanding pain in people who have had breast cancer

There are a few different types of questions. One type is multiple choice, where you click the circle next to your choice. The circle will turn green.

PAIN / DISCOMFORT

- ○ I have no pain or discomfort
- ● I have slight pain or discomfort
- ○ I have moderate pain or discomfort
- ○ I have severe pain or discomfort
- ○ I have extreme pain or discomfort

Another type of question has a sliding scale. When you first see the scale, the block will be at zero. Click the block and drag it to the number you choose. If you want to leave it at zero, just click on the block once.

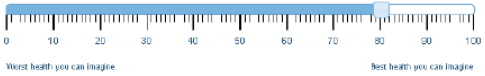
We would like to know how good or bad your health is TODAY.

This scale is numbered from 0 to 100.

100 means the best health you can imagine.

0 means the worst health you can imagine.

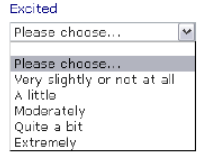
Click on the scale and then move the slider to indicate how your health is TODAY.



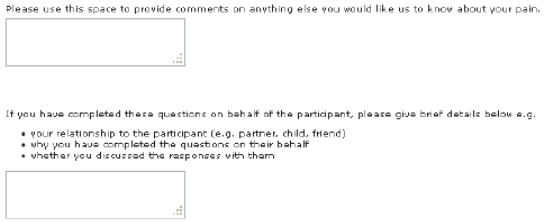
Understanding pain in people who have had breast cancer

Another type of question has a drop-down box for you to choose your answer.

When you click on 'please choose...', a list will appear like this:

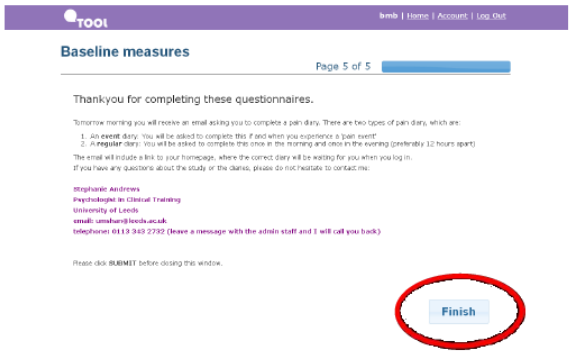


The last type of question is one where you can type a short answer. There will be a box under the question where you type your answer. You do not have to type anything if you don't want to.



Understanding pain in people who have had breast cancer

When you have finished the questionnaire, please make sure you press FINISH otherwise your answers will not be recorded.



This is what the homepage will look like when a regular diary day has been completed (one morning diary and one afternoon diary). The pain event diary stays open all day.

If you have any questions or queries, please do not hesitate to contact Stephanie on 0113 343 2732 (please leave a message with the admin staff and I will get back to you) or email umshan@leeds.ac.uk .

Understanding pain in people who have had breast cancer

Support Booklet Feedback

What have you found helpful about this booklet?

What has not been so helpful in this booklet?

Is there anything else which could have been included in this booklet?

Any other comments about the booklet

Thankyou for completing this feedback. Please detach this sheet and give it to the researcher at your interview.

Appendix H: Interview topic guide

Main questions are in **bold type**, other points are prompts

1. Housekeeping
    - Thank the participants for their participation in the study (5 mins)
    - The interview will last 30-45 minutes
    - The interview will be recorded
    - They will not be identified in any report – quotes will be anonymous
    - This interview discuss how they have found taking part in the research
2. Introduction
    - The researcher has briefly checked their online diaries but they have not been analysed & feedback isn't available
3. Taking part in the research (5-10 mins)
    - 2 weeks of recording your pain online
    - **How did you find the study?**
        i. Started with event/regular – how was that?
        ii. Then did regular/event recording – how was that?
        iii. Was one type preferable?
    - Did the recording affect their pain, or how they thought about their pain?
    - In this study they could not view previous responses. What are their thoughts on this?
4. Definition of a pain event (5-10 mins)
    - **How did you find defining a pain event at the start of the study?**
        i. How did you find deciding whether their pain was an 'event'?
        ii. Did their definition of a pain event alter at all?
5. Pain predictions (5-10 mins)
    - **How did you find predicting your pain in this study?**
        i. Is this the first time they have explicitly predicted their pain?
        ii. How accurate do they think they were?
        iii. What would it be like to predict pain over longer time periods e.g. a week or a month?
6. Closing the interview (5 mins)
    - Would they recommend taking part in a study like this to anyone else?
    - Would they take part in a similar study in the future?
    - Ask for any other comments about taking part
    - Thank the participant for their participation
    - Reiterate confidentiality
    - Ask whether they would like a summary of the results via email
    - Participation in the study is now complete

Appendix I: Codes, categories and themes

Meta-theme	Theme	Category	Codes		
Making sense of experiences	Community of cancer	Gratitude for medical care	• Appreciated hotel during radiotherapy • Breast cancer was found early by a routine mammogram • Breast care nurses are good and supportive • Cold cap - glad to have had it • Diagnosed quickly after biopsy • Differences between staff	• Felt lucky to have only needed one operation • Grateful to be alive Lucky to have caught it early • Not feeling supported by doctors for other conditions	• Pleased it was a quick process from diagnosis to surgery • Pleased with appearance after surgery • Reassurance from medical team that pain is normal • Scar might be neat because a plastic surgeon did it • St James' have been good
		Pervasiveness of cancer	• Are more women surviving • Cancer is 'rife' • Family cancers and treatments • Had treatments at same time as Mum	• Notice cancer cases more after diagnosis • Surprise at the number of people treated at Bexley Wing	• Surprise at young people being diagnosed with breast cancer
		Feel better off than other people with cancer	• Curiosity about reconstructions • Glad not to have a young family • Other people are worse off	• Others' experiences of treatments are more painful • Others have misunderstood their own prognosis	• Surprise that another patient had chemo while pregnant • Think that a mastectomy would feel strange to have done
		Wanting to connect with other cancer patients	• Desire to keep in touch with other chemo pts • Desire to support others with cancer	• Sad to lose touch with other pts • Seeing familiar patients at appts	• Wondering about how other patients are doing
		Curiosity about other participants	• Enquiries about other participants		
	Personal experience of cancer	Complexities of decision making around cancer treatments	• Balancing effects and side effects of anti-cancer medication • Factors affecting timing of corrective surgery	• Issues involved in deciding on treatment options • Tablets have caused more pain than surgery	
		Sharing details of own diagnosis of breast cancer	• Breast cancer wasn't a lump • Called for routine mammogram by letter • Didn't think about mammogram results after having it done • Fear after finding out mammogram wasn't normal	• Have to trust doctors • Initial mammogram was clear Keen for family members to be tested • Mammogram results - delay	• Mammogram results - quick • Never thought cancer would happen to me • Wondering what others think of their diagnosis
		Sharing details of own treatments	• Cancer medications prescribed • Can't remember name of tablets • Carpal tunnel test didn't find anything • Chemo sites varied	• Curiosity about own body • Found carpal tunnel test painful • Had a new type of surgery • Mixed feelings about mammogram	• Other conditions and medications • Seeking medical advice for back pain • Using medication to determine whether cancers are the same

		Found treatments difficult	• Blood tests are frightening • Chemo isn't nice • Didn't have symptoms before treatment • Disagreement with doctors about pain ratings	• Fatigue after treatments • Feeling ashamed during chemo Pain and discomfort immediately after surgery • Radiotherapy was extended by a day	• Reluctant to tell others about having had cancer • Struggle for access to veins after chemo • Treatments are difficult but get on with it • Worries about money
	Complexity of changes in pain	Fluctuations in pain	• Able to be more active over time • Did have typical pain during the study • Didn't have typical pain during the study • Every day is different	• Noticing pain as it increases • Pain doesn't have a pattern • Pain frequency - daily • Pain frequency - rarer	• Pain has a pattern • Pain improving over time • Pain sensations changing over time
		Complexities around taking analgesics	• Decision making - painkillers • Discrepancy in opinions about taking analgesics • Don't know when pain will come • Don't like taking them • Don't want to rely on painkillers	• Don't want to take painkillers every day • Don't want to take strong painkillers • Grin and bear it Nothing you can do about pain • Painkillers are effective	• Painkillers aren't always effective • Potential to reduce pain • Saving painkillers for severe pain • Side effects of painkillers • Want to be aware of pain
		Discussing and comparing different pains	• Arm pain feels like burning • Childbirth was most painful experience • Cold cap more painful than hip replacement • Collapsed joint was very painful	• Crushed finger was unbearable pain • Headaches can be very painful • Leg cramps are painful • Neck pain from pinched nerve	• Sharp pains take breath away • Stabbing pains are less frequent • Wrist pain is the worst
		Proactive pain management	• Proactive pain management - activity and physiotherapy • Proactive pain management - analgesics	• Proactive pain management - protecting area of body	
	Desire to understand pain	Impact of study on pain and understanding of pain	• Using diaries did affect pain or understanding of pain	• Using diaries didn't affect pain or understanding of pain	
		Mood, fatigue and pain are connected	• Fatigue and pain are related • Pain is less scary when you know what it is	• Pain led to anger • Worrying makes pain worse	
		Perceived causes of pain	• Amount of pain related to size of scar • Cold cap - painful • Lymph node surgery was worst part of treatment	• Pain due to internal healing Pain from side effects of medication • Pain from specific activities Pain from surgery scarring	• Pain from treatments • Scared next mammogram might be painful • Surgery worsened existing back problem • Unsure whether pain is due to treatments
		The cognitive element of pain prediction	• Can only predict pain if it has a pattern • Predictions changed as pain changed	• Use activity levels to predict pain • Using past experiences to predict future	
		New pains are worrying	• Interpreting new pains - might have cancer • Might be arthritis		
	Scaling pain	Cognitive element of scaling pain	• Duration and quality of pain affect pain scale rating	• Linking pain scale with behaviour • Ratings vary depending on pain experiences	• Using type of pain relief as a proxy of pain intensity
		How the pain scale is used	• Change in pain scale over time • Using the pain scale during the study	• Using the pain scale in everyday life	
		Reflections on scaling task	• Difficulty describing pain using IMPACCT labels	• Pain threshold • Reflection on task	• Scales are less useful because they are subjective

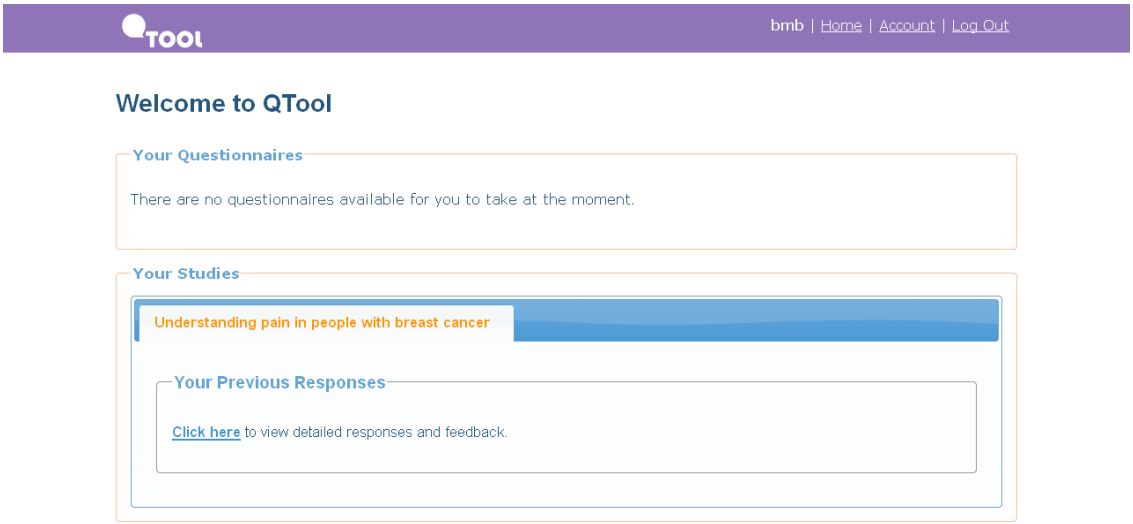
		Misc	• Scaling IMPACCT words • Scaling intensity-affect labels	• Scaling own words during task	
Uncertainties about the future	Life looks different now	Lasting side effects after treatment	• Didn't expect to have lasting effects from treatment	• Lasting effects of chemo - smells • Lasting weakness or numbness from surgery	
		Understanding own limitations	• Adapting usual activities • Avoid activities that might cause pain • Back pain recovery can't be rushed • Can't do as much as in the past • Concern about when others might not be able to help with daily activities • Determination to carry out usual activities	• Diagnosis prompted re-evaluation of attitudes • Difficult to carry out usual activities Disagreeing with family about limitations Frustration at inability to do things • Grateful to others who help with daily activities	• Have to rely on others for daily activities • New attitude towards tasks - do them gradually • Planning when pain will have least impact • Used to have demanding jobs • Work expects physical effort
		Pain will always be there	• Acceptance of pain • Expect to have pain	• Get used to pain • Predict that pain will always be there	• Predicting long term easier because pain will get worse
		Managing rest and relaxation	• Activities to take mind off pain • Coping with treatment - short holidays	• Don't like crowds any more • Don't want surgery to spoil holiday	• Holidays are important • Want to be left alone sometimes
	Need for support	Importance of others understanding me	• Cold cap - hid illness • Family need support and information • Family reminding you of limitations	• Feel lucky to have supportive family • Get fed up • Look well so others don't understand	• Others don't understand prognosis • Others don't understand treatment
		Others don't understand recovery	• Having cancer has changed me • Longer term care is lacking	• Others don't understand that recovery is long and complex	• There's more to getting over cancer than pain
		Difficulties in accessing cancer support networks	• Support group attendees much older • Unable to access support while working		
	Future health	Not sure what future health will be	• Ageing • Annual check-ups • Concern about whether weight loss will make scar more pronounced • Dieting • Fear of needing treatment again • It would be a joy to wake up pain free	• Lack of knowledge about life expectancy • Lack of opportunity to discuss mortality Looking for certainty in order to make future plans • Planning own death and funeral • Questioning own life expectancy	• Questioning own prognosis after bereavement • Questioning whether doctors withhold information about life expectancy • Reassurance from bone scan • Think everything is OK now • Worried cancer might come back
		Feeling that mammograms are essential	• Mammogram - lowering screening age • Mammograms - asking researcher if she will have one		
Research is beneficial	Positive experience of taking part	Mixed opinions about not being able to see previous diaries	• Felt ambivalence of not seeing previous diaries • Felt benefit of not seeing previous diaries	• Felt difficulty of not seeing previous diaries	
		Taking part in study was convenient	• Convenient to complete diaries • Diaries became part of routine • Diaries were quick to complete • Easy to complete diaries	• Email prompted event diary completion • Liked having support booklet in paper form • Not always convenient to complete diaries in a timely way	• Support booklet helpful • Use of shorthand in diaries • Usefulness of daily emails

		Felt benefits of taking part	• Helpfulness of study • More able to do jobs • New behaviour in managing pain	• New understanding of pain • Positive impact of taking part	• Thought study was good • Used to ignore pain to get things done
		Diaries captured all relevant information	• Diaries match experience • Included all pains in diaries	• New pain started after study finished • Understood when to complete diaries	
		Pain prediction was difficult but interesting	• Prediction was a difficult task • Surprise at predicting improvement in pain	• Thought predictions were accurate • Thought some predictions weren't accurate	• Unable to predict certain types of pain • Unable to predict pain over longer periods
		Comparing event & regular diaries	• Event diaries difficult to complete straight away • Identifying pain events was straightforward • Liked event diaries	• Liked regular diaries • No preference for either diary type Preferred diaries to baseline measures	• Preferred event • Preferred regular • Preferred to complete diaries in evening
	Positive about research	Enthusiasm for research	• Ideas for future research • Medical developments for cancer • Medical developments for other conditions	• Recommend study to others • Suggested improvement to the study • Telling others about participation	• Willingness to take part in future research • Would like a summary of the results of this study
		Desire to be a good participant	• Wanting to do the study correctly • Willingness to complete diaries	• Worries about not completing diaries	
	Limitations of current study	Diaries didn't entirely reflect experience	• Diaries didn't match experience • Forgot to complete event diary		
		Practical barriers to participation	• Unable to complete diaries due to building work	• Unable to complete diaries due to travel	
		Some parts of the study were confusing	• Confused on one day about what to do • Confusion between pain scale and EQ-5D scales	• Unsure what to do after missing a diary	
N/A	Technological problems	Adaptations required for this study	• Adaptations made to computing equipment • Adaptations needed to computer usage	• Issues were resolved	
		Difficulties with equipment or software	• Computer failure • Internet failure	• Limited computer or internet access • Q-tool failure	• Q-tool not compatible with all devices
		Difficulties with using equipment or software	• Lack of confidence or skill using computers • Needing help to adapt computing equipment	• Unable to select desired answer	
		Unsure of impact of technology problems	• Unsure of impact of technology problems		
Other	Other	Miscellaneous	• Admin error at GP • Affirmation (participant) • Can't remember some details of study • Misc	• Question (participant) • Researcher speech • Thinks brain surgeons are amazing	• Third party speech • Unrelated environmental noise • Unrelated statement

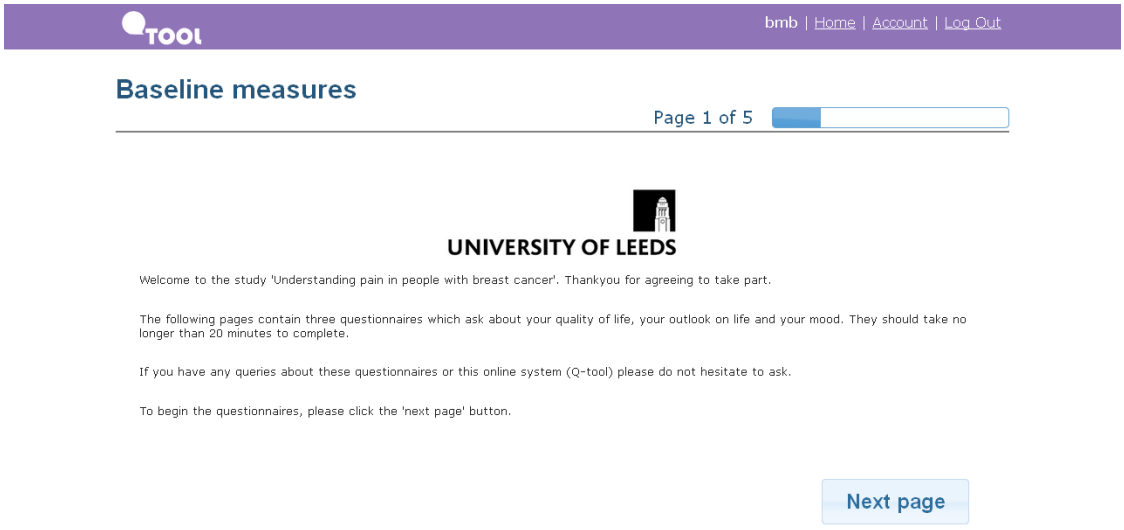
Appendix J: Q-tool screen shots

Home screen listing available questionnaires

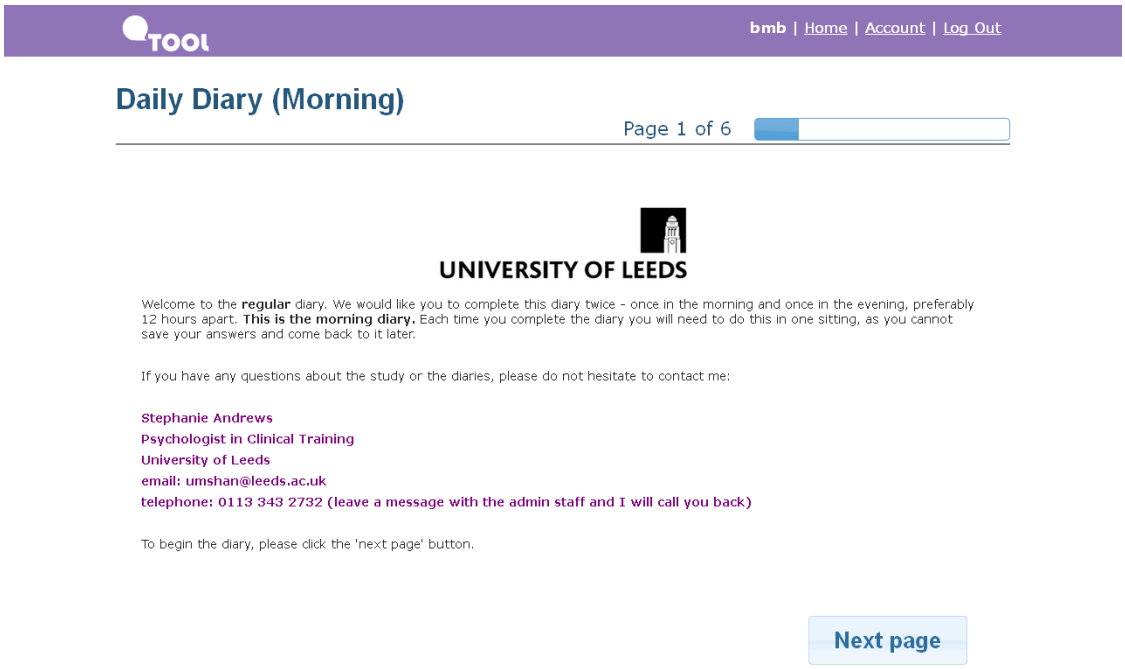
Depiction of the homepage after a regular diary day has been completed (one morning diary and one afternoon diary)



Page 1 of baseline measures (containing EQ-5D, Lot-R, PANAS)



Page 1 of regular diary – introduction and contact details



Page 2 of diary showing pain scales