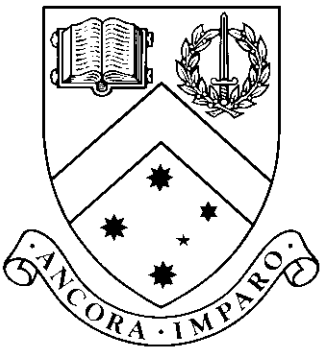
A context aware higher frequency data collection approach to studying chronic pain

by

Tian Yu Goh, BITS(Hons)



Thesis

Submitted by Tian Yu Goh

for fulfillment of the Requirements for the Degree of

Doctor of Philosophy (0190)

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June, 2018

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Abstract

This research project investigates the impact of incorporating the patient's context using a higher frequency data collection approach, to support longitudinal studies in chronic pain.

Chronic pain is a global health problem that plagues humankind. The nature of pain is not very well understood, with existing research being unable to identify therapies and treatments that have a strong, positive effect on pain. Experts have identified a need to understand the nature and experience of pain itself, along with what actually causes pain. Existing medical studies rely on non-technological means to collect data, i.e. paper-based questionnaires that are administered at 3-weekly or monthly intervals to patients in-person or via mail. This results in high data collection costs, which is typically offset by selecting wider intervals for data collection.

The main shortcoming of such data collection methods is that the data can only provide a 'big picture' view of the patient's pain experience. Recent research suggests that pain fluctuates irregularly, and has an individualistic nature. This implies that the focus should be on capturing a detailed view of pain that enables the understanding of the patient's pain experience. In utilising lessons from other research areas, it is possible to understand the nature of a phenomena by including its context in the study (Green et al. 2009). Although there exists research that collect some context of pain, there are none that capitalise on the advances in online and mobile technology to collect contextual data for chronic pain.

The goal of this research project is to design and develop an approach that utilises online technologies to enable the collection of contextual data at higher frequencies for chronic pain. In doing so, the research is also able to elicit knowledge about: i) using a higher frequency data collection approach; ii) designing higher frequency data collection instruments; iii) the impact of using such an approach; iv) modelling

the patient's context; v) designing contextual data collection instruments; and vi) the impact of incorporating the patient's context. This research uses a participatory design science approach that involves the design, development and evaluation of two exploratory case studies about: i) a well known pain condition, tennis elbow; and ii) an unknown pain condition, low back pain.

This thesis developed a descriptive contextual model based on a literature survey of the existing measures and variables that were collected by medical studies. The model was refined based on domain expert feedback and used in the two case studies. These case studies implemented the higher frequency data collection approach, which I present using an architecture. The study protocols and data collection instruments were designed in a participatory manner, involving domain experts throughout the work, using secure online data collection systems that I designed and developed. The research conducted both qualitative and quantitative analysis on the data obtained from both case studies using a variety of methods, including thematic analysis, linear mixed effect models, generalised linear models, and contextual analysis of pain trajectories. I refined the architecture components, and elicited design principles for the development of higher frequency questionnaires, and contextual questionnaires using the findings of the two case studies.

To our knowledge, this is the first work that explores the incorporation of the patient's context using a higher frequency data collection approach in chronic pain. I demonstrated that the higher frequency data collection approach enables the collection of data with a higher explanatory power, and enabled the identification of previously unknown pain fluctuations that occur irregularly. The incorporation of the patient's context has identified new directions for research, and potential contributing factors of chronic pain. The findings of the analysis indicate that the existing data collection frequencies in chronic pain research are not sufficient for estimating the pain experienced by the patient. This implies that the existing measures used in trials of medication and treatment returning a weak effect (i.e. -8.5 to +8.5) may be a result of this incorrect interval selection. This thesis also identified a number of future directions for research stemming from the results. The findings have informed theoretical understandings, and furthered practical knowledge in both information systems for digital health, and medical chronic pain research areas.

A context aware higher frequency data collection approach to studying chronic pain

Declaration

I declare that this thesis is my own work and has not been submitted in any form for another degree or diploma at any university or other institute of tertiary education. Information derived from the published and unpublished work of others has been acknowledged in the text and a list of references is given.

Tian Yu Goh
June 29, 2018

Acknowledgments

This thesis has become a reality as a result of the support and help of many individuals.

I offer my thanks to all the participants that took part in this research; for their time and data - you have greatly contributed towards enabling a new perspective and the elicitation of new knowledge in this area.

I am exceedingly grateful to my supervisors, Prof. Frada Burstein and Dr. Pari Delir Haghighi for the advice provided and time spent working together through the last four years.

Thank you to my examiners, for the time taken to provide constructive feedback for this thesis.

Thank you to my medical colleagues, Professor Flavia Cicuttini and her RA team, Professor Rachelle Buchbinder, and Dr. Allison Macpherson, for their continued support through the years for my work.

Professor Leonid Churilov, Professor Rory Wolfe, and Dr. Margaret Staples, for the help provided in statistical analsysis.

My graduate research milestones panel members: Dr. Michael Morgan, Dr. Maria Indrawan-Santiago, Dr. Chris Ling, and Dr. Matthew Butler, thank you for your support of my work, as well as the timely and constructive criticism and comments.

I am greatly indebted to the graduate research student community at the Faculty of Information Technology, on both Caulfield and Clayton campuses. The community has been a great source of support for me whilst on this journey.

Greg, Liz, Tennyson, Yuri, Ariesta, Prajwol, Misita, Dwi, Danny, Megan, thank you for all the tips, jokes, laughter, lunch-times, help and moral support that you have given me.

Sue, Helen, Julie, Allison, Danette, and all the other faculty administration staff, a huge thank you for the help and advice given, as well as support from the Faculty.

Thank you to Jonny, Phil, Moses, Farid and the rest of my teaching team, who have been extremely supportive and understanding in the months leading up to my submission.

Thank you to my family and close friends, for everything.

I would also like to acknowledge the funding support that has been afforded to this thesis by the Faculty of Information Technology, the Monash Institute of Medical Engineering, and by an Australian Government Research Training Program Scholarship.

Finally, thank you, the reader for picking up this thesis. I hope that you find it useful.

Ancora Imparo

Tian Yu Goh

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June 2018

Chapter 1

Introduction

In the last decade, e-Health has become an area that describes digital and technological solutions, that benefit and enhance the quality of healthcare. Doctors have used technology in the form of sensors and handheld devices to collect data from patients, as is seen in various studies (Silva et al., 2015; Hayn et al., 2015; Fook et al., 2008). More recently, technologies such as the Apple ResearchKit and CareKit (Apple Inc., 2015, 2016) have changed how doctors perceive the usefulness of technology in healthcare. Researchers are using these technologies as tools to provide better insight to patients about their condition, improving patients' self-management of health, and informing care providers about treatment and patient conditions (Apple Inc., 2016). There has been a move towards personalised care, which introduced a need for more data on the patient's condition and context (Goh et al., 2017). This information is required in order to best provide accurate care for the patient. Traditionally, such data would have been collected during trips to the hospital or doctor using physical paper questionnaires, and in some cases, over the telephone check-ups on a patient's progress (Huang and Matricardi, 2016; Raju et al., 2012). Not too long ago, doctors scoffed at collecting this type of data on a frequent basis due to the problems faced with manpower and costs, but with the introduction of health monitoring devices that utilize sensors, mobile technology and the internet, this has become a reality. The use of technology in e-Health has introduced new dimensions for consideration in the design of systems, such as data analytics, security and data privacy (Kerr et al., 2017; Kalgotra and Sharda, 2016). Recent advances in mobile technology and the internet have seen a slow but increasing adoption rate, paving the way towards personalisation of care, which is, care that is tailored or adjusted depending on the symptoms shown by the patient (Goh et al., 2016). This is especially important for patients who are suffering from chronic conditions that will either require a very long time for recovery, or are not expected to recover at all.

One of such global health problems that currently plague humankind is pain. It is estimated that 20% of the global population suffers from persistent pain, and that an additional 10% are diagnosed with chronic pain each year (Goldberg and McGee, 2011). Currently, majority of the studies in this field are longitudinal, and focus on either the identification of factors and causes contributing to chronic pain, or the trial of medication and treatment procedures. The primary goals of such research is to further the current knowledge about pain itself. Unfortunately, the nature of pain is not very well understood (Maher et al., 2016). This is made difficult by the fact that pain is a subjective, self-reported variable. Although research has been able to identify methods of treatment involving medications to reduce pain, this does not constitute treatment, and is ultimately only a measure to reduce the amount of perceived pain. This is especially true for some of the top contributors towards disability in chronic pain, such as low back pain. A recent review of low back pain found that the effects of pharmacological therapies are not as effective on chronic pain as previously thought (Maher et al., 2016). Through discussions with domain experts, I found that two emergent issues impacting longitudinal studies in chronic pain are: i) the cost of data collection for an extended study over a long period of time using repeated measures; and ii) the lack of knowledge regarding contributing factors towards non-specific chronic pain. I believe that these two issues are not to be addressed in isolation, and should be solved together.

Maher et al. (2016) described a current outstanding research priority for studies, which is to understand the nature and experience of pain itself, along with what causes pain (Maher et al., 2016; Souza and Frank, 2011; Olson, 2014). In learning from lessons learnt in other fields such as psychology and behavioural sciences, it is common to study the context of a phenomena in order to understand its nature. If I consider the phenomena to be pain, it can then be said that the context of pain is about understanding the situation that surrounds the pain event. In other fields, i.e. psychology and behavioural sciences, it is common to consider various context factors such as activity, mental state, employment effects, and sleep habits (Green et al., 2009; Mishler, 1979). Studying the full context could potentially provide insight and a deeper understanding of the mechanisms related to the pain. Existing studies currently consider some aspect of context as a scoping measure when collecting data. However, there are none that consider the full context around pain.

The problem faced with data collection when considering the context of the pain experience is not just cost, but also the existing frequencies in which data is collected. For example, clinical trials in the area mostly collect sparse interval data, i.e. once every three weeks or every month, and utilize face-to-face, telephone-based, or mailed-in questionnaires to collect data. The reason why cost is a problem is simple math -

the higher the frequency and the longer the duration of the study, the higher the costs required for data collection. Therefore a common solution to this would be to widen the intervals of data collection, which reduces the overall amount of data points. The data collected then provides a 'big picture' view, with much lower costs, at the expense of excluding potentially useful detail from data being collected.

Given recent advances in technology, it is clear that there is an opportunity to enable such contextual higher frequency data collection using online technology. In using such an approach, I am then able to explore the potential and impact of data collected at higher frequencies, when coupled with data about the patient's context of pain.

1.1 Problem Statement

Chronic pain is a global health problem that affects a growing percentage of the world population each year, and contributes towards disability. Researchers do not currently know much about the nature of chronic pain, nor about factors that contribute towards or trigger pain. The literature indicates that existing studies do not collect data on a frequent enough basis, with most studies only collecting pain data every 3-weeks or at monthly intervals. There are lessons to be learnt from other fields that focus on studying the nature of a phenomena using the context around it. However, models that describe or classify context for chronic pain do not exist. Utilising current advances in online technology, there is potential to implement a higher frequency data collection approach, that enables the incorporation of the patient's context of pain, to further the horizon of understanding in the field of chronic pain.

1.2 Research Questions

This thesis aims to address the gaps identified in medical literature by introducing a socio-technical approach to studying pain. Therefore this work is exploratory in nature, and designed to understand the impact and means for which an higher frequency data collection approach using technology to overcome limitations in existing research can be used.

The objectives of this research are to: i) design and develop an approach that uses online technologies to enable the collection of higher frequency data, and explore the impact of using such an approach; and ii) take advantage of the opportunity

offered by the higher frequency data collection approach to consider the study of the patient's context.

As discussed previously, studying the patient's context had potential in furthering existing understanding of the nature of pain. In doing so, I explore the integration of the patient's context into existing chronic pain models, and into data collection instruments.

Through discussions with medical domain experts, the research questions have been formulated to address the issues discussed in the previous section. These questions are presented as follows, and discussed further in Chapter 3.

RQ1: What can be learned from a higher frequency data collection approach in chronic pain?

RSQ1.1: How higher frequency data collection instruments can be designed?

RSQ1.2: What is the impact of a higher frequency data collection approach on chronic pain studies?

RQ2: What can be learned from incorporating the patient's context in chronic pain?

RSQ2.1: How to model the patient's context in chronic pain?

RSQ2.2: How data collection instruments that incorporate context can be designed?

RSQ2.3: What is the impact of incorporating the patient's context in chronic pain studies?

The following section will outline the research approach for this thesis.

1.3 Research Approach

In this thesis, the aim is to solve a real world problem by designing an artifact. This melds closely with the description of what design science research is about (Hevner et al., 2004; March and Smith, 1995). The core of the research problem being solved is deeply embedded in the medical space, and I consider that the 'problem owners' are essentially the medical domain experts. In order for our work to be correct and of use to the problem owners, there is a need to have a strong focus on the collaboration between the researchers and medical domain experts. I proposed a Participatory Design Science Methodology (ParDSM) that extended the research framework described by Peffers et al. (2007). ParDSM adds participatory components that were identified by McKemmish et al. (2012) in their work on inclusive research design. I provide more detail on the ParDSM approach in Chapter 3.

This thesis used two exploratory case studies to answer the research questions. I developed secure online systems to use for data collection in both case studies. The first case study was a proof of concept case study that allowed us to begin by exploring the potential data that can be had using a higher frequency data collection (HFDC) approach. The first case study focused on a relatively well known condition, tennis elbow, and was designed as an add-on analytical component to a real-world clinical trial. Given that the condition is well known, I was able to determine if the HFDC approach can provide more descriptive or useful data to medical research. This case study is described in further detail in Chapter 4.

The second case study utilised what I learned from the first case study and further refined the HFDC approach. This study is an exploratory data collection study that was designed to elicit the impact and understand what can be learnt from using the HFDC approach on low back pain when combined with the patient's context. The case study is described in Chapter 5.

This two-case study approach allowed us to iterate over different aspects of the design, development and evaluation stages for further refinement of the artifacts. The research approach was designed in collaboration with domain experts to better understand the problems faced in the field. This thesis was participatory from the beginning as the problem is owned by the medical domain experts; thus the results, findings, as well as the methods, processes and systems developed needed to meet current clinical research practice, and be validated to some extent. I had constant discussion, negotiation, analysis and reflection throughout this research in order to find a way to shift the current clinical thinking and introduce a new paradigm in studying pain.

The research approach for this thesis is discussed further in Chapter 3.

1.4 Significance and Contributions

This research is the first work, to the best of our knowledge, that explores the incorporation of the patient's context using a higher frequency data collection approach. The study explored a significant depth of knowledge by first reviewing the existing state of the field, then designing and developing the higher frequency data collection approach as discussed above. I worked closely with medical domain experts and users using a participatory approach embedded in the research methodology. As a result,I was able to ensure that the work being done in this thesis was both valid and useful to the medical domain of research, and contribute to further development of the methodology. I conceptualised context factors for chronic pain by reviewing and

identifying data collected by existing studies and constructed a descriptive contextual model for chronic pain. This model was developed and refined in conjunction with medical domain experts, and represents the first descriptive model that describes context for chronic pain.

This thesis also contributed unique insights as a result of the research approach taken. I conducted two real-world case studies, using secure online systems that were purpose built. The first case study used an live clinical trial, and the findings demonstrated the validity and potential of the higher frequency data collection approach. The second case study was a participatory effort in designing and conducting an exploratory data collection study, which returned useful insight into the fluctuating nature of pain, and allowed us to identify issues and further research directions for both the medical and information systems field. The analysis that was conducted through both case studies resulted in unique, new findings that contributed towards understanding limitations of the existing approaches in chronic pain. I was also able to affirm the strength of the high frequency approach with the inclusion of the patient context for studying chronic pain.

This thesis began by narrowing down a specific area of research to focus on, and then drilling down into its depths. The results and findings that I have arrived at are rich and allowed us to identify further issues and areas for future research.

The contributions of this thesis is described in the following subsections:

1.4.1 Contributions to knowledge

- **Contribution to knowledge on the use of context for chronic pain research**. This thesis is the first in studying the context of chronic pain. The findings and descriptive contextual model for chronic pain sets a baseline towards future research. This thesis provides a formalisation to the different factors observed in chronic pain research, and classified them by contextual factors. The model provides a classification for researchers seeking to identify contextual factors or variables to collect, and to use in a contextual reasoning approach. The model was published in Goh et al. (2015).

- **Contribution to knowledge on higher frequency contextual data collection for chronic pain**. I designed a higher frequency data collection approach that incorporated the patient's context for chronic pain, using advances in online and mobile technology to overcome limitations of traditional paper-based data collection for chronic pain studies. I utilised the higher frequency data collection approach to enable the collection of useful context

around the patient's pain. The findings indicate that the patient's context is useful in identifying contributing factors of pain, and provides a pain trajectory which is more accurate and representative of the pain experienced; and identified previously unknown fluctuations which are of interest to medical domain experts. These results were published in Goh et al. (2016) and Goh et al. (2017).

- **Contribution to knowledge on the understanding of pain**. This thesis contributes knowledge to medical research on the existing understanding of pain. I demonstrated using higher frequency data that pain has a fluctuating nature, and that pain is individualistic, i.e. no two patients have the same pain experience. The data collected also allowed the identification of varying activities that may have an impact on pain. I have also identified similarities to the overall patterns of pain, which could be classified in future research.

- **Contribution to knowledge on systems design for e-Health and medical contexts**. This thesis discussed and elicited guidelines for systems design to consider when developing higher frequency data collection systems that collect sensitive medical data. Based on the design and development process of the two case studies, I elicited a set of design principles from the findings for the design of such higher frequency data collection systems. I also identified factors impacting participants' willingness to use such systems (Goh et al., 2017).

- **Contribution to knowledge on the selection of data collection intervals for chronic pain**. Currently, medical studies in chronic pain collect data at sparse intervals, which represent a problem, in that they do not provide an accurate view of the pain experienced by the patient. The findings suggest that the data collected at such frequencies result in under-estimation or over-estimation of the pain experienced over a given month, which represent a contribution of our understanding of the data collected at higher frequencies, and sets out some future research directions.

1.4.2 Contributions to methodology

- **Contribution to design science methodology**. The proposed extension of the existing DSRM model with a participatory component adapted from inclusive research design represents our contribution towards a new methodological framework that improved and sustains participatory design science research, with an emphasis on the participatory, inclusive drivers.

- **Contribution to contextual analysis of pain trajectories**. I developed a process to analyse contextual pain data using the method of annotation on a plotted patient pain trajectory.

1.4.3 Contributions to practice

- **Contribution to the design of high frequency questionnaires for chronic pain**. I developed a set of high frequency questionnaires for online and mobile platforms, using a participatory approach and evaluated them in a case study for low back pain. I contributed a set of design principles and guidelines in developing similar questionnaires for chronic pain conditions for online and mobile platforms.

- **Contribution to the design of contextual data collection for chronic pain**. I provided a set of guidelines describing how to implement and select contextual data based on the descriptive contextual model designed for chronic pain. I have also elicited a set of factors that I recommend be collected.

1.5 Thesis Outline

The overall thesis outline is illustrated in Figure 1.1 below.

This thesis is structured as follows:

Chapter 1 - This chapter provides an overview to the thesis and introduces the research questions and research approach, as well as outline the significance and contributions expected in this work.

Chapter 2 - This chapter provides a literature review to the areas of chronic pain management, as well as longitudinal studies in pain management and the existing data collection and analysis methods used. I define and discuss context and contextual data in the context of chronic pain before discussing the development of a descriptive contextual model for chronic pain.

Chapter 3 - This chapter outlines and discusses the research approach taken in this thesis. I discuss and define the participatory design science methodology (ParDSM) and outline the steps that I plan to take in this research. I discuss the research questions, along with considerations for design in case studies one and two. I then provide an overview to the research data analysis methods used, and state the ethical considerations of this thesis.

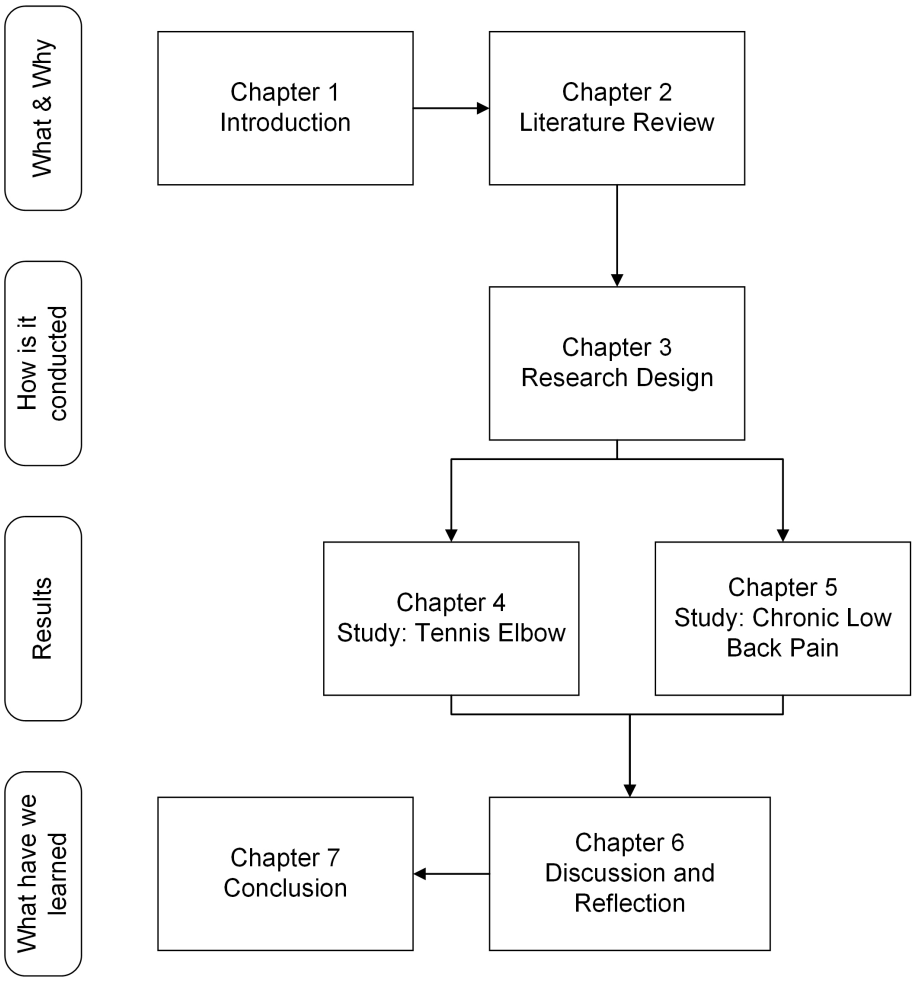


Figure 1.1: Thesis Structure

Chapter 4 - This chapter discusses the first case study used in this research. I discuss the background and motivation for the case study, along with the study design and protocols used. I follow up by outlining the system design and development considerations, as well as the data analysis performed. I close the chapter by discussing the results and findings from this case study.

Chapter 5 - This chapter provides the second case study used in this research. The chapter begins by outlining the background and motivation, discussing the study design and protocol, outlining the system design and development, and the data analysis that I conducted. Finally, I present the results and findings from this case study.

Chapter 6 - This chapter is a discussion that brings the findings from both case studies together. I provide a cross-case discussion based around the items learnt from each case study, followed by addressing each research question and close by discussing some other findings arising from this work, along with reflecting on the existing practice within medical and development spaces.

Chapter 7 - This chapter closes the thesis by providing a summary to the research, and summarising the results of the research questions from Chapter 6. I close by providing an outline of the contribution that this thesis has made to methodology, knowledge and practice.

Chapter 2

Literature Review

This research aims to introduce a different approach to studying chronic pain using a higher frequency data collection approach, in conjunction with the inclusion of the patient's context. In order to do so, there is a need to review existing research for chronic pain, to understand what the current state of the data collection and analysis methods are in the field. I found that the majority of research in chronic pain tends to be longitudinal. Therefore, this chapter provides a review on key areas and concepts that relate to chronic pain management, longitudinal studies in the pain management, and context awareness.

The chapter begins by providing an overview of the concepts and key areas in chronic pain management and longitudinal studies in Section 2.1 and 2.2, before discussing the current state of research as seen from the literature on two key areas: i) data collection, and ii) data analysis in Section 2.3. Section 2.4 provides a definition of context and context awareness, before discussing its relevance and importance to chronic pain. Finally, I will discuss contextual data and review the existing models within chronic pain that consider some aspects of context, as well as provide a short discussion towards developing a descriptive context model for chronic pain. The key findings from the literature and research gaps are summarised at the end of the chapter in Sections 2.5 and 2.6.

2.1 Chronic Pain Management

In Australia, an estimated 19.2% of the population suffer from chronic pain (Henderson et al., 2013), and this affects an estimated 36.5 million work days each year, costing over $34 billion a year to the economy (Pain Management Research Institute, The University of Sydney, 2014). A review conducted in the United States recently, discovered that it costs between $560 to $635 billion annually, and that the costs

listed were conservative, but they already exceed the economical costs of the "6 most costly major diagnoses", which included cardiovascular diseases, injury and poisoning (Gaskin and Richard, 2012, pg. 723). It is clear that chronic pain is a global problem that has a large impact on the economy, and the global population.

The International Association for the Study of Pain defines chronic pain as "pain that persists beyond normal tissue healing time, which is assumed to be 3 months" (Merskey, 1986). Pain is a self-reported measure, and is not only subjective, but it also varies between individuals due to differences in pain sensitivity and tolerance (Woodrow et al., 1972; Jensen et al., 1986).

Pain can be categorised by their respective clinical states, which are: i) Deep Somatic Tissue, ii) Viscera, iii) Headache and facial pain, iv) Neuropathic pain, and v) Cancer pain (McMahon et al., 2013). Currently, low back pain (contained within the Deep Somatic Tissue category) is the main chronic condition that contributes towards disability (Maher et al., 2016).

Chronic pain can begin as acute pain due to some injury or condition that a patient might have. Up till recently, it was thought that chronic pain was simply an extended period of acute pain, which research now shows to be incorrect (Niv and Devor, 2004; Tracey and Bushnell, 2009). This realisation sparked off a change in the way that researchers understand pain, driving a move towards the understanding of chronic pain as an entirely different area with its own measures, causes and effects (John Walsh, 2017).

As chronic pain is a condition that typically lasts for an extended period of time, medical experts tend to refer to the treatment plan for these as a pain management plan. The research field of pain management is vast and is considered to be a critical work area, which is demonstrated by the enormous growth in publications over the last decade. Due to the nature of chronic pain, a majority of the research in this field is classified as longitudinal studies, and the following section will provide an overview of the current state of longitudinal studies within chronic pain.

2.2 Overview of Longitudinal Studies

Longitudinal research is described as research that uses longitudinal data. A common definition of longitudinal data is data that results from observations or collection from subjects, that occur at multiple measurement points in time (Bijleveld et al., 1998; Diggle et al., 2002). This contrasts with cross-sectional studies where only a single measurement is obtained per subject (Zeger and Liang, 1992). As a result, longitudinal data tends to be rather costly to collect, since in some cases it requires

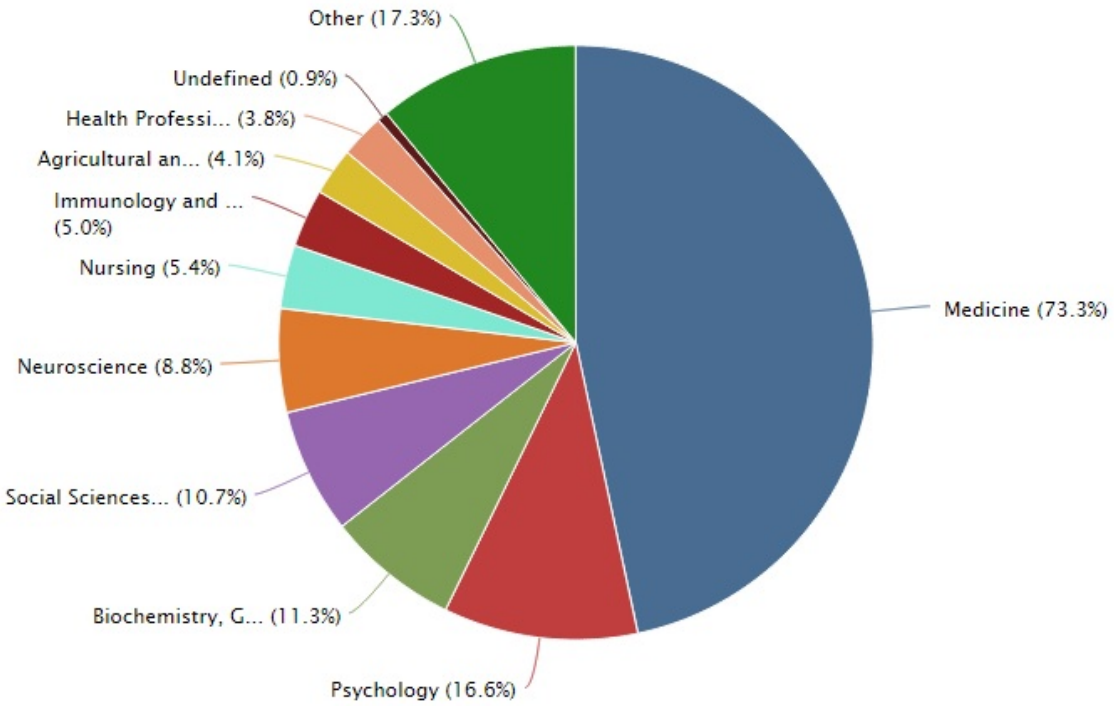


Figure 2.1: Scopus Database search for longitudinal research (Elsevier, 2014)

researchers to follow their subjects over a period of time; or to ensure that the subjects within the study will cooperate such that the data collected is consistent and complete (Bijleveld et al., 1998). The concept of longitudinal studies have been around since the 1970s, and the field has been continually growing and evolving to its state today. Longitudinal studies tend to be carried out when: i) the object of interest is the change within some phenomena of the subjects under study; ii) the main way to observe the change is to collect repeated measures over time; and iii) the causality of the phenomena is assessable by analysing such changes over time (Bijleveld et al., 1998). Longitudinal studies allow researchers to describe, explain or even forecast, or predict changes happening to the subjects in the study, and these can be said to be some of the aims in a general sense (Bijleveld et al., 1998).

Longitudinal studies encompass a large multitude of research fields, and an unrestricted literature search on the Scopus database returned 138,685 publications, with the field of medicine (73.3%) taking up the largest share of publications, followed by psychology (16.6%), biochemistry (11.3%), social sciences (10.7%), neuroscience (8.8%) and nursing (5.4%) as seen in Figure 2.1. In trying to describe, explain or predict changes, researchers have a wide variety of analytical methods and data collection methodologies in analysing and collecting the data needed.

Earlier analytical methods were based on the analysis of variance (ANOVA) model (Fisher, 1956). Since then, the appearance of repeated-measures multivariate analysis of variance (MANOVA) along with the univariate (ANOVA) models have led to

the development of many other methods (Fitzmaurice et al., 2009). Currently, some of the more common methods include the use of latent growth curve models using structural equation modelling to study intra-individual change in pain(Menard, 2002). Some other methods commonly used are the multilevel analytical methods (Cano et al., 2005), log-linear (Bao et al., 2003), univariate (Croft et al., 2001) and multivariate analysis (Cassou et al., 2002) methods for modelling longitudinal data and variance of such data.

I observed that the data collection techniques used over the decades have made a slow, but gradual move towards the inclusion of information and communication technology in enhancing the ease in collecting data. Some common methods observed involved collecting data via physical mail; in which studies sent or provided subjects with questionnaires and postage-paid envelopes, or financial remuneration towards the costs of postage (McGorry et al., 2000; Dunn et al., 2006). Other methods include in-person questionnaires, or over the telephone interviews (Henschke et al., 2008). More recently, some studies have started adopting mobile texts as a method of collecting data easily from subjects (Githinji et al., 2014; Macedo et al., 2014). Some studies utilise online questionnaires to collect data (Beiter et al., 2008; Perrone-McGovern et al., 2011; Walthouwer et al., 2014). In addition, the recent advances in development and miniaturization of sensors and wearable sensors in healthcare has been identified as an opportunity (Gupta et al., 2018), and has spurred their use in some studies (Denkinger et al., 2010; Fournet and Barrat, 2014).

I have provided an overview of the analysis and data collection in the area of longitudinal studies. I note that the analytical methods for longitudinal studies available are gradually evolving as time passes, in order to: i) capture or analyze the data available in explaining, describing, or even predicting the patterns of change and the nature of the phenomena being studied; and ii) to develop better approaches for dealing with missing or incomplete data.

The nature of the longitudinal study involves observing subjects over a period of time with multiple data collection points (Bijleveld et al., 1998; Diggle et al., 2002). This means that the researchers have to follow the subjects over time, and these subjects can be moving from city to city, or decide to drop out of the study, or occasionally forget to report the data at the point in which it was meant to be collected. This is a common problem that researchers have to deal with and in the past, a decision would be made to drop the data collected for that subject to reduce further costs (Manca and Palmer, 2005). As the data is relatively hard to come by and is expensive to collect, researchers use statistical methods to 'fill-in' or interpolate across the missing data (Gibbons et al., 1993).

Data collection techniques in use have gradually evolved and have shown to be slowly adopting the use of technology, and this has been seen in the use of online questionnaires, mobile text and wearable sensors (Medhanyie et al., 2015; Githinji et al., 2014; Kristjánsdóttir et al., 2011; Boulos et al., 2011). The use of wearable sensors for data collection provides a new interesting dimension to the depth and richness of the data collected, as they can provide a continuous stream of data that is readily available at any time, and provide benefits such as lower cost of collecting data, and the ability of capturing reliable, valid, responsive measures (Lorincz et al., 2009; Dobkin and Dorsch, 2011).

As this thesis mainly focuses on pain management, the next section will provide an overview of longitudinal studies within pain management and its relevant methods.

2.3 Longitudinal Studies in Pain Management

Reviewing the works in the area of longitudinal studies within pain management field, I can classify these studies into three main areas: i) research that focuses on investigating causes and treatments for specific pain; ii) clinical trials for drugs and treatments that can block or ease pain; and iii) studies that focus on identifying factors that can affect pain. The general goal of these research studies is to further our understanding of the nature of pain itself. This is difficult due to the fact that clinical pain is self-reported (Malhotra and Mackey, 2012), subjective in nature (McGuire, 1984; Abu-Saad and Holzemer, 1981), and difficult to measure objectively and accurately (Loder and Burch, 2012).

Initial research targeted pain receptors in attempts to reduce or numb the pain, but did not contribute to better care that lead to long term cure or effective treatment (Spiegel and Bloom, 1983; Johnson, 1974). Recently, researchers and experts alike have begun to acknowledge the need to address the issue in multiple dimensions, that includes but is not limited to the physical, psychological and environmental conditions revolving around the patient (Guzmán et al., 2001; Korff and Simon, 1996; John Walsh, 2017). The nature of pain requires the research conducted to be longitudinal, in order to observe the effects or the trends and progress of pain. While experts have identified the need to examine other dimensions (Pain Management Research Institute, The University of Sydney, 2014; Deyo et al., 2014; Smith et al., 2001), there has not been any large scale work in examining as many of these dimensions at once. Existing research seems to focus on three main areas: i) design of intervention studies to provide better treatment for pain and explain treatment effects (Mansell et al., 2014); ii) how to better manage such pain from a multidisciplinary perspective (Crofts et al., 2014; Hoffart and Wallace, 2014); and iii) how to use technology in

reducing the effects or impact of pain (Singh et al., 2014; Wiederhold et al., 2014). It has been acknowledged that more data is needed if the goal is to understand pain, and its nature (McCracken et al., 2004).

Two key areas of research are the data collection and data analysis methods used. I provide in the following two subsections, a discussion of the: i) data collection methods seen in the existing literature, and ii) data analysis methods currently practised in longitudinal studies specific to pain since 2000.

2.3.1 Data Collection

This section will provide a review on the data collection techniques seen in the existing literature, and also discuss the data collection techniques in use in this field, as compared to others within longitudinal studies. I find it necessary to begin by defining the data collection process as follows:

I define data collection as a process that has five main characteristics; *data* is collected via a *collection mode* using an *instrument* from a *data source* at a specific *collection frequency.*

I define each characteristic as follows:

Data - I define data as the actual variables of interest in the study. This can refer to a derived score that is attained by calculating responses to a series of questions, or individual responses to questions that have been collected. It can also refer to data obtained from collection devices, such as sensors.

Collection Mode - Collection Mode is defined as the "method or approach used for the collection of data" (Jans, 2008, pg. 483). For example, an instrument can be administered by various modes, such as over the telephone, via mail, over the internet, or in person. The modes have their own benefits, for example: administering a survey over the telephone is better than doing it via mail as it ensures that the patient understands the questionnaire, and the person conducting the survey can follow up on specific items of interest.

Instrument - Instrument is defined as the tool or device used in objectively determining, or facilitating the collection of the value of an item to be measured, which is adapted from the Oxford (2014) definition. For example, a questionnaire or survey, an interview, or statistical tests.

Data Source - Data Source is the source of the data to be collected from, which includes but is not limited to sensors, doctors, participants (subjects under study).

Collection Frequency - Frequency describes how often the data is being collected. For example, daily, weekly, intervals of weeks 3, 6, 9.

I observed that almost all research in this area use questionnaires as a data collection instrument. The questionnaires used fall within two categories that have different objectives.

Characteristic-based questionnaires - I define characteristic-based questionnaires as a questionnaire that objectively obtains one or both qualitative and quantitative information on the characteristics of the participant, which may include demographical data such as age, or gender. Some other types of characteristics include alcohol use, drug use, if the subject smokes, or activity related data such as exercise.

Score-based questionnaires - I define score-based questionnaires as questionnaires that score responses to produce a single numeric score in a validated manner. These score-based questionnaires are used to collect pain information as well as data from other disciplines such as psychology and disability (Davidson, 2014; Linton et al., 2011; Robinson et al., 1997). An example of such a questionnaire is the Roland-Morris Disability Questionnaire which records a series of responses to questions that can be scored and determines a value of disability (Roland and Fairbank, 2000).

In regards to the collection mode, the majority of the studies reviewed use either i) in-person; ii) mail; or iii) over the telephone interviews to collect data. There were some studies that used mobile text technology for data collection (Macedo et al., 2014), and barely any that used the Internet in collecting the data from participants.

Data sources seen in the studies typically revolve around the participant, as expected. Some studies have considered some kinds of context and have included sources such as the participant's: i) family (Souza and Frank, 2011); ii) teachers (Erne and Elfering, 2011); or iii) doctors (Shaw et al., 2011).

During data collection, one of the essential variables under study is the patient's pain intensity. As mentioned previously, pain is a self reported variable. This means that it is not 'clinically' obtainable using a non-subjective measure, and relies on an instrument on which a participant uses to report their perceived pain. Three most commonly used and accepted simple instruments for measuring pain are the: i) Visual Analogy Scale (VAS) (Bijur et al., 2001); ii) Numerical Pain Rating Scale (NPRS) (Farrar et al., 2001); and iii) Categorical Rating Scale (CRS) (Hartrick et al., 2003). These instruments are classified as pain scales, and these typically represent some form of a scale that goes from 'no pain' to 'worst possible pain' using either visual, textual, or numerical means. Pain scales are very subjective to individual pain tolerance thresholds, and is frequently described as 'subjective' pain intensity (Jensen et al., 1986).

The VAS is a 100 mm line represented horizontally, with the left end of the scale typically representing 'no pain', and the other end representing 'worst possible pain'. The user marks off a point on the line, which is then measured in millimetres and recorded as the value of pain intensity.

The NPRS is usually a 11-point scale from 0 to 10 representing 'no pain' to 'worst possible pain'. The user selects a number that they feel appropriate in representing their pain intensity.

The CRS is usually defined as a set of categories which a user will select from to represent their pain. The set of categories could, for example, be 'No pain', 'little pain', 'mild pain','serious pain'. One such scale is the Pain Index, which is a six point categorical scale that runs as 'none, very mild, mild, moderate, severe, very severe'. The selected value is then either rated from 0 to 5 (in the case of the Pain Index), and recorded as the value, or recorded as the actual category (e.g. mild).

Another instrument to measure subjective pain is the McGill Pain Questionnaire, which is a scoring questionnaire that provides "quantitative measures of clinical pain that can be treated statistically" (Melzack, 1975, pg. 277). Some other scoring questionnaires for pain include the Brief Pain Inventory (Cleeland and Ryan, 1994), and the Roland-Morris Back Pain Questionnaire (Stratford et al., 1998; Riddle et al., 1998).

Pain is not the only variable typically collected in these studies. Other categories of data such as demographical data including age, gender, education, height and weight (Henschke et al., 2008; Dunn et al., 2011); psychological and psychosocial variables such as anxiety, depression, somatization (Dunn et al., 2013; Adamson et al., 2007); medical history data including past and current history (McGorry et al., 2000; Henschke et al., 2008) were observed as being the most common sets of data collected. Similar to pain, the typical instruments used were questionnaires and interviews.

Recently, some studies have begun to use pain diaries (McGorry et al., 2000), which are logs kept by the patient that typically combine a pain scale and an optional component which the thoughts and experience on the pain can be included. In these studies, the measure of pain is commonly embedded within a larger questionnaire instrument, which is then conducted either in-person, over the telephone, or via mail.

In comparison to longitudinal studies in other areas, cross-referenced data from other sources used in longitudinal studies of chronic pain were limited in scope, unlike in weather prediction, where data from multiple sources, for example satellites, locally distributed weather stations and sensors were used to accurately predict or forecast the upcoming weather patterns (Wick et al., 2013), or in weather aided

traffic prediction models that combined weather data with traffic data (Dunne and Ghosh, 2013). One such study utilized weather data from the National Oceanic and Atmospheric Administration (NOAA), cross referenced with daily pain ratings collected using diaries to investigate the relationship between weather conditions and reported pain values (McGorry et al., 1998).

I observed that the existing studies do not really rely much on technology for data collection. For example, one study used diaries which consisted of participants filling out questions in a diary format daily, and mailing them every week to the researchers, which is relatively costly and time consuming (McGorry et al., 2000). There is a relatively low adoption rate of technology for data collection within the chronic pain research area.

The frequency of the data collection methods observed tend to range from a single point at baseline, to daily, monthly, 3 monthly and then to specific uneven intervals. Of the studies reviewed, there was only one that obtained daily data about the patient's pain. I believe that it is neither realistic for a single point of data collection over an extended period of time (for example, a month), nor sufficient to understand the context or experience of the patient, or provide enough depth into the analysis. It has been shown that the intensity of pain can vary across the course of a single day, and can worsen or improve as time passes, affected by a variety of factors that could include the ingestion of painkillers (Bandura et al., 1987; Benedetti, 2002).

There have been studies into the accuracy of patient recall on their pain levels, and show that while there is a small bias that could affect the reported results, it is not a major problem with shorter durations (Schneider et al., 2011; Turk and Melzack, 2011). However, this stems back to the lack of understanding of pain itself. Considering that the goal is understanding the experience and nature of pain, then the data should be collected about the entire experience from multiple dimensions (O'Sullivan, 2012), not a summary of the average experienced pain. It has been suggested that more accurate data can be obtained using diaries as they are based on real-time experiences rather than recalling the pain that the patient experienced earlier (Turk and Melzack, 2011). As mentioned, the pain intensity can fluctuate through the day due to its influence of other factors. Some of these factors can be affected by the pain intensity itself, for example, chronic pain can influence psychosocial factors (Davis and Heaney, 2000). However, these factors have not been studied together, except studies that utilize diaries in analysing the effect and context around the patient's pain (Karoly et al., 2014; Thastum and Herlin, 2011).

There is an increasing number of studies using a multidisciplinary approach for pain, with multiple dimensions being considered during data collection and analysis. I feel that this is partially due to the recognition that there is a need to have a shared

understanding of the pain experience, which would involve understanding the context around the episodes of pain. Studies have also begun to adopt the use of technology. For example, there has been an increase in collection modes such as the use of the internet for conducting questionnaires or surveys, as compared to using the mail. Some studies have used sensors in data collection. Dekker-van Weering et al. (2012) used movement sensors to determine activity and provide contextually aware feedback to the patient in exploring if personalized messages with visual feedback is related to pain intensity levels. Another study by Van Weering et al. (2011) looked into the accuracy of patient self-reports of activity, and discovered that the self-reports were not accurate when compared to objective measurements by sensors. These studies demonstrate that it is useful to utilize sensors in obtaining accurate data from patients, and another convenient point is that the data can be streaming to a server automatically, without requiring the patient to manually provide that information. The use of sensors have enabled the automated collection of objective measures from other dimensions such as the environment or activity. The introduction of sensors as data collection devices have opened up an opportunity for researchers to collect more information about the situation, or context around the patient's self-report of pain. Longitudinal studies for chronic pain have been following a very traditional path of research, which can be seen in the slow adoption of technology, lessons and ideas from other fields. The use of sensors and diaries are not new to research as a whole, but there are lessons that can be drawn from other fields in evolving the way that the data can be collected, and the analysis done such that multiple dimensions, or the context around each individual's pain experience to be better understood and considered. Existing studies tend to focus on individual context factors, or a small subset of them. It is critical to have the ability to understand the context around a patient's pain, and lessons can be learnt and applied from other fields of research that use context and context awareness concepts on a regular basis.

This section provided an overview of the state of the field in data collection. The following section will continue by discussing the use of data analysis in chronic pain longitudinal studies.

2.3.2 Data Analysis

The previous section presented an overview of the data collection methods used for chronic pain in longitudinal studies. This section will provide an overview of the classical data analysis methods used.

As with the typical longitudinal studies, the analytical methods are statistical in nature. Existing handbooks for longitudinal studies tend to categorize statistical

methods into their parametric / non-parametric types (Fitzmaurice et al., 2009). The existing analytical methods used in recent studies tend to lean towards correlation analysis, modelling of variances and the relationships between variables. I classify the analytical methods observed into four general classes of methods: i) Cluster Analysis, ii) Structural Equation Modelling, iii) Regression Analysis, and iv) Mixed Models.

Cluster Analysis - These methods have a single goal, which is to cluster sets of items in such a way that the items in the same set will be more alike to each other than to those in other clusters (Kaufman and Rousseeuw, 2009). There are a large variety of algorithms that accomplish this task, which includes the k-means algorithm and the hierarchical clustering model (Jain, 2010). Cluster analysis is more typically used to identify similar patterns of pain among participants (Axén et al., 2011), and then making inferences on the characteristics of each cluster to identify significantly similar or dissimilar variables. These clusters tend to be based around the pain fluctuation or the pain intensity over time.

Structural Equation Modelling (SEM) - SEM is a technique that is used to discover causal relationships using assumptions of those relationships, and statistical data (Kline, 2011). SEM comprises of confirmatory and exploratory models, in which theory can be developed and tested (Weston and Gore, 2006). The most common type of model seen is the Latent Class models (Samuelsen and Dayton, 2010) and growth curve models (Duncan et al., 2013), with both sometimes combined. These methods are most commonly used in testing assumptions of causal relationships between variables, and typically is a manual process in which the model is slowly fit using certain measures such as the Akaike Information Criterion (AIC), the Bayesian Information Criterion (BIC), among others (Claeskens and Hjort, 2008). A typical study would see models being built around single latent classes, and then increasing in number of classes to find the best model fit to provide the best estimation of likely relationships, before being interpreted (Dunn et al., 2011). Latent Class analysis has the ability to identify unobservable subgroups within a population (Collins and Lanza, 2010), and is particularly useful where there is one main latent variable and a series of related observable variables. The latent growth curve model allows estimation of 'change' over time, and allows dependent variables to be modelled with covariates over time. Latent growth curve models also posses the attribute of being able to analyse predictors of individual differences (Duncan and Duncan, 2004) in how and which variables affect the trajectory.

Regression Analysis - These methods are used in analysing the relationships between variables, and in understanding the average values of a specific dependent variable given changes on a specific independent variable (Kleinbaum et al., 2013).

Methods seen include the generalised linear and linear regression models, among others (Montgomery et al., 2012). These models are typically used in forecasting changes and identifying correlation between the variables in analysis. For example, a study used regression analysis in identifying factors that were associated with poor prognosis of chronic pain (Henschke et al., 2008).

Mixed Models - These models consist of the other studies that did not use any of the above three classes of methods. The methods in this category comprise a minority of the publications in this area of research. These include univariate and multivariate models (Ho, 2006).

The literature suggests that the most common analysis model used is the latent class model, and these studies were trying to identify factors or predictors that could lead to chronic pain. The majority of these studies collected data over a long period of time and used SEM and latent class modelling to test their assumptions about the causal relationships between specific factors and chronic pain. Latent class modelling has been used to identify pain profiles across multiple pain sites, suggesting that focusing on single pain sites can be obscured or inflate risk factors (Adamson et al., 2007; Dunn et al., 2011).

There are many tools available that provide capabilities in computing these models, some of which are SAS (S. A. S. Institute, 2011), SPSS (SPSS, 2008), MPlus (Muthén and Muthén, 2008) and LatentGold (Vermunt and Magidson, 2008). However, the SEM models tend to be hard to automate with regards to model selection and fit, unlike cluster analysis models which can be configured to provide the best fit automatically.

Thus far, I have discussed some common analytical methods used in longitudinal studies for pain management. The following subsection will discuss the primary method used in presenting pain data.

2.3.3 Presentation of Results: Pain Trajectory

Through our review of the literature, I observed that the main method used in presenting pain over time in a graphical manner relied on a pain trajectory. The pain trajectory is a two dimensional graph that plots pain intensity over time intervals (Chapman et al., 2011). There are two types of trajectories commonly used, linear and quadratic (Stanford et al., 2008). The linear form of the trajectory consists of straight lines plotted between sets of data points, whereas the quadratic form uses quadratic functions to optimize a curved line between data points. Many studies utilize this trajectory to show the overall progress of the patient, the presence or lack of improvement, as well as the acuteness of the pain episode. The pain

trajectory demonstrates two main features of interest, the initial reported pain level, representing the intercept; and the progress towards resolution of the pain level, which represents the slope. A negative slope trajectory demonstrates a decline in reported pain level over time, which generally means the patient's condition is improving, and a positive slope trajectory demonstrates the opposite, which is an increase in reported pain level over time, a degradation in the patient's condition. It is agreed that the measure of pain trajectories are precise enough to classify patterns of reported pain in a reliable manner for patients (Chapman et al., 2011). Studies have used a variety of methods in trying to generically classify patients based on their overall pain trajectory, for example, clusters labelled as 'persistent mild', 'recovering', 'severe chronic' and 'fluctuating' (Dunn et al., 2006).

It can be seen that the pain trajectory is the most common method of studying the progress of pain, but is not easily extended with more dimensions of data representing other variables due to its nature. The statistical methods seen generally utilize the trajectory in classifying or clustering groups of patients based on their general patterns, or correlations of the pain trajectories, and have been used in various aims, for example to identify general groups or clusters of patients based on their pattern of progress and improvement on the trajectory (Dunn et al., 2006; Tamcan et al., 2010).

The concept of assessing contributing or risk factors to pain other than the ones typically collected, such as the demographical and medical history data, have been around for a few years now. There have been studies looking at the relationship with pain and psychological factors (Linton and Shaw, 2011; Main and George, 2011), work and family factors (Shaw et al., 2013), environmental factors (Edefonti et al., 2012; Steffens et al., 2014) and psychosocial factors (Soklaridis et al., 2010).

As discussed in the previous chapter, the focus of our research is to implement a higher frequency data collection approach that also incorporates the patient's context. Thus far, I have provided an overview of the existing data collection and analytical methods used within the pain management space, and found that existing studies consider some type of context as a contributing or as a risk factor for pain. In the next section, I will define context and context awareness, and discuss the current state of the field for modelling contextual data.

2.4 Context Awareness

The concept of context and context awareness has been around since the 1990s, but it was only in the last decade when this area of research had really evolved. The

previous section highlighted the need for context around a patient's pain experience to be understood. This section will: i) define context and context awareness, ii) discuss context in chronic pain longitudinal studies and how data collection and analysis techniques can consider context, iii) discuss contextual data for chronic pain, and iv) provide an overview on context reasoning and modelling.

2.4.1 Context and Context Awareness

There are many definitions for context. I use Dey definition of context that states: "any information that can be used to characterize the situation of an entity, where an entity can be a person, place, or physical or computational object" (Dey, 2001, pg. 304). There are other simpler definitions by various studies that refer to context as the situation, the location or the environment around a phenomena (Ward et al., 1997; Schmidt et al., 1999). Similarily, Ryan et al. (1998) defined context as the user's identity, location, surrounding environment and current time.

Context Awareness then refers to the ability of a process, system, or program to consider the context by sensing states of its environment and itself, in order to react appropriately (Schilit et al., 1994).

In considering chronic pain, I define an event as a single slice of pain experience between two points in time. The context around each event can provide valuable information about the situation. For example, in weather prediction, the context in terms of the location, historical trends, topological features, to name a few, are considered when making a forecast for that specific location. The weather prediction can be made solely on the radar and traditional measures such as air pressure, humidity, wind, etc, but it has been shown to be less accurate when the context wasn't taken into account (Lorenc and Marriott, 2014). In applying that concept to chronic pain, the interest of context is then on the information about the situation around the pain experienced at that particular point in time. For example, some questions that can be asked to obtain information around the situation when a user experiences a change in pain are: what were they doing at that time? What were the environmental conditions around them (temperature, humidity, wind chill, etc.) at that time? Are they currently on medication or some treatment plan?

The following section will elaborate on relevance of context applied to longitudinal studies.

2.4.2 Relevance and Importance of Context

As previously mentioned, the concept of context is not new to longitudinal research. Existing longitudinal studies already consider aspects of context (Cook et al., 2002; Bowen et al., 2008), and it can be seen that it is almost necessary for research to consider some aspect of context in order to scope or focus their efforts. Currently, there are no well developed taxonomies or models that exist to describe situational and contextual factors in relation to humans (Kelley, 2003), especially in the field of chronic pain. There are reports that context is usually considered to a minor extent, and is "often unrecognised or under-appreciated" (Johns, 2006, pg. 389).

The study of context is predominant in the other fields such as psychology and behavioural sciences, and studying multiple contexts in attempts to understand the situation had been recommended as it may provide important information. Similarly, research in fields such as child development (Morales and Guerra, 2006; Furlong et al., 2003), or even research in management (Meyer et al., 2011; Mueller and Lee, 2002) also study multiple contexts. (Cook et al., 2002) stated that studying multiple contexts can result in correlations between contexts, which would have important implications that can be due to "confounding with correlated but unmeasured contexts, and ... ignorance of this correlation will probably result in overestimating the effect of the single measured context" (Cook, 2003, pg. 152).

Longitudinal studies of chronic pain have also considered single contexts, and to some extent multiple contexts, but are limited in that they do not consider the 'greater picture' of the entire situation around the pain experience. Studies commonly collect demographical and pain intensity data (Dunn et al., 2006; Adamson et al., 2007). Other studies also consider exercise, or physical activity (Adamson et al., 2007; Dunn et al., 2011). Some studied disability resulting from pain (Henschke et al., 2008; Smeets et al., 2006), and others looked at the costs resulting from specific types of chronic pain (Wenig et al., 2009; Ivanova et al., 2011). Another area of interest are the factors of employment, quality of life and if chronic pain affected working abilities (McDonald et al., 2011; Brochet et al., 2009). Some studies considered the patient's medical history (Henschke et al., 2008; Dunn et al., 2011). Other studies considered vices such as smoking and alcohol use as a factor to chronic pain (Balagué et al., 2012; Bergström et al., 2007).

The instruments used in collecting such data generally are questionnaires that have been validated for a specific use. For example, the Roland-Morris Disability Questionnaire (RMDQ) is commonly used to obtain a measure of disability (Macedo et al., 2014; Dunn et al., 2006). Other examples include the Pain Self-Efficacy

Questionnaire for self-efficacy (Macedo et al., 2014); and Patient Health Questionnaire for somatization (Dunn et al., 2013).

The concept of context has been utilized to an extent in existing studies. A number of existing questionnaires currently being used as data collection instruments have the potential to provide contextual data, that can help in the understanding of chronic pain.

The following section will discuss contextual data, and discuss modelling such data.

2.4.3 Contextual Data

Contextual data is data about the context of a phenomena. In chronic pain, there are no existing models that currently describe the categories and types of contextual data collectable, thus this research begins by identifying various instruments that can be utilized in such a manner for collecting contextual data. Considering the various types of data currently being collected in the existing longitudinal studies of chronic pain, it is needed to first clarify that not all sources of data are considered to be contextual, or suitable for use in a contextual sense. From the literature, I identified six different types of instruments that have been used in chronic pain studies: i) pain scales; ii) questionnaires; iii) diaries; iv) sensors; v) social media; and vi) cross referenced data.

This research classifies cross referenced data as a type of sensory data, as they are typically derived from various measuring instruments, or sensors, such as temperature sensors or activity sensors. Therefore there are five instruments which will be discussed as follows:

Pain Scales - Pain scales provide the main measure of pain itself. Contextual data provides information on the context of the phenomena, which in this case is pain. Therefore, I classify pain as being one category of contextual data.

Questionnaires - As discussed previously, there are two types of questionnaires; score-based and characteristic-based questionnaires. Questionnaires typically collect data that are used for statistical models and inferences, and the majority of the current instruments as used in chronic pain do not yield information that can be considered context.

Diaries - Previously, it was mentioned that diaries have been used in collecting data about pain, and about the patient's thoughts and experience of the pain itself. The concept of context that has been discussed is about collecting data on the experience and situation around the patient at the point of the phenomena being studied, and therefore diaries are extremely suitable as an instrument for contextual data.

Diaries are typically described as a personal record of events, experiences and thoughts. In longitudinal studies of chronic pain, diaries have been used in studying the context of the patient's pain, as informed by their written experiences (Karoly et al., 2014; Thastum and Herlin, 2011). It was also mentioned previously that research suggests that diaries provide a more accurate way of obtaining such contextual data as they are commonly based on real-time experiences, rather than the memory of a past experience, which would depend on the accuracy of the patient's recall ability (Turk and Melzack, 2011).

Diaries are not a new form of instrument in some other areas of research. For example, in studying Attention Deficit Hyperactivity Disorder (ADHD), a structured electronic diaries was used to examine contextual triggers of ADHD (Whalen et al., 2002). The study chose to use electronic diaries to overcome limitations of regular questionnaires in assessing multiple factors at once (Henker et al., 2002; Whalen et al., 2002, 2006). The electronic diary was a mobile Personal Digital Assistant (PDA) device which was loaned to the participants for use (Whalen et al., 2006).

Another research study analysed the reactivity, compliance and patient satisfaction with using electronic diaries as compared to questionnaires, and found that there was a preference for the diaries as a form of self-report, and suggest that the diary is a better instrument to collect information on the experience of pain (Stone et al., 2003; Gaertner et al., 2004).

More recently, studies have slowly moved from using electronic diaries on PDAs to using mobile phone devices. (Sternfeld et al., 2012) used a cell phone diary, concluded it was equivalent to using paper diaries, and is a reliable and valid approach to self-reported activity.

Since 2009, development of applications (apps) for smartphones to implement diary features along with pain tracking features have become available, although not all of these apps have shown to be effective, and have a risk of misleading individuals (Rosser and Eccleston, 2011). The same study identified the need for further research to guide the development of these apps and their contents, and that there exists a wide potential benefit for such apps to be created (Rosser and Eccleston, 2011; O'Neill and Brady, 2012).

Mobile diaries have been trialled in various fields, for example in the area of chronic pain, Kristjánsdóttir et al. (2013) demonstrated that a mobile diary with personalized medical feedback can improve recovery. Other studies have validated the use of mobile diaries in monitoring pain and patient experiences, and researchers agree that such diaries improve timeliness and compliance of data (Jamison et al., 2001, 2002, 2006; Kristjánsdóttir et al., 2011).

Thus it can be seen that diaries, especially mobile diaries, are exceedingly useful in collecting contextual data, as well as other information such as pain intensity, in a manner that is satisfactory to the patients, while having a high patient compliance and timeliness of self-reported data.

Sensors - There have been two main areas for use of sensors thus far; to track movement and exercise that can influence pain (Weering et al., 2009; Shum et al., 2007), and to track the weather conditions in discovering its effect on pain (Jamison et al., 1995; Fors and Sexton, 2002). Context is addressed here in the situation occurring around the patient, or even what the patient is doing at the point of the phenomena, and therefore sensors are considered as suitable as an instrument of contextual data.

These sensors provide a passive way of collecting data with little to no interaction required from the researchers, and have the capability to stream data continuously. This means that the data can always be available, and it is possible to then do analysis on changes over time.

Over the last decade, the interest and move towards the use of sensors in research has been growing. The adoption of sensors in use within medical and elderly care areas originated from work within mobile and wireless sensor networks, where it was shown that sensors have the ability to detect events and occurrences of specific phenomena of interest. For example, in research published about fall detection for the elderly, the feasibility of using such sensors to detect fall events was demonstrated (Chen et al., 2006). Some other research demonstrates the capabilities of such wireless sensor networks in remote monitoring of healthcare related factors and environmental data (Glascock and Kutzik, 2000; Ko et al., 2010). It was shown that data can be collected automatically without interaction from researchers, and "enables daily care and longitudinal medical monitoring and diagnosis" (Wood et al., 2008, pg. 26).

Longitudinal studies are complex due to the need to collect the same set of variables for a given participant over a long period of time, at multiple data collection time points. Simply put, the more data is collected, and the more data collection time points there are, the higher the cost of data collection. Sensory data allows for the automation of the collection of some data, and can reduce the cost of data collection. Another benefit is that these sensors can be made unobtrusive, and thus not change or affect the participant's way of life (Kaye et al., 2011; Glascock and Kutzik, 2000).

Therefore, it can be seen that sensors are a feasible way to automate collection of contextual real-time data with regards to patient activity, with little to no impact on the patient's lifestyle.

Cross-referenced data - At times, the data required is not available first hand from the user, or through sensors that are available from the user. One such example is the weather and environmental data at the user's location. Previous studies have used data from third party sources, accessed through an Application Programming Interface (API)[1] (McGorry et al., 1998). The data obtained is then cross-referenced and correlated with the other available data. For example, obtaining weather data for a user's location from an API then adding it to the user's data set based on the specific time and date.

Social Media - Social Media has been used in studies in other fields of pain such as fibromyalgia to collect data on patient using social media networks about their experiences (Kallinikos and Tempini, 2014). Another study analysed social media sites in cancer care to examine how more support and information can be provided, and suggested that social media can influence behaviour in patients, which can change the course of treatment (Koskan et al., 2014). Delir Haghighi et al. (2017) demonstrated how it was possible to utilise sentiment analysis on social media data from Twitter in eliciting and classifying positive and negative experiences in fibromyalgia. Therefore, social media is a good instrument for contextual data as it includes information about the experience of the patients.

Social Media can be defined as "web-based services that allow individuals to: i) construct a public or semi-public profile within a bounded system; ii) articulate a list of other users whom they share a connection; and iii) view and traverse their list of connections and those made by others within the system." (Ellison, 2007, pg. 211). Some examples of such services would include Twitter (Asur and Huberman, 2010), FaceBook (Mangold and Faulds, 2009) and forums such as a fibromyalgia support group forum (Chen, 2012).

I have provided examples that demonstrate the potential of social media, which is to: i) provide contextual data on patient self-reported experiences; and ii) affect outcomes of pain using social support with information and experience sharing. It was highlighted in research that the psychological and emotional factor of a patient, along with the support and timely information provided can affect the outcome and experience of individual patients (Montoya et al., 2004; Bernard et al., 2000). Research also shows that patients turn to the use of social media to relate and share experiences with other people who have similar experiences (Ahmed et al., 2010; De Choudhury et al., 2014).

As discussed previously, one important item that contextual data has the ability to capture is the experience of a patient. In the context of chronic pain, this is important in understanding the nature of pain itself. It can be agreed that social media is an

[1] An API is an interface that provides data through a request from a web service.

instrument that can provide a deeper general understanding of the patients' pain experiences. However, I will not explore social media in the context for this thesis, but retain the concept for future studies.

This section identified six existing instruments used by similar fields that can be used to provide contextual data. As seen in the previous section, existing studies have considered some types of context, such as family and activity, but none of these studies have considered modelling the context together to increase the depth of analysis. The following section will discuss context models and approaches.

2.4.4 Context Modelling

Context modelling refers to the definition and storage of contextual data in an abstract and simplified manner that is processable by computers, and also form the basis for a contextually aware system that is able to process and analyse context (Baldauf et al., 2007). Generally, context models can be defined as belonging to one of two categories: **Type I**: models that are integrated and empowered with reasoning components
Type II: models that intend merely to identify and define key contextual attributes and factors for a specific use.

2.4.5 Existing models from the literature

I reviewed the literature for context models within the chronic pain research area and found that Type I models for reasoning did not exist, and that there were two main Type II models. The two models are the: i) biopsychosocial model; and ii) burden model.

The biopsychosocial model for chronic pain is a heuristic approach to chronic pain. It represents a set of neuroscience processes in pain, as well as the psychosocial factors which include psychological and social components. The model attempts to describe pain as an event that involves specific structures or systems in the human body that were caused by various changes in anatomy, pathology or physiology. The main factors or classes or factors that can be derived from this model is shown in Figure 2.2 where the authors have used a conceptual model to represent the processes involved. The model presented consists of three aspects: i) biological ("bio"); ii) psychological ("psycho"); and iii) sociological ("social") (Gatchel et al., 2007).

In contrast to the biopsychosocial model, the burden model shown in Figure 2.3 describes a testable model of the overall burden that captures the full breadth as

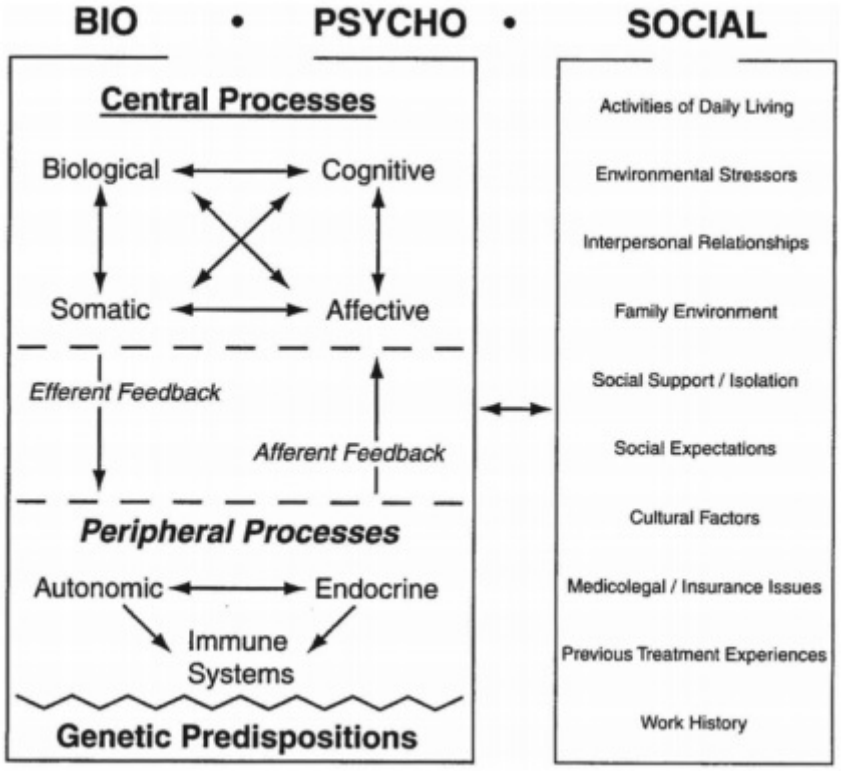


Figure 2.2: Biopsychosocial model (Gatchel et al., 2007, pg. 583)

experienced by patients and observed by experts (Buchbinder et al., 2011), for low back pain. The model was developed using a grounded validity approach using concept-mapping workshops to identify items, and further workshops along with statistical analysis to organise the identified items into clusters that formed the conceptual model. It describes six main categories of burden, which are: i) Physical; ii) Psychological; iii) Social; iv) Employment; v) Treatment; and vi) Positive Effects. Each category then contains further factors which can be broken down to specific variables such as the category 'Employment' containing: i) 'Effects in the workplace'; and ii) 'Employment situation effects'.

Thus far, I have provided an overview of the two main pain models that exist within the literature. The next section will provide an overview to the development of a descriptive contextual model.

2.4.6 Developing a descriptive contextual model

It is clear that there are not any existing models that classify or describe contextual features within chronic pain. In order to model the context around a patient's pain, it is necessary to have a descriptive model that provides a means to classify the context. I reviewed existing studies in pain to identify collected variables that can be considered contextual. I examined existing literature from 2000 till 2015 and identified

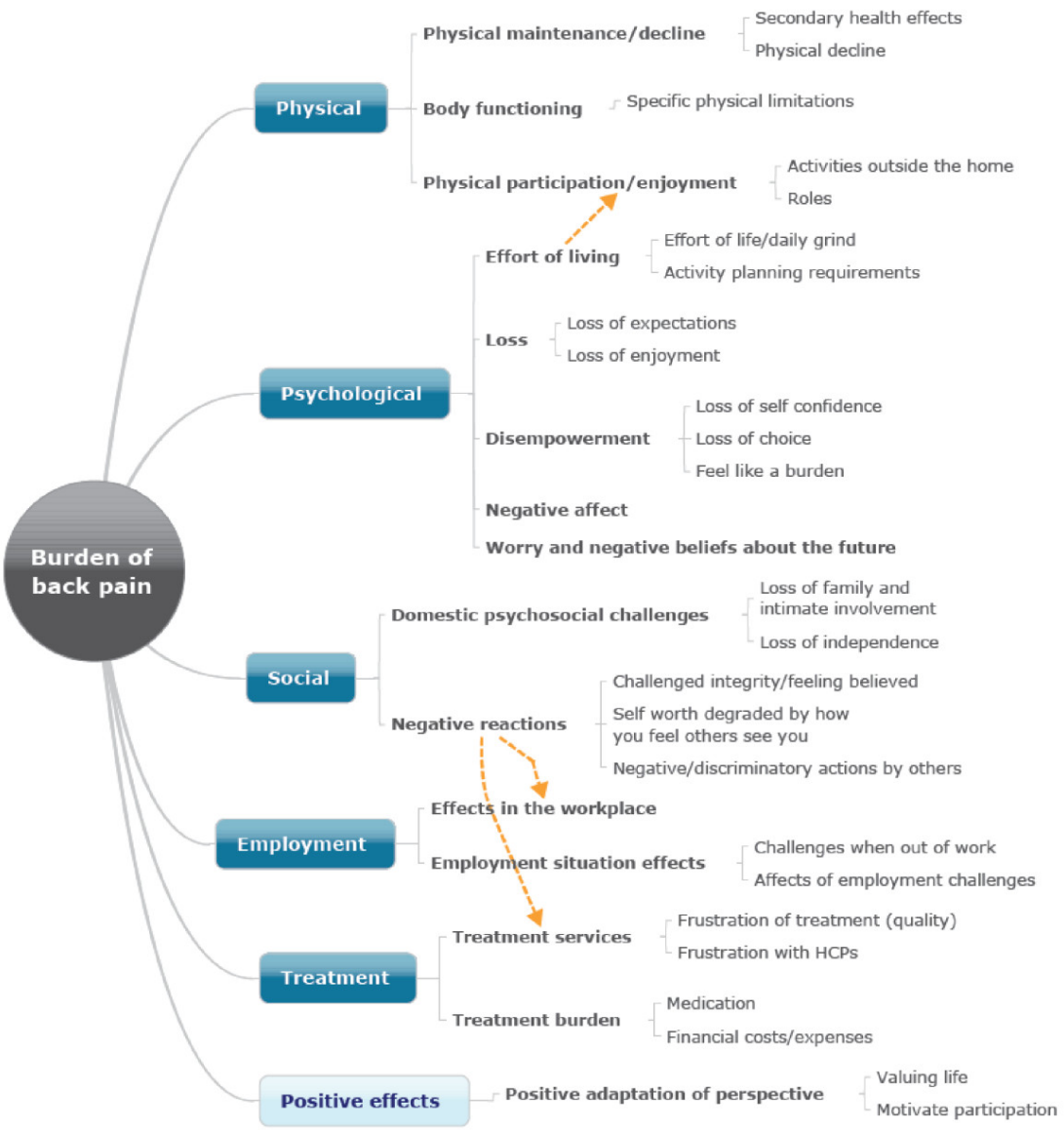


Figure 2.3: Burden model (Buchbinder et al., 2011, pg. 7)

variables that could be grouped into factors, as well as factors that could be construed as context to the patient's pain, and important background data that could be used in statistical analysis of chronic pain. I was able to identify some studies that focused on specific groups of factors (Leboeuf-Yde, 2000; Pincus et al., 2002), as well as studies that considered single or multiple factors (Souza and Frank, 2011; Shaw et al., 2013). As discussed in the previous section, I identified a model that describes six factors that contribute towards the burden of low back pain (Buchbinder et al., 2011), that also validated the naming scheme for the model. I will extend this model using contextual attributes and factors identified from studies. For example, Dunn et al. (2006) classified 'absence from work' as work-related, and measured disability using

a modified Roland-Morris Disability Questionnaire (RMDQ). Stanford et al. (2008) categorised 'adolescent anxiety/depression' as psychosocial or emotional factors. I continued identifying variables from papers in this manner until I reached saturation and did not find any new variables or categories to include. A sample of these studies are included in Table 2.1 along with the study frequency of data collection.

Table 2.1: Contextual factors in a sample of research studies (Goh et al., 2015, pg. 6)

Study	Factors	Frequency
Macedo et al. (2014)	Demographics, Physical, Psychological, Treatment, Pain, Medical History	Monthly
McGorry et al. (2000)	Pain, Disability, Medical History	Daily
Dunn et al. (2006)	Demographics, Employment, Psychological Pain, Disability	Monthly
Henschke et al. (2008)	Demographics, Employment, Physical, Psychological, Treatment, Pain, Disability, Medical History	Week 6, 3rd Month, 12th Month
Dunn et al. (2011)	Demographics, Physical, Psychological, Pain, Medical History	3-Monthly
Dunn et al. (2013)	Demographics, Psychological, Pain, Disability	Monthly
Steffens et al. (2014)	Demographics, Pain, Psychological, Physical, Environment	Once
Edefonti et al. (2012)	Pain, Psychological, Environment	Daily

I consulted domain experts to review and confirm the naming and categorisation of variables before representing them in a graphical model as shown in Figure 2.4. This initial model was published in a conference paper (Goh et al., 2015). I describe the factors below in four groups: i) external influences; ii) internal influences; iii) current activity; and iv) other information relevant to the condition. I also describe some suggested methods of obtaining such data.

I describe factors about external influences as follows:

Employment - Employment is defined as occupation related details, and includes the type of work, which describes the nature of work being done, for example physical work or office work. Other points are the effects on the employment situation, and the effects on the workplace. Variables here can be collected using a questionnaire or survey implemented online or within a mobile application. Information such as the occupation details can be obtained once and updated as necessary, but the information on the patient's perceived effects on their employment or workplace can be provided in the form of guided questions in a mobile diary.

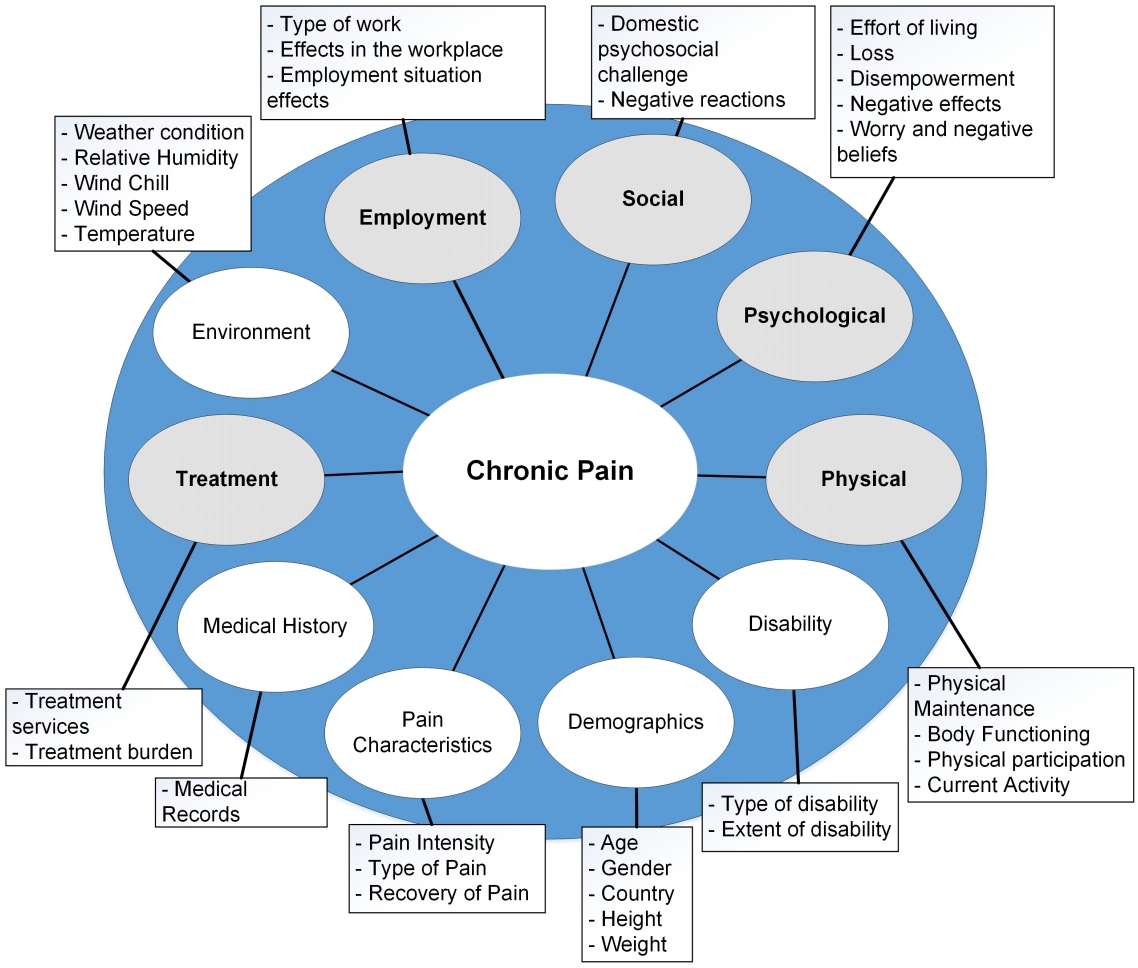


Figure 2.4: Descriptive Contextual Model

Environment - Environment includes data about the context of weather, e.g. the temperature, and extends to wind chill, wind speed, wind direction, wind gust, air pressure, precipitation and relative humidity. I suggest that such information can be collected from available sensors on the device or via bluetooth, or from third party sources such as the local meteorological station using an API by obtaining the location data from the GPS sensor on the mobile device.

I describe the factors about internal influences:

Social - Social refers to the extent which the patient is interacting with other people around him or her. This includes psychosocial aspects at home, or negative reactions about the pain that are expressed towards others. Data in this category can be collected using questionnaires or diaries on the mobile devices or over the web.

Psychological - Psychological discusses aspects such as disempowerment, effort of living, negative mental effects, worries, life satisfaction, and depression. A majority of the aspects in this category are typically collected via questionnaires. These questionnaires can be conducted over the Internet in a browser or on the mobile

device, and other information such as the feelings and thoughts of the patient can be derived from diary entries on the mobile diary.

I describe factors about current activity:

Physical - Physical refers to the exercise and activities that are being carried out by the patient. It includes the exercise, or physical maintenance, or lack thereof, body functioning, participation in physical activities, and the current activity context. Some variables here can be collected via questionnaires or questions that the user answers, which includes information about their participation in physical activities. Other variables such as the current activity context can be obtained by using activity algorithms over accelerometer data collected from the sensors on the mobile device or wearable sensors such as fitness trackers.

Finally, I describe the factors containing other information relevant to the condition:

Pain Characteristics - Pain Characteristics refers to attributes that discuss the actual pain, or recovery of pain that the patient is experiencing. This can be collected using the mobile diary, or with simple questionnaires that can be also implemented on the mobile device or over the Internet in a web browser.

Demographics - Demographics are the quantifiable statistics of the patient to a population. Examples include age, gender, ethnicity, country and suburb. These data are typically collected once at the start of the study, and usually are obtained using questionnaires.

Disability - Disability is defined as information about the patient's disabilities. This information can be either collected from the patient's medical records or provided by the patient in a questionnaire.

Medical History - Medical history contains information about the patient's medical records and previous history. This is typically provided by a third party (secure) data store, or by the patient.

Treatment - This factor discusses the current treatment services received or the burden of such treatment, and can be collected from questionnaires or cross-referencing data from medical secure databases, for example the hospital that the patient is receiving treatment from.

This section provided an overview of the development involved in designing an initial descriptive context model. The following section will summarise the findings from the literature.

2.5 Findings from the literature

Based on the literature reviewed, there are a number of limitations and opportunities that exist.

First, the intensity and experience of pain can vary across the course of a single day, and the existing frequencies of data collection are not frequent enough to completely understand the nature of pain. Studies in this field typically have a slow adoption rate in the use of technology for data collection, with almost all studies using a set of paper questionnaires that were either completed in-person, over the phone, or via mail. There is an opportunity to capitalize on the potential of using online technologies to enable the collection of more detailed data to do with the 'context' of the pain episode, which can make a significant contribution to pain trajectory studies.

Second, the concept of assessing contributing factors to pain other than the ones typically collected, such as the demographical and medical history data, is not new to the field. There have been studies looking at the relationship with pain and psychological factors (Linton and Shaw, 2011; Main and George, 2011), work and family factors (Shaw et al., 2013), environmental factors (Edefonti et al., 2012; Steffens et al., 2014) and psychosocial factors (Soklaridis et al., 2010). There are two models that were identified, which are the biopsychosocial and burden model, which were designed for specific uses. However, there have not been any works that describe an overarching model that describes these factors from a contextual perspective, which have led to the development of our initial model.

Third, the use of data from sensors is not a new concept to the field of longitudinal studies. Research has shown that the use of sensors in e-Health represent an opportunity for studies who still solely rely on self-reported or observational data (Gupta et al., 2018). It allows for data collection at a larger scale in a passive manner, with minimal user input required. It also reduces the cost of data collection, and reduces the amount of interviews that researchers would otherwise have to spend in order to collect the same amount of data. It increases the accuracy of the data collected to some extent, as the data would be less prone to user input bias and errors. On the other hand, the use of sensory data have some limitations, such as the sensor accuracy, along with the need for the user to be always carrying the sensor device in order for accurate data to be collected. Another limitation would be that the algorithms used in interpreting the sensory data would need to be validated and accepted as being accurate enough for the researchers' purposes.

Fourth, the ability to use external data via Application Programming Interfaces (APIs) to correlate third party data, such as weather and environmental information

from verified weather stations will reduce the potential cost of having to deploy equipment and resources in collecting such data first hand. Certain types of data, such as weather data, can be verified by asking the user some confirmatory questions. For example, confirming that the weather took a turn for the worse; or that there was a sudden drop in temperature. Some limitations of the use of an API would be that an internet connection would be required as most of such services would be available over the internet, and that in the case of weather, a general location of the user would be required in obtaining the closest weather station information. Another limitation would include the potential cost of subscribing to the API for access to the data.

Fifth, social media brings a new source of data which can be analysed to obtain generalised information about user experiences. Previously, the main source of such data would be forums and discussion boards for specific ailments. The advent of social media introduces some opportunities such as the ability to relate user experiences to other data that is provided by the user, and to obtain general information about the user's experience of an ailment. Other forms of analysis can be performed, such as sentiment text analysis to obtain information about the user's psychological and emotional state. As mentioned previously, social media is out of scope for this thesis but I consider it as a potential rich data source for future research.

Sixth, as previously discussed, diaries have been used to some extent to obtain information from users. Diaries allow for the collection of data from users in their own words, and the collection of their current experience, rather than the recollection of an experience during an interview by the researcher. Mobile diaries introduce the capability to collect real time data, and real time user experiences. Mobile diaries also allow for the collection of sensory data from the device itself when needed, which reduces the amount of data processing required at the server side.

Seventh, it is difficult to identify multiple correlations on variables, which are causal relationships that exist when a set of variables are within the range of some values (Cohen et al., 2013). This could be due to the fact that most statistical methods cluster or classify sets based on the pain intensity or the pattern of pain over time. Currently, most studies collect pain data on an infrequent basis, i.e. collecting pain data on a monthly, or a less frequent interval. This is a problem as it has been shown that the intensity of pain can vary across the course of a single day, and can worsen or improve as time passes, affected by a variety of factors that could include the ingestion of painkillers (Bandura et al., 1987; Benedetti, 2002).

Eighth, in attempts to identify the relationships between variables, or factors that contain sets of variables, the trend seems to use single variable comparisons with regression, to see if a specific variable has a significant relationship with the pain, or

recovery. This does not take into consideration the idea that pain is of an individual nature, hence no two patients would experience pain the same way even if other factors can be matched (Olson, 2014). This suggests that the concept of attempting to start off understanding the nature of pain by analysing it as a large cohort of clusters is not able to identify the effect on each individual. One particular study analysed patient experiences of the impact of chronic pain also supports that point to the effect where they acknowledge that their findings are of "limited generalisability as ... patients' perceptions of their pain experience changes as the pain varies alongside their lifestyles and ... in the context of the lives of the people around them" (Souza and Frank, 2011, pg. 316), which suggests that the focus for analysis should be on individual patients', not the entire cohort. For example, correlation analysis on the variables for each patient to identify patterns for the individual and then generalising those to the group, sorted for similarities in other factors such as social, family, environment, to name a few.

The previous section has outlined the current research, limitations and opportunities that exist within the chronic pain management space for longitudinal studies. The following section will summarise the chapter.

2.6 Chapter Summary

The field of chronic low back pain has shown tremendous growth in the last decade, but there is still much unknown about the nature of chronic low back pain, and the factors that influence it. Researchers currently agree that there needs to be careful consideration of multiple dimensions when studying chronic pain, and there is a need to understand the pain experience - which I define as the 'context' around each occurrence, or each pain episode.

Pain trajectories currently remain the most useful and important visualization tool for researchers and clinicians alike, to understand the progress of a patient's pain. Currently, these are primarily used to monitor a high level progress of the patient's pain, but there is an opportunity to expand its use by increasing its granularity. The data represented in the pain trajectory tends to have wider collection frequencies due to the cost of collecting such data, which results in a 'large picture' view of the pain progress. This is useful where the primary purpose of the pain trajectory is simply to monitor pain progress over time, and when there is a need to monitor how specific treatments are having an effect or lack thereof. Increasing the collection frequency would result in a more detailed or granular view of the pain progress, which would bring into focus the fluctuations within weeks and pain episodes. This can potentially

allow for the targeting or understanding of the probable causes and reasons for the pain to be fluctuating, and lead to better treatment plans being tailored.

I have provided an overview of the current state of the chronic low back pain longitudinal studies, and outlined several opportunities and limitations that currently exist, specifically to do with the use of richer sources of data and the limitation of existing studies in exploring contextual reasons for changes in pain. The lack of granularity brought about by the typically wide data collection intervals poses a problem for collecting sufficiently detailed and useful information about the context around changes in pain. There is also a lack of a generalised overarching descriptive context model to define and provide a classification for what can be considered contextual factors and variables in this field. This research seeks to help address these gaps.

The next chapter will provide an overview to the research design and approach for this thesis.

Chapter 3

Research Approach

This chapter describes the methodological approach taken to conduct this research, and specifically discusses our research objectives and design. I discuss the reasons for including a participatory component in our methodology and the resultant extension that I define as the participatory design research methodology. The research design includes a breakdown of our research activities answering our research questions, as well as some considerations for design in the two case studies. Finally, I describe the analytical methods used, as well as briefly outline the ethical considerations in this research.

3.1 Research Objectives

This thesis aims to address the gaps identified in medical literature by introducing a different approach to studying pain. Therefore this work is exploratory in nature, and designed to understand the impact and means for which an higher frequency data collection approach using technology to overcome limitations in existing research can be used. I utilise online and mobile technology in implementing the higher frequency data collection approach in this thesis.

The research objectives can be summarised as follows: i) design and develop a method that uses online technologies to enable the collection of higher frequency data; ii) explore the impact of using such an approach; iii) explore the integration of the patient's context into existing chronic pain models; iv) explore the inclusion of the patient's context in pain using a higher frequency data collection approach; and v) explore the impact of including context when studying chronic pain.

This thesis addresses the following research questions:

RQ1: What can be learned from a higher frequency data collection approach in chronic pain?

RSQ1.1: How higher frequency data collection instruments can be designed?

RSQ1.2: What is the impact of a higher frequency data collection approach on chronic pain studies?

RQ2: What can be learned from incorporating the patient's context in chronic pain?

RSQ2.1: How to model the patient's context in chronic pain?

RSQ2.2: How data collection instruments that incorporate context can be designed?

RSQ2.3: What is the impact of incorporating the patient's context in chronic pain studies?

The questions were formulated from the results of discussions with medical domain experts, and will be discussed with greater detail in Section 3.3.

3.2 Participatory Design Science Methodology (ParDSM)

Design science is a problem-solving methodology, that seeks to derive "knowledge and understanding of a design problem and its solution are acquired in the building and application of an artifact" (Hevner et al., 2004, pg. 82). The inherent nature of the overarching problem; the lack of knowledge about a yet unproven method to study pain - requires careful development of the research approach. I chose design science as its inherent problem solving nature as a methodology allows the clear flow of processes and knowledge throughout its phases. Peffers et al. (2007) described the methodology as an iterative process flow with four possible entry points for research, with a linear iteration through processes of: i) Identify Problem; ii) Define Objectives; iii) Design & Development; iv) Demonstration; v) Evaluation; and vi) Communication. I use design science methodology in building artifacts to solve the problems that have been identified. Through the building and instantiation of such artifacts, I am able to derive new knowledge and understanding of both the problem and solution.

As I am working on a medical problem, I consider the 'owners' of the research problem to be the domain experts within the medical field of research. The support of the medical domain experts is critical to the success of this work. Therefore, in order to ensure the validity and the usefulness of our work, the inclusion of medical

domain experts in this research is critical, not just as users, but as equal partners - as participants in our work.

Cocks and Cockram (1995) described participatory research as a problem that has been identified and brought to the attention of the 'domain experts', who then work together in a common alliance to solve the problem with a focus on the interests of the 'domain experts'. Participatory research has been considered an enabler of partnerships between stakeholders, which are typically defined into three categories: i) domain experts; ii) domain users; and iii) researchers (Chappell, 2000; Schuler and Namioka, 1993). Therefore a critical component of the methodology used in the work needs to be participatory in nature. I adapted as the participatory component, five key drivers identified by McKemmish et al. (2012) from their work on inclusive research design, represented in a double hermeneutic spiral shown as: i) Reflecting; ii) Analysing; iii) Negotiating; iv) Values; and v) Expectations.

Therefore, in considering a specific approach or framework to use within the design science space, it is clear that I needed an approach that would allow us to consider the participants and the iterative nature of research in a single framework. I found the Participatory Action Design Research (PADR) approach by Bilandzic and Venable (2011), but do not implement it as the framework treats users as a grouped entity and does not focus on the separation of roles within the users. Additionally, the PADR approach was conceived as a framework to support urban informatics, focuses on the human-computer interaction between people and technology. I extended the design science research methodology framework by Peffers et al. (2007) with the participatory component as seen in Figure 3.1. This strengthens the collaborative aspect, while still maintaining the iterative flow through different design science processes, and allowing the prescription of McKemmish et al. (2012)'s five key drivers for participation. I designed the participatory design science methodology (ParDSM) approach to support participatory work in design science for IT medical research in the field of e-Health.

One other key difference in our model is where the research entry point is defined. I believe that while it is common for projects to begin at other entry points as identified in Peffers et al. (2007)'s work, such as objective, design and development, or client/context initiated entries; the research 'component' in such projects only really begins when a concrete problem is identified. For example, a common scenario is where medical researchers approach IT/IS researchers to build a system. This remains a 'system development' or 'system design' project until the researcher can recognize and identify the 'problem' that building the system will resolve. Therefore, the key entry point to the ParDSM approach is problem-centred, and this will guide the identification of the core research problem.

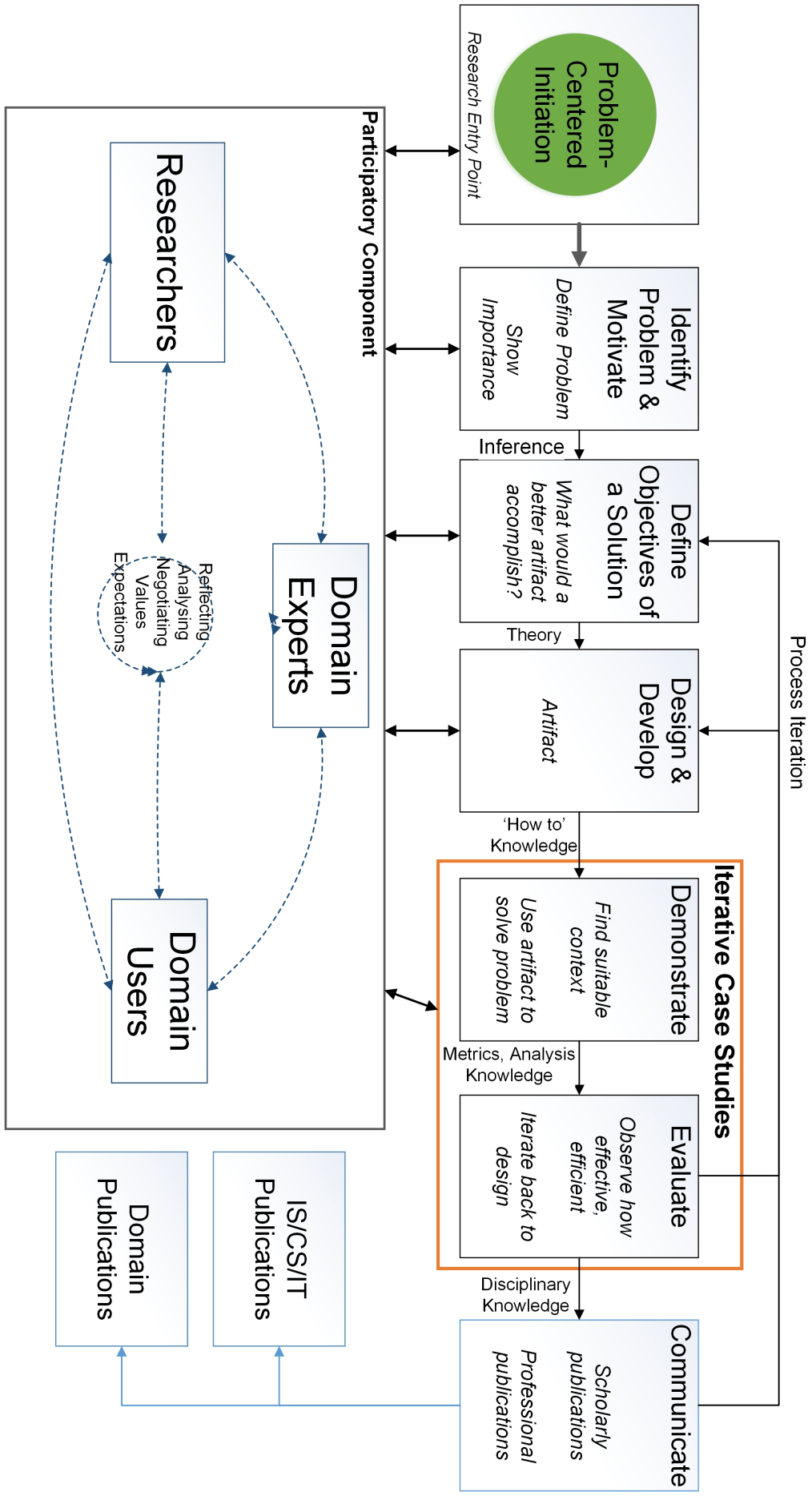


Figure 3.1: Participatory Design Science Methodology (ParDSM) (adapted from Peffers et al. (2007))

The main components present within the ParDSM model are described as follows:

Participatory Component

I define the participatory components as the active, cooperative engagement between researchers, domain experts, and domain users involving the five key steps of: i) Reflecting; ii) Analysing; iii) Negotiating; iv) Values; and v) Expectations. These five key drivers have been adapted from McKemmish et al. (2012)'s work on inclusive research design. These five key drivers are: i) Reflecting; ii) Analysing; iii) Negotating; iii) Values; iv) Expectations. This allows us to design a research process that is inclusive, by guiding communication between the participants using these five drivers. The problem owners of the defined problem are the domain experts and/or the domain users, not the researchers. This ensures that the researchers do not over reach in their expertise, and that the work will be grounded in an applied or reality based manner to actual domain experts and users in a useful manner.

Iterations

I define iterations as the logical process loop between steps, or within steps. ParDSM is flexible in that it allows for micro-iterations within steps, major-iterations that involve case studies in demonstrating and evaluating artifacts, that allow for minor-iterations during any phase or step. By iterating work, it allows the revision and incorporation of feedback and lessons learnt, with the final result produced by that step being refined and of greater use to both researchers and participants. Thus I believe that it is important to ensure that the research design includes iterations to allow for the active participation and inclusion of knowledge generated by all participants.

Research Entry Point - Identify Problem and Motivation

The starting entry point to research begins with the identification of a problem. Once a problem has been identified, it is necessary to confirm the validity of the problem and motivation with the participants, i.e. the domain experts and domain users. The input from the participants will assist in concretely defining and scoping the problem, and identify the importance from all three perspectives. This grounds the research in reality rather than on the theoretical level.

It is necessary at this step to negotiate and set expectations for the levels of participation of the domain experts, users and researchers. I find that in information technology (IT) research, a lot of work is done from the researcher's perspective of the problem, and therefore sometimes the system that is built as a result; even though it received good evaluations, never actually get used as intended. It is important for the researcher to consult the domain experts and users to ensure that ongoing

progress, especially when building artifacts and defining objectives; continues to make sense to the domain experts or users.

The cycle of consultation and negotiation between researchers and domain experts should continue throughout the project in order to ensure that the work done has a useful impact. The impact of the work is strongly dependent on how the research follows existing domain practice. It may be an interesting project or work from an IT perspective, but not necessarily so in the specific domain and this means that the problem owners will never be the researchers, but always the domain experts and users.

Define Objectives of a Solution

The second step is to identify the objectives that the research will have. There needs to be discussion and negotiation of these objectives with the participants to reach an agreement. Typically the researchers will begin by identifying the potential impact and benefits which is inferred from the problem and motivation, then negotiating this with the domain experts. This step also serves to set expectations of the work by participants. There can be major iterations in defining sets of objectives in increasing sizes, much like the layers of an onion where each iteration builds onto work from the previous one.

Design and Development

The third step involves building an artifact. The artifact combines current knowledge and potential theories to create an artifact that may be a system, process, architecture or components. The artifact is designed and developed by the researchers, with input from the other participants in the form of feedback, reflections, and values. It may be necessary to micro-iterate between versions of artifacts during this process.

Demonstrate and Evaluate using Iterative Case Studies

The fourth and fifth step may be combined or conducted separately. The artifact needs to be used in a suitable context to demonstrate the potential and create 'How-to' knowledge. This may require implementation of the artifact as part of a system that is used in a case study. The evaluation of the artifact and its implementation will generate metrics, enable analysis and generate knowledge about its impact and effectiveness. At this point, feedback in the form of reflections, as well as further analysis of the effects from all participants is required.

The results of the case study should return knowledge that can be fed back into the design of the artifact, which could trigger a new major iteration for the artifact.

Communicate

The final step involves communicating the research outcomes and case study outcomes via publications in both the expert domain and information systems / computer science / information technology publications where relevant.

The remaining sections in this chapter will continue by outlining the research design, objectives, methods and ethical considerations.

3.3 Research Design

The research design implemented ParDSM and ensured that I considered the participation of medical domain experts as a critical component of the work, in order to better understand the problems faced within the field. This also ensured that the measures and means from which I collected, analysed and presented medical data, were valid and of use to the medical domain experts. Furthermore, the participatory component of this thesis stems from the collaborative effort between three parties: i) researchers; ii) domain experts - 'clinicians', and iii) domain users - 'pain sufferers'. The methods and means developed in this research through negotiation, analysis and reflection needed to meet current clinical research practice, and be validated to some extent. Throughout the work, there was constant discussion and negotiation between parties in order to find a way to shift the current clinical thinking and introduce a new paradigm.

Based on the gaps identified, I formulated the research questions that are described as follows:

RQ1: What can be learned from a higher frequency data collection approach in chronic pain?

The first research question is about exploring the use of a higher frequency data collection approach. The aim is to understand the benefits and demerits or limitations of using such an approach. I break this question down into two sub-questions (RSQ) which are outlined as follows:

RSQ1.1: How higher frequency data collection instruments can be designed?

The first sub-question is to first determine how the existing data collection instruments used in chronic pain can be transformed for use online, and in a higher frequency data collection approach. One such concern when using the same instrument at higher frequency is the time required to complete a questionnaire. Traditional questionnaire tend to be long and have been designed to be completed on paper. The aim of this question is to elicit a set of guidelines in the design for higher frequency data collection instruments.

RSQ1.2: What is the impact of a higher frequency data collection approach on chronic pain studies?

The second sub-question is aimed at understanding the impact of using a higher frequency data collection approach. This includes exploring the pros and cons of using such an approach, and an understanding of some kinds of data analysis and results that become possible by doing so.

RQ2: What can be learned from incorporating the patient's context in chronic pain?

The second research question is about exploring the integration of the patient's context into chronic pain. The patient's context is important as it may be useful in furthering research into the nature of pain. The aim here is to explore the impact and effects that the patient's context has on studying chronic pain. In answering this question, I divide it into three sub-questions which are outlined as follows:

RSQ2.1: How to model the patient's context in chronic pain?

The first sub-question seeks to understand how a patient's context for chronic pain can be modelled. Currently, there are no model or architectural descriptions of a patient's context for chronic pain. The goal is to develop a descriptive model of context for chronic pain that can be used in mapping variables to contextual categories.

I identify design principles that need to be considered when creating data collection instruments that incorporate context. Examples of data collection instruments can include questionnaires and systems that instantiate or implement these questionnaires.

RSQ2.2: How data collection instruments that incorporate context can be designed?

The second sub-question is about designing data collection instruments that incorporate context in chronic pain. The goal is to develop a set of design principles for the development of a contextual data collection instrument in chronic pain.

RSQ2.3: What is the impact of incorporating the patient's context in chronic pain studies?

The third sub-question aims to explore the impact of integrating context into the analysis of pain data. The two goals are to develop a set of guidelines or recommendations on analysing pain data that includes the context of pain, and to explore the impact of using the patient's context in analysing pain.

Figure 3.2 illustrates the implementation of ParDSM for this thesis. As mentioned previously, the domain experts were hesitant in using a higher frequency data collection approach, as they did not feel that there would be more useful information that could be obtained. Therefore I designed this research to use two main iterations, each over a single case study. The two case studies are exploratory and have different

aims in answering our research questions. The first case study (CS1) was designed to be a proof-of-concept pilot, that would focus on a known condition, in order to demonstrate the potential of using a higher frequency data collection approach with online technologies. It also enabled us to demonstrate the value in a contextual, higher frequency data collection approach for studying pain. The second case study (CS2) was designed from bottom up using new data collection instruments that were developed in a participatory manner, and focused on an unknown pain condition. The study was exploratory, and served to instantiate and evaluate the refined artifacts from CS1 in answering our research questions. The process flow for each case study revolves around a major iteration to provide input, analysis and reflection back into the research objectives, as well as the artifact design. I describe these case studies with further detail in Chapters 4 and 5.

I utilised controlled experiments without a control group for both CS1 and CS2. Hevner et al. described controlled experiments as being used to study an artifact within a "controlled environment for qualities" (Hevner et al., 2004, pg. 86) such as usability. I did not use a control group because I felt that the comparison of pain between individuals is not meaningful, as different people will have varying pain tolerances and experiences. Instead, this research conducts comparative analysis between the traditional frequencies of data collection and higher frequencies, to determine and study the impact of such an approach on the data collected. The main measure for evaluation within these experimental, exploratory studies in this research is the impact, which is demonstrated during the analysis and discussion of the results obtained from each study, and from the domain experts perception and interpretation of the results.

Table 3.1 provides an overview of the overall research stages and their input to answering the research questions.

3.4 Considerations for Design

Based on the literature review and the research aims, I elicited a set of high level design principles to form an initial architecture for the higher frequency data collection (HFDC) approach that incorporated context. I provide an architecture for the higher frequency data collection approach in Figure 3.3. The architecture uses a server-client model to represent the web application, which enabled storage of the data collected in a single location.

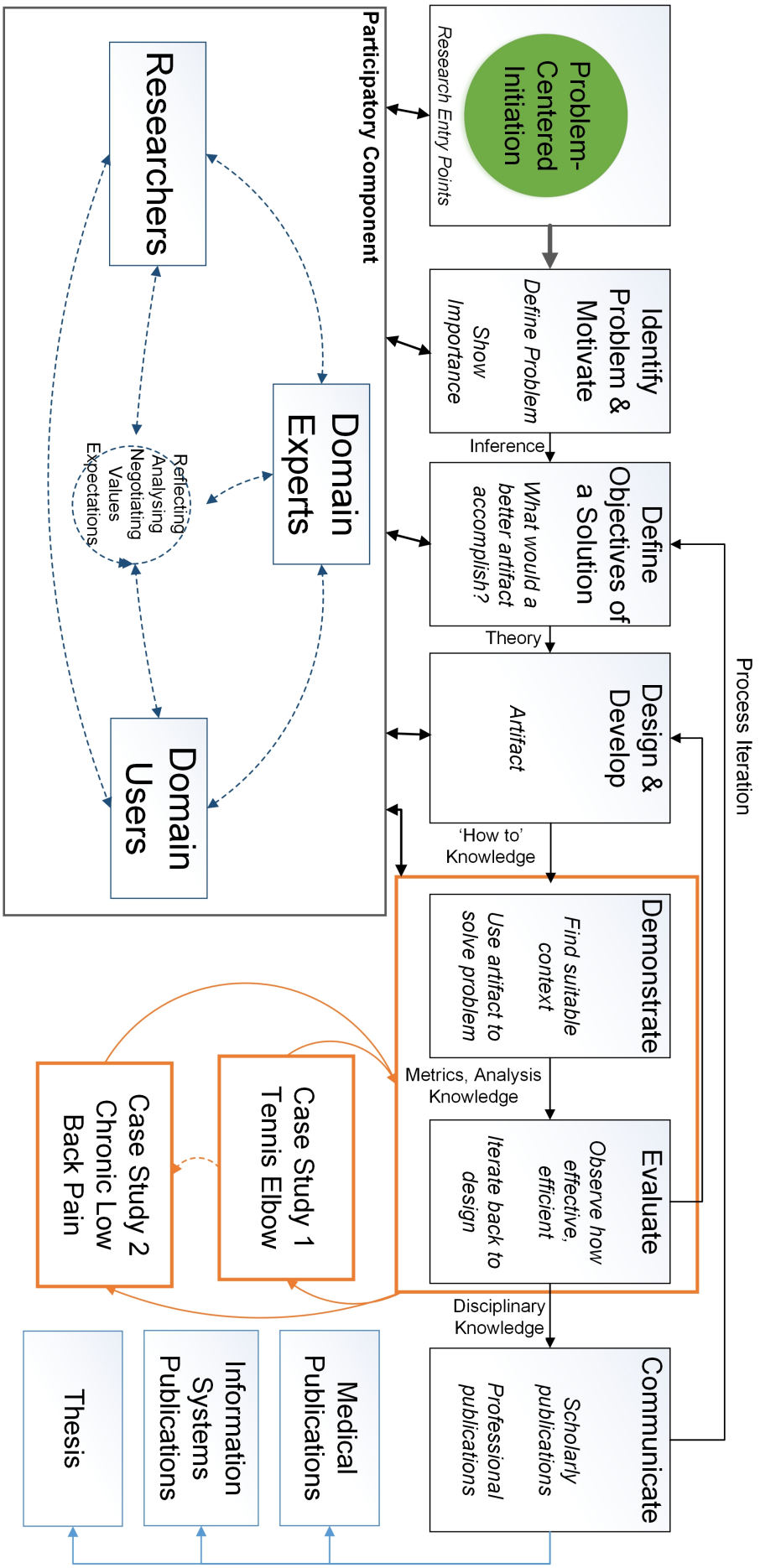


Figure 3.2: Research Methodology using ParDSM

Table 3.1: Research Stages and Mapping to Research Questions

No	Stage	Activities	RQ
1	Problem Identification	Literature Review Problem Formulation Negotiation/Discussion with Experts	Reviewing Literature Gap identification
2	Define Objectives (Overall)	Define RQs Negotiate Objectives with Experts Identify Artifact goals	Define research questions Identify research objectives Design research approach
3	Design & Development	Literature Review (Context) Identify Contexts Identify Pain Models Propose Models Design Context Model Expert Evaluation for Model	 RQ1 RSQ1.1 RSQ2.1 RSQ2.2
4	Communication	Publish Initial Model and Approach	RQ1 RSQ2.1 RSQ2.2
5	Demonstration (CS1)	Design instantiation of model in CS1 Collaborative design of system	RSQ1.1 RSQ1.2 RSQ2.2
6	Evaluation (CS1)	Analysis of preliminary data Expert Discussion on impact of findings Research findings support work	RQ1 RSQ1.1 RSQ1.2 RSQ2.2
7	Design & Development	Revise model using findings	RQ1 RSQ2.1 RSQ2.2
8	Demonstration (CS2)	Design second instantiation of model in CS2 Collaborative design of contextual instrument Collaborative design of system	RSQ1.1 RSQ2.1 RSQ2.2 RSQ2.3
9	Evaluation (CS1)	Final analysis of data Expert discussion on impact of findings	RQ1 RQ2
10	Communication	Publish findings from CS1	RQ1 RQ2 RQ2
11	Evaluation (CS2)	Collaborative exploratory analysis of data Analysis of user experience Expert discussion on impact of approach	RQ1 RQ1 RQ2
12	Design & Development	Refine model using findings Formalise guidelines and design principles	RQ1 RQ2
13	Communication	Publish findings from CS2 Publish findings from research	RQ1 RQ2

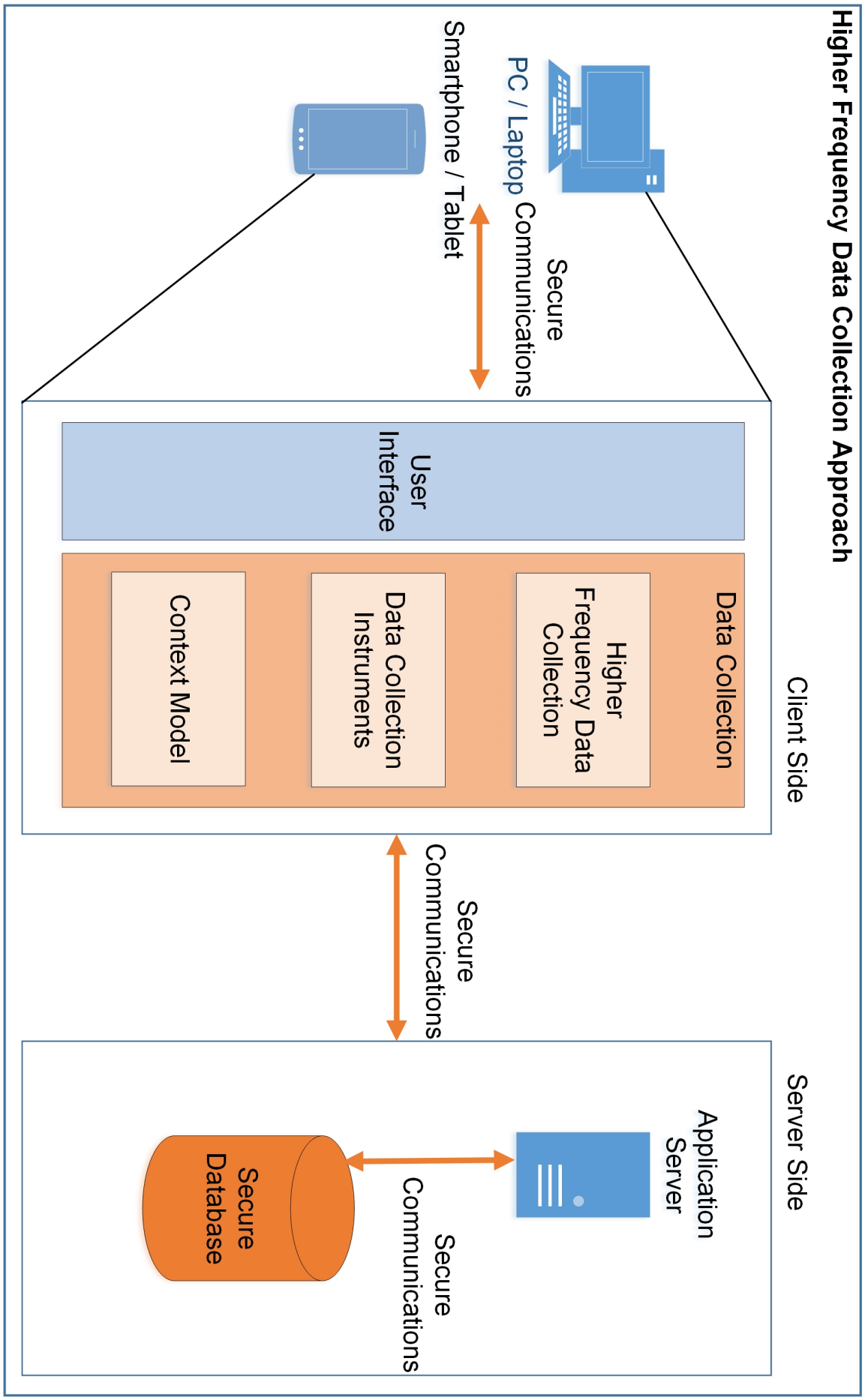


Figure 3.3: Architecture representing high level design principles

There are five design principles that have been identified: i) higher frequency data collection; ii) patient context; iii) mobile accessible; iv) secure; v) user interface considerations. I describe these design principles as follows:

Higher frequency data collection - A core aim of this thesis was to utilise online technology in enabling higher frequency data collection. The architecture contains a core principle that the data collection should be conducted at higher frequencies, i.e. weekly or daily. I feel that it is ideal if the data collection is conducted close to real-time, which would rely on patients' reporting their changes in pain as they perceive it. This is similar to how a diary would be used to record memories of pain experiences. The data collection component also includes an overlap of the data collection instruments. This is because it may not be appropriate to use existing questionnaires for data collection, as some of the instruments are quite lengthy and require some time to complete them.

Patient context - Another aim of this thesis is to incorporate the patient context in studying chronic pain. I included this as a context component that utilises the context model discussed previously in Chapter 2. The context model informs the selection and design of data collection instruments, based on context factors that the study aims to collect.

Mobile accessible - As mentioned previously, I aim to use online and mobile technology to enable the HFDC approach. The systems that are developed will be designed to be mobile friendly, which would increase the ease of use of mobile devices such as smartphones or tablets. This enables the patients to use the system for reporting pain at any given time of the day on any of their Internet enabled devices.

Secure - Researchers have identified the issues of security and privacy for health-related data (Kerr et al., 2017). The data collected in these systems would contain medical data that is sensitive. I need to ensure that the data collected was transmitted in a secure manner, and stored in a secure location that does not allow unauthorised access. Previously, when using pen and paper questionnaires, this would be simple as it required that the researcher simply lock up the papers in a secure cabinet. However, when it comes to electronic data; ensuring that the data collected is securely stored and transmitted is much more difficult, and requires explicit consideration.

User interface - The user interface design should consider existing guidelines for graphical user interface design, such as Nielsen (1995)'s ten usability heuristics.

In designing and evaluating the systems used for CS1 and CS2, I elicited and negotiated further design considerations for the system from our medical domain experts in each case study. The following subsections will give a brief overview of CS1 and CS2.

3.4.1 Case Study One (CS1)

The first case study was designed as a proof of concept study to explore a known condition of pain, in overcoming the domain experts' hesitance over the higher frequency data collection approach. The study focuses on tennis elbow, which is a known condition that is a result of the overuse of specific muscles at the elbow, leading to persistent elbow pain (Winston and Wolf, 2015). It was reported that about 67% of persistent elbow pain are attributed to tennis elbow, and it has a typical recovery period of 1-2 years for 90% of patients (Descatha et al., 2016). As tennis elbow is a condition with a known outcome and is treatable, the assumption from the clinical point of view is that there is very little to be added to the body of knowledge in this area by trying to understand the patient's pain experience, using a higher frequency data collection approach.

I developed the first case study as an add-on analysis that would adjust the data collection schedule for a real world clinical trial. The clinical trial is investigating the value of specific injections when compared to placebo, and is run across multiple sites in Australia, and registered on the Australian New Zealand Clinical Trials Registry as ACTRN12613000616774. I developed a secure, mobile-friendly, online web application that collected data using digital form representations of the physical paper questionnaires. The web application used PHP, HTML, JavaScript and CSS with a focus on simplicity and was designed to be a 'digital' version of the actual paper forms. I discuss further details in Chapter 4.

Through discussions with our clinical partners, I elicited a set of design considerations for the system, which are outlined in Table 3.2.

Table 3.2: Design Considerations

Item	Description
Text colour	Black Tones
Headings	Bold emphasis for questsion headings
User progress	Progress bar at the top of the questionnaire to show progress
Emphasis of text	Question emphasis to follow the paper questionnaire styles
Errors	Errors are to be shown in red
Navigation	Navigation menu should be at the top of the page
Home page	User home page should show questionnaires due
Secure	Data collected needs to be stored securely

From an implementation perspective, a majority of the work lies in designing digital versions of the paper form elements that were still representative of the paper versions, and conformed to the validated style questionnaire. One of the considerations for

design I faced was the issue of the security and privacy of the system. This is vastly different and much more challenging to ensure when compared to traditional methods of data collection. For example, most trials use pen and paper questionnaires to record results and data. The physical media can be easily secured by locking it up in a cupboard in a secure space. However, when the data is stored online, digitally; it becomes a different problem as the data has to be stored in a secure server in an encrypted manner, and when being transmitted; needs to be encrypted to prevent other people from being able to read it in-transmission. I had to ensure that the data collected was transmitted in an encrypted manner, and that the data was stored in a secure way that conformed to the relevant legislation and laws.

In implementing a higher frequency data collection approach, I studied the existing clinical trial design and negotiated with our clinical partners, proposing data collection frequency changes to the existing protocol. This work was pitched as an add-on analysis component to an approved clinical trial for tennis elbow, which enabled us to study the impact of using such an higher frequency data collection approach on a known condition that had an expected recovery period. In addition to the data collection frequency, I also considered environmental contexts for the patients participating in the clinical trial. The data collected is explained in further detail in Chapter 4.

3.4.2 Case Study Two (CS2)

Based on the results of the first case study, I designed the second case study to explore the use of the higher frequency data collection approach with the inclusion of patient context. I focused on an unknown pain condition, low back pain. Within the chronic pain space, low back pain is currently the main contributor to disability, and affects much of the global population (Hoy et al., 2014; Maher et al., 2016). The majority of chronic low back pain suffers are diagnosed as non-specific, which means that the causes of their pain is unknown (Maher et al., 2016). I felt that this was a good fit for our approach as the existing medical studies have not made much headway in understanding the nature of low back pain.

I developed this study from the ground-up, and designed it as a one month exploratory data collection study. I had to develop and design our own data collection instruments, as none currently exist that elicit the context of pain experienced. The questionnaires used validated measures for pain and disability. The web application for CS2 used the same web programming languages to the instantiation in the CS1, with the implementation using PHP, HTML, CSS and JavaScript.

Participatory design was used in developing new data collection instruments in the form of questionnaires that will allow the collection of participant pain context. The collaboration included domain experts that were able to ensure that the questionnaires used validated measures and collected data that would be of statistical and descriptive value.

The questionnaires were designed over three months, with constant discussion and adjustment of the questionnaire variables, question wording, digital design and layout between us and the domain experts. A secure online data collection system was then built to for the questionnaires designed. I used the design considerations from CS1, with a focus on the user's mobile experience as I expected most of the participants to use some form of a mobile device to access the system daily. As with CS1, one of the major challenges was ensuring the security and privacy of the data collected.

The measures for evaluation were defined as the results of the descriptive statistics and pain trajectory when comparing a higher frequency data collection method (daily) to weekly data collection. This is similar to that of CS1, but with the inclusion of the contextual data collected.

The second case study ran over two months, collecting contextual pain data daily for a period of 33 days. The study participants were able to access the system through a mobile browser, and were sent daily reminders via email at a user selected time. The data collected was plotted onto pain trajectories and results were reported on the contextual data in explaining fluctuations of pain, as well as the impact of the weekly versus daily data collection. Domain experts evaluated and provided feedback on the design and impact of the weekly versus daily data collection, and the measures defined were reported. I explain CS2 in greater detail in Chapter 5.

3.5 Research data analysis methods

The research methods used for analysis are mixed methods and include a wide range of qualitative and quantitative analysis methods. Specifically, I used qualitative thematic analysis, statistical analysis, descriptive statistics, as well as the pain trajectory and area under the curve measures for pain.

NVivo was used to perform qualitative thematic analysis (Fereday and Muir-Cochrane, 2006) to identify themes and code the data collected from the exit questionnaires, as well as the notes taken from the phone and email contacts between the study participants and the researchers. The thematic analysis was aimed at understanding the impact that using such a system had on the participant. The questions on the questionnaires were intentionally open-ended in order to capture the user experience.

I used Stata 14 (StataCorp LP, 2014) and R (R. Core Team, 2013) to run the linear mixed effect models, as well as the generalised linear model for both case studies. This allowed us to test for any statistical significance in the data collected, at a cohort level and on the individual level.

I used SPSS 24 (SPSS, 2008) to plot pain trajectory and pain experience graphs and calculate area under curve for the pain experience. This was used with descriptive statistics and manual coding of the reported user activities to gain a contextual understanding of the user's patterns and what caused reported fluctuations that were shown on the pain trajectory. The pain experience was plotted as the area under the curve as the total pain experienced by the patient. This was used to contrast different data sets based on the intervals of data collection, i.e. 1 month vs daily, and allowed an understanding of the differences in experience that would be obtained by each data set.

I also developed a new process to analyse the pain experience graph which was annotated with the patient's contextual activities. This is described with more detail in Chapter 5.

3.6 Ethical Considerations

This research comprises of two main case studies which involve participants. Extra care was taken to ensure that the privacy of these participants was not breached over the duration of these studies. Each case study has applied for and had been granted ethics approval from various ethical committees. Further details of this approval is included where this thesis discusses each study in Chapter 4 and 5.

3.7 Chapter Summary

The main purpose of this chapter was to outline the research design and approach taken for this thesis, and to explain the use of design science methodology and our subsequent extension as ParDSM. I summarised the proposed research activities and outputs in Figure 3.4.

I described the ParDSM methodology that was extended with participatory components and a problem centered research initiation based off Peffers et al. (2007)'s original DSRM Model. I defined the two main research questions and laid out the considerations for design towards the two exploratory case studies that I will conduct, which included an initial architecture for the HFDC approach incorporating the

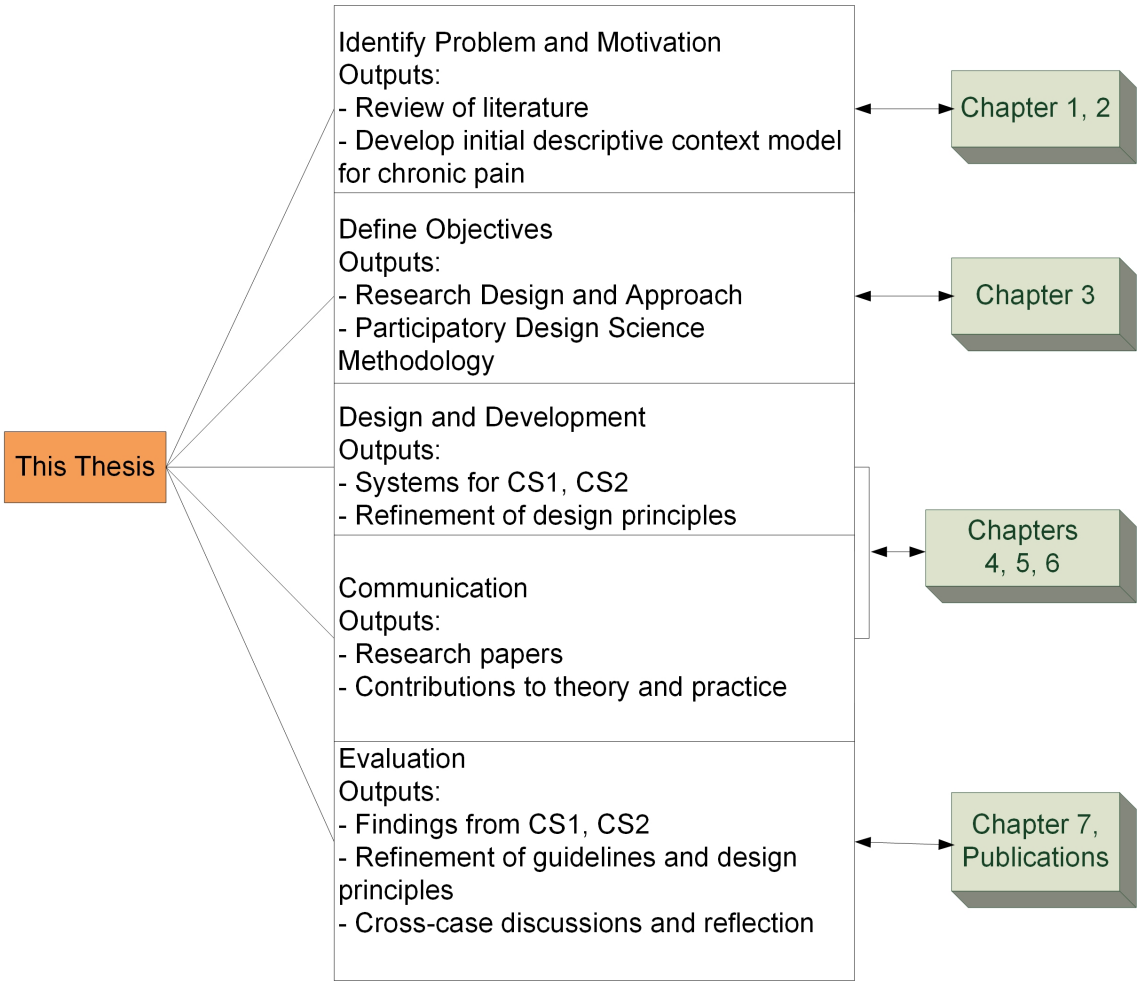


Figure 3.4: Summary of proposed research processes and outputs

patient's context. I briefly described the analysis methods that will be used for this research, with finer detail of these to come in the next two chapters.

Chapters 4 and 5 will contain the two exploratory case studies, including their respective motivations, study design and protocols, an overview of the data analysis conducted, as well as a discussion of the results and findings. Following that, Chapter 6 will bring the two case studies together with a discussion on what was learnt from each case study that lead to further refinement and revision of our results, and conclude by discussing the findings relating to the research questions.

Chapter 4

Study: Tennis Elbow

This chapter presents the first case study that was designed as a proof of concept, in testing out the higher frequency data collection approach and to obtain some preliminary data to support the research approach for answering our research questions. The chapter is structured as follows: Section 4.1 outlines the background and motivation to the case study, followed by a description of the case study design and protocol in Section 4.2. I continue by outlining the design and development stage in Section 4.3, before discussing the data analysis methods used in Section 4.4, accompanied by the results and discussion, followed by our findings for this case study in Sections 4.5 and 4.6 respectively. I conclude the chapter with a summary in Section 4.7.

4.1 Background and Motivation

The case study is based off an opportunity where one of our clinical partners had an ongoing clinical trial in the recruitment phase, and I was invited to study the condition by making a case to enhance the clinical trial with this case study as an add-on analysis component. The clinical trial is a randomised trial of treatments for Tennis Elbow.

Tennis Elbow is also known as Lateral Epicondylitis (LE), which is an injury that stems from the overuse of specific muscles at the elbow, that leads to persistent elbow pain (Winston and Wolf, 2015). Currently, about two thirds of persistent elbow pain are attributed to LE, and it has a typical recovery period of 1-2 years, for up to 90% of the patients (Descatha et al., 2016). The current focus of treatment for LE is to relieve pain and restore elbow function. As LE is a condition with a known outcome and is treatable, one assumption from the clinical point of view is that there is very little to be added to the body of knowledge in this area by trying

to understand the patient's pain experience, using a higher frequency data collection (HFDC) approach.

Therefore, it was necessary then to establish certain goals for this case study, to serve as a proof of concept: i) demonstrate that more informative results can be elicited using a HFDC approach; ii) determine how increased data collection frequencies can improve the depth of understanding on the trajectory of pain; and iii) explore the usefulness of such data in explaining changes in pain due to contextual reasons.

These goals allowed us to establish a case for the use of technology in instantiating the HFDC approach, and to understand the impact of this approach on the analysis of pain in this study. The study design enabled an initial exploration towards answering the first research question, and explore the potential in the second research question.

4.2 Study Design and Protocol

The clinical trial that I am working with is a randomised, controlled trial that investigates the value of platelet rich plasma injections or glucocorticoid injection compared with placebo for LE. Ethics approval for this study was granted by the Cabrini Hospital Human Research Ethics Committee (HREC # 05-04-02-13), the Monash University Human Research Ethics Committee (Project # CF13/765 - 2013000342), the Sydney Local Health District Ethics Review Committee (RPAH Zone) (Protocol No X13-0401 & HREC/13/RPAH/556) and the Queen Elizabeth Hospital (SSA/15/TQEH/165). The trial is registered under the Australian New Zealand Clinical Trials Registry as ACTRN12613000616774.

I began by studying the protocol that was set out by the clinical researchers. The original study design specified the use of paper based questionnaires that were to be returned by mail. There were fourteen questionnaires, of which seven were to be completed by the participant on their own, two be completed by the attending doctor and the remaining five completed on paper in the presence of the attending nurse or doctor. I include a copy of the questionnaires used in the Appendix A. As the design of the existing questionnaires were intended for completion on paper, they did not translate directly into an electronic copy. I had to first adapt the seven questionnaires used for participants into an online, electronic format. This resulted in four main changes, which are outlined as follows.

The first change involved identifying the type of response best suited for the question asked. On the paper questionnaire, these were typically all shown as a selection of numbered choices. For example, a question requiring a 'Yes' or 'No' response can use radio buttons or a drop down list to display possible choices; however, questions

that ask the user to select one option from multiple choices (e.g. a, b, c, d, e) should be represented using a drop down list.

The second change was to identify questions with complex logic, and to represent them on their own section or page so as to not confuse the user. One such example is in the case of a question asking for the medications that were taken over the week; the question had an option that would not require the remaining parts of the question to be answered which stated "I didn't take any medication in the past seven days". However, if the patient selected one or more of the medications, then it was necessary to enter further information about their prescription, which included the quantity and frequency of the dose. At the same time, these complex logic questions required proper validation of the responses to ensure that the user entered choices were correctly selected.

The third change was to streamline the questionnaires such that related questions showed up on the same section or page when being answered electronically. This included re-pagination of the questions as represented on the paper questionnaire form, into cohesive sections on the electronic copy. It was also important to ensure that: i) the user was not required to scroll too far down a single page to complete question on the current page; and ii) the user was 'guided' through the questionnaire and that it was straightforward to use.

The fourth change made was primarily due to our goal of investigating if a higher rate of data collection will provide more informative results. I modified the intervals for the pain variables to be weekly for Weeks 0 to 12, and 4-weekly from Weeks 12 - 52 as shown in Table 4.1. This allows a direct comparison of data collected at the old intervals at Weeks 0, 3, 6, 12, 24 and 52 to the increased frequent interval, which would allow us to determine if there were further changes in pain during this time, and if there were any unusual patterns of pain over this time.

Table 4.1: Adjustments in interval for data collection

Variable	Original Interval	Adjusted Interval
Overall Pain	Weeks 0, 3, 6, 12, 24, 52	Weekly from 0 - 12, 4-weekly from 12 - 52
Pain at night	Weeks 0, 3, 6, 12, 24, 52	Weekly from 0 - 12, 4-weekly from 12 - 52
Activity pain	Weeks 0, 3, 6, 12, 24, 52	Weekly from 0 - 12, 4-weekly from 12 - 52

Based on the context model outlined in Chapter 2 and previously published by Goh et al. (2015), I negotiated with our study partners to collect some additional

contextual data. The selection of variables was based on research that suggested that some symptoms of pain can be individually affected by certain conditions such as weather (Bossema et al., 2013). The study collected environmental context data on the minimum temperature, maximum temperature and humidity of the participant's home suburb at the point of report, as well as an independent living (disability) measure, exercise (physical) measure, and employment effects (employment) measure. This provided further value to the clinical trial as the add-on analysis component to the current outcome measures.

The pain data collected was obtained by using three questions that asked for the 'worst pain level experienced in the past 24 hours' for 'overall pain experienced', 'activity-related pain', and 'pain experienced at night' on a vertical 11-point Visual Analogue Scale (VAS) from 0 to 10, with 0 representing 'no pain', and 10 representing 'worst imaginable pain'.

The environmental weather data was collected using a third party data source, which uses aggregated data from multiple meteorological services for accuracy, forecast.io (2016). This data was queried based on the 24 hour block backdated from the time of report made on the system, based on the participant's home suburb and postal code. The data was batch processed after the completion of the week 12 questionnaires by the participant.

The data for disability was obtained through the Assessment of Quality of Life (AQOL) (Hawthorne et al., 1999) questionnaire. There are three questions that pertain to independent living, which are: i) "Do I need any help looking after myself? (options)"; ii) "When doing household tasks ... I need _ help (options)"; and iii) "Thinking about how easily I can get around my home and community ... I can .. with ___ difficulty (options)".

The data for exercise was primarily obtained through the Patient-Rated Tennis Elbow Evaluation questionnaire, based on the question asking to rate on a scale of 0 to 10, the difficulty in doing recreational or sporting activities in the past week.

Employment effects was assessed using an open ended question contained within the Impact on Work section in the Cost and Consequences questionnaire for weekly and four-weekly intervals.

4.3 System Design and Development

I built an online secure data collection system to collect data from the participants in the study. One of the challenges during implementation of such a system were the security and privacy considerations for the data being collected. This meant that I

had to ensure the data collected was stored and transmitted using secure means, i.e. transmitting the data in an encrypted manner, and storing it in an access-restricted database that was also encrypted.

The design of the system was based on specific requirements that were elicited in discussions with the clinical partners that were outlined in Chapter 3. There was a design decision taken by the clinicians to keep the system design simple with as few colours used as possible. It was also a requirement that the system is fast and responsive, and that the participants can access the system via mobile devices. The system was built as a PHP application, using JavaScript for client-side validation of the questionnaire responses. The system stored data in a secure MySQL database, and the system did not have the ability to overwrite data stored in the database. This allowed us to ensure that data was not deleted or modified once it was written to the database. Figures 4.1, 4.2, and 4.3 show the system viewed from (a) a computer, and (b) a mobile phone.

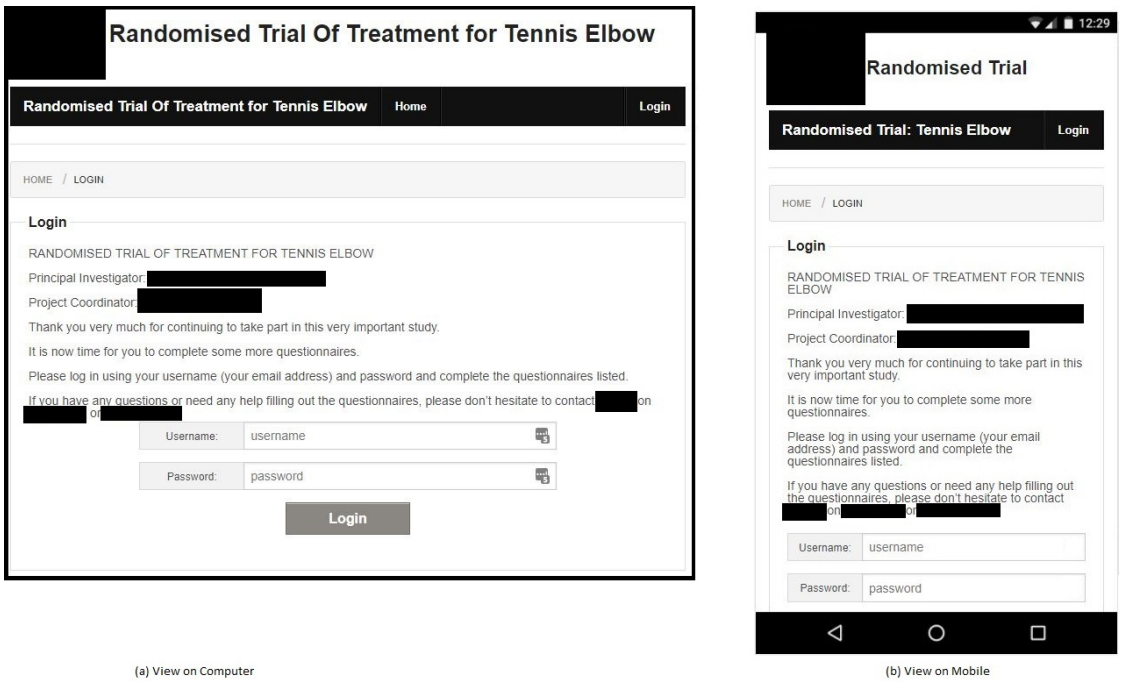
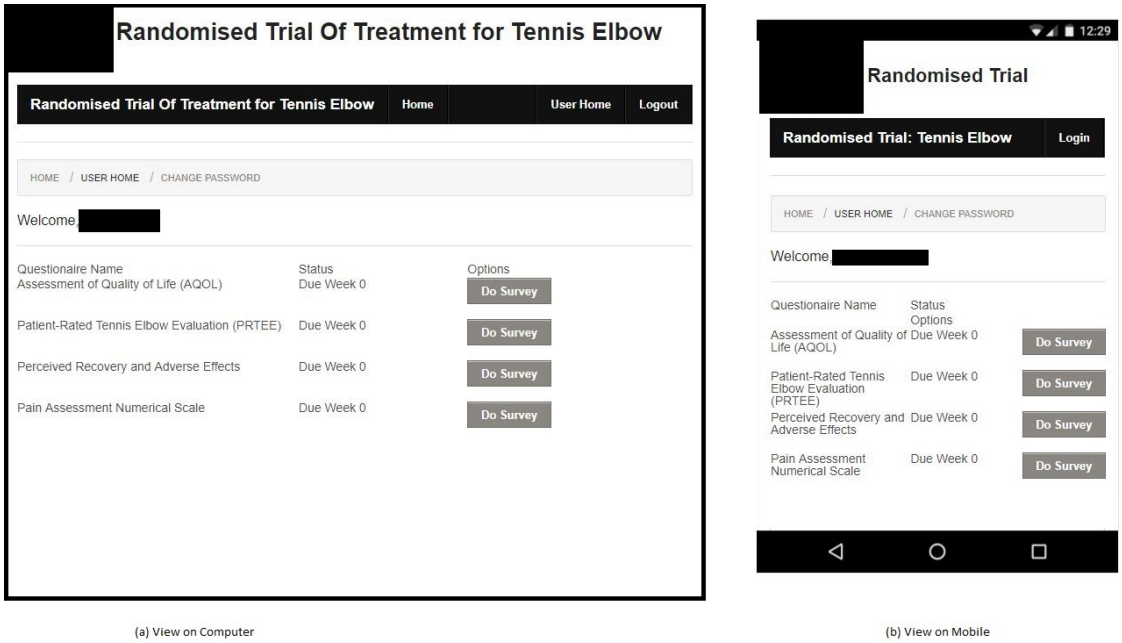


Figure 4.1: Login screen

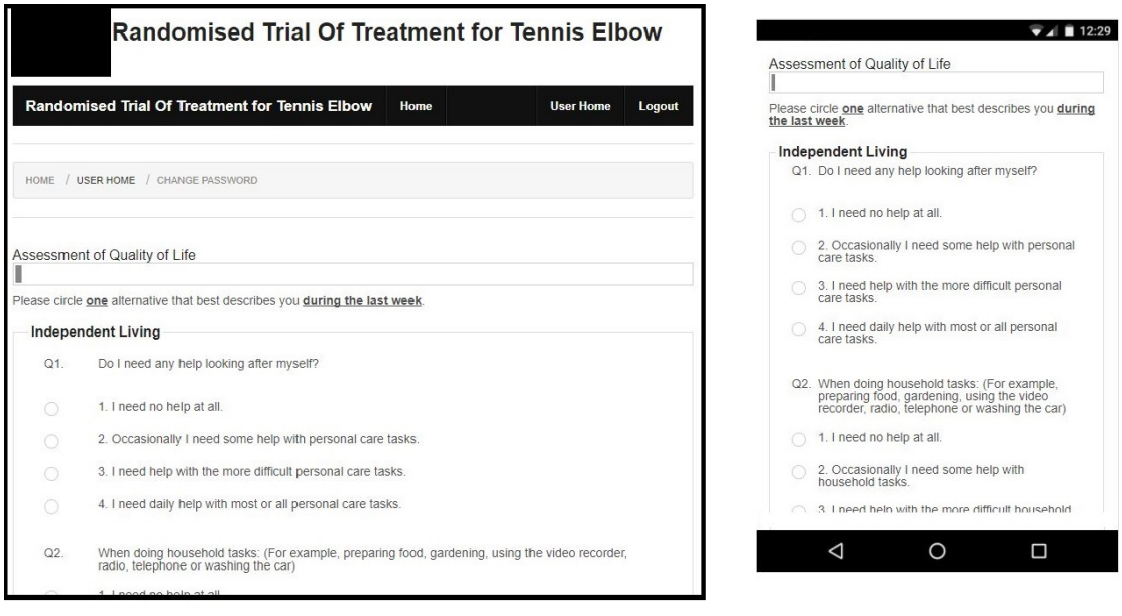
The process flow for participants was designed to be as simple as possible. When a participant logged into the system, they were presented with the home page that showed which questionnaires were currently due as shown in Figure 4.2. They would then click on the questionnaire to complete them. The questionnaire was loaded by a module that handles pagination of the questionnaire, as well as storing the data entered thus far. An example of one such questionnaire is shown in Figure 4.3. Once the participant submits the questionnaire, the data was then written into



(a) View on Computer

(b) View on Mobile

Figure 4.2: User Home



(a) View on Computer

(b) View on Mobile

Figure 4.3: Questionnaire Sample

the database and cleared from memory for security reasons. Participants were sent reminders weekly to complete the questionnaires. These reminders were recorded on a page in the administrator's view that could be accessed from the administrator's dashboard as shown in Figure 4.4. The clinical staff followed up by phone if the participant failed to complete the questionnaire a day after the reminder was sent.

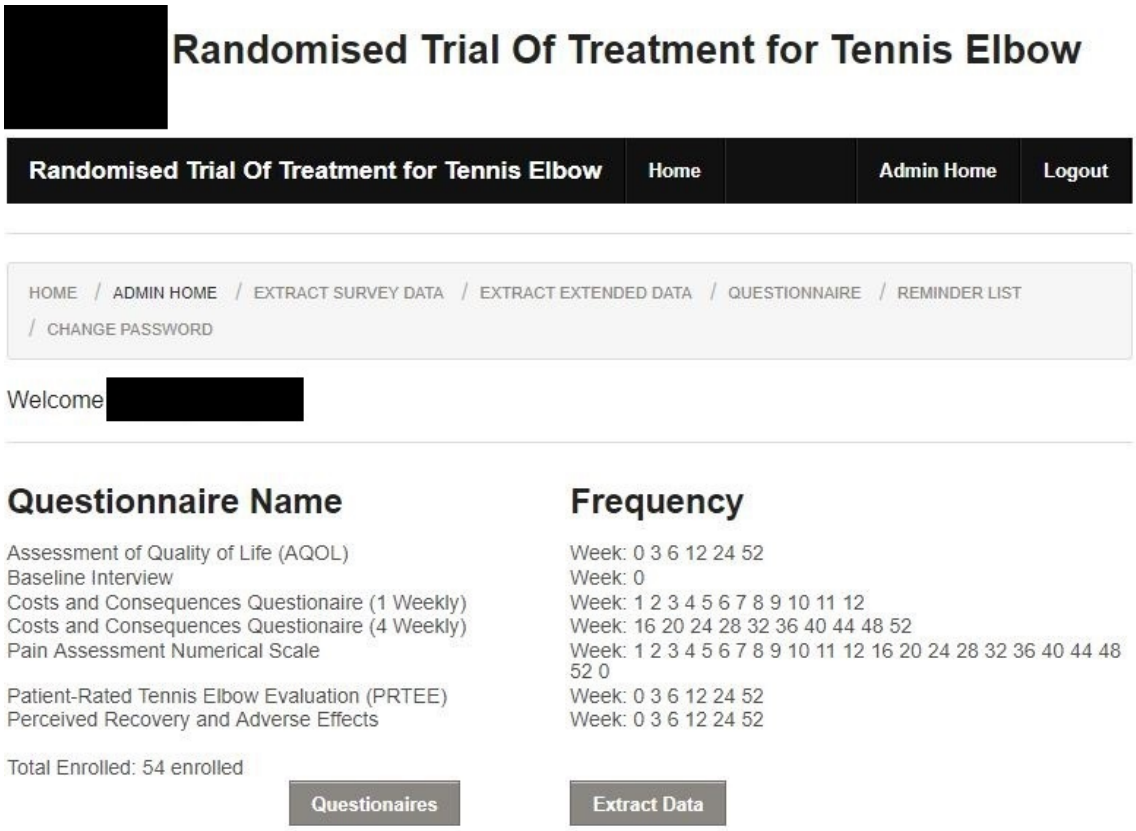


Figure 4.4: Admin Dashboard

As some participants opted to complete paper forms, it was necessary for the administrator to be able to enter the data from the paper questionnaires into the system. Figures 4.5, 4.6, and 4.7 show the functionality that allowed an administrator to search for and select a participant, then complete that participant's questionnaire on their behalf. The data captured in this manner had an additional flag on the database to indicate that it was completed on the participant's behalf.

4.4 Data Analysis

The clinical trial ran over four years using the data collection system that was built. I excluded some data from the analysis due to the accuracy and frequency of the variable. The variables in the context categories for disability, physical and employment were only collected at weekly or 4-weekly intervals, which made it hard

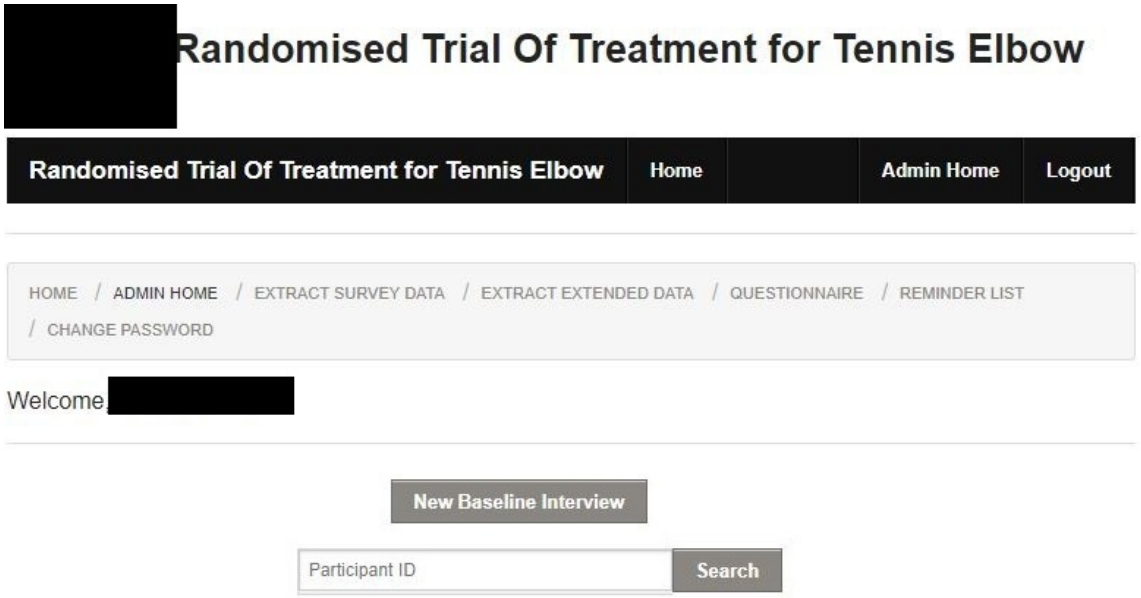


Figure 4.5: Admin - Search for Participant

Figure 4.6: Admin - Select Participant

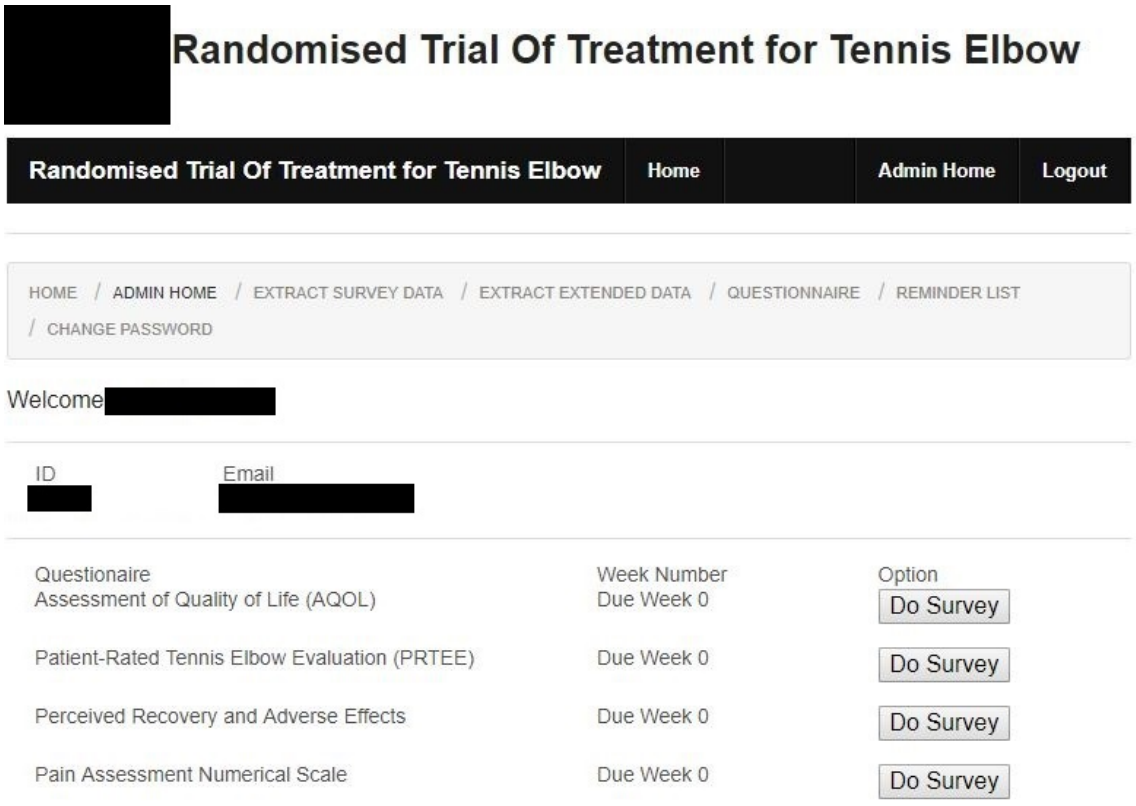


Figure 4.7: Admin - Select Questionnaire

to explain the pain intensity over the previous 24 hours that were reported at weekly intervals. The variables, their respective context categories and the exclusion status are indicated in Table 4.2 as follows.

Table 4.2: Variables in Context Categories

Variable	Context Category	Excluded
Overall Pain	Pain Characteristics	
Pain at night	Pain Characteristics	
Activity pain	Pain Characteristics	
Min Temperature	Environment	
Max Temperature	Environment	
Humidity	Environment	
Independent Living	Disability	X
Exercise	Physical	X
Employment Effects	Employment	X

There were three stages to the data analysis for this case study.

This study was exploratory in nature, with the aim to understand the impact of using a HFDC approach. I defined the impact as the difference in the descriptive

ability of the pain trajectory collected for each participant, when compared to the data that would have been collected at the frequency set out in the original protocol. This meant that the pain trajectory on the sparse (original) data collection frequency was compared directly to the pain trajectory that was collected using the modified frequency.

The first stage was a comparison of the pain trajectory for sparse intervals versus weekly intervals. Graphs were plotted for each participant over the three pain variables as pain over time using SPSS 24 (SPSS, 2008) software. I described the differences observed on the plotted pain trajectory between the sparse and weekly intervals, in order to: i) understand the differences in explainability of the data collected at those respective intervals; and ii) explore the impact on the patient's outcome.

The second stage used statistical analysis. I fitted a linear mixed model with fixed and random effects, with pain as the dependent variable, and minimum temperature, maximum temperature, humidity and type of pain coded as fixed effects in Stata 13 (StataCorp LP, 2014). The interval clustered within individual participants was coded as the random effect in the model. The type of pain was coded as a categorical factor with overall pain coded as the comparison group (1), with the activity-related pain and pain at night coded as (2) and (3) respectively. The statistical model was fitted based on discussion and consultation with three independent bio-statisticians to ensure correct parameters and model fit. This allowed us to determine if there were any statistical significance to the environmental variables collected for this dataset.

Finally, the third stage used the exit questionnaire that asked questions on the online versus paper data collection method. The exit questionnaire was analysed using qualitative thematic analysis in NVivo software (Fereday and Muir-Cochrane, 2006) to identify themes and code the data collected from the questionnaire. The goal of this analysis was to understand the preferences and reasons behind the participants' choices of paper or online data collection methods.

The following section will outline the results and discuss our findings from this case study.

4.5 Results and Discussion

The study was split into two cohorts. The first cohort had online questionnaires with sparse pain data intervals. The second cohort used online questionnaires with the weekly pain data intervals as described previously. For the purposes of the first and

second phases of analysis, I use only data obtained from the second cohort. However, for the third phase, I use data obtained from both cohorts.

At the time of analysis, the study had 83 participants in the first cohort, and 56 participants in the second cohort. The data collected was processed, and for the purposes of the first two phases of analysis, I required that the data conform to the following criteria: i) no missing data from Weeks 0 to Week 12; and, ii) data was entered either directly on the system or keyed on their behalf on-time, i.e. week 3 report provided in week 3, by a researcher. This resulted in a drastic reduction in data available, with a final set of 10 participants that fell within these requirements. The main reasons for exclusion were: i) late data entry; ii) data being keyed in late by the researchers; or iii) data being provided 'in bulk' to the researchers every month. I note that at the point of analysis, the clinical trial was still ongoing. However, the small sample size does not affect the study as the objective was to explore the usefulness of a HFDC approach, as well as to determine how such an approach can affect the usefulness of results illustrated by the pain trajectory. Furthermore, as this is a three-arm clinical trial, the randomisation binding for treatments is unknown as the trial is still ongoing. The results and discussion therefore make no reference to the different treatments afforded to the different arms of the clinical trial.

This section addresses the results in three phases as described in the previous section. Preliminary results were previously published by Goh et al. (2016).

4.5.1 Comparison of pain trajectory data between different intervals

A pain trajectory is a two dimensional graph that plots pain intensity reported over time. This data is plotted for the first 13 points of data from Week 0 to Week 12. The general expectation from our clinical collaborators is that the weekly data will be an extension of the average pain between the sparse interval data, with little to no fluctuation between the original reporting points of Week 0, 3, 6, 9 and 12. A clinically significant difference in pain would be one that is at least a change of two points on the numerical scale.

The graph plotted three sets of pain data, with overall pain displayed in purple; pain at night in blue; and activity-related pain in green. The solid line plot shows the full weekly data collected, with the dashed line plot showing the trajectory for the data only using the sparse intervals.

Figure 4.8 shows an example of a very erratic pain trajectory. The weekly data shows major fluctuations over the weeks although it shows major improvements for overall

pain after week 4. The interesting parts of the trajectory are the peaks that are not captured when comparing the plotted line between the sparse and weekly interval data. The sparse interval data shows a major fluctuation at week 3, before drastically improving in the following weeks. This does not represent the pain experienced by the participant when the weekly pain trajectory is studied.

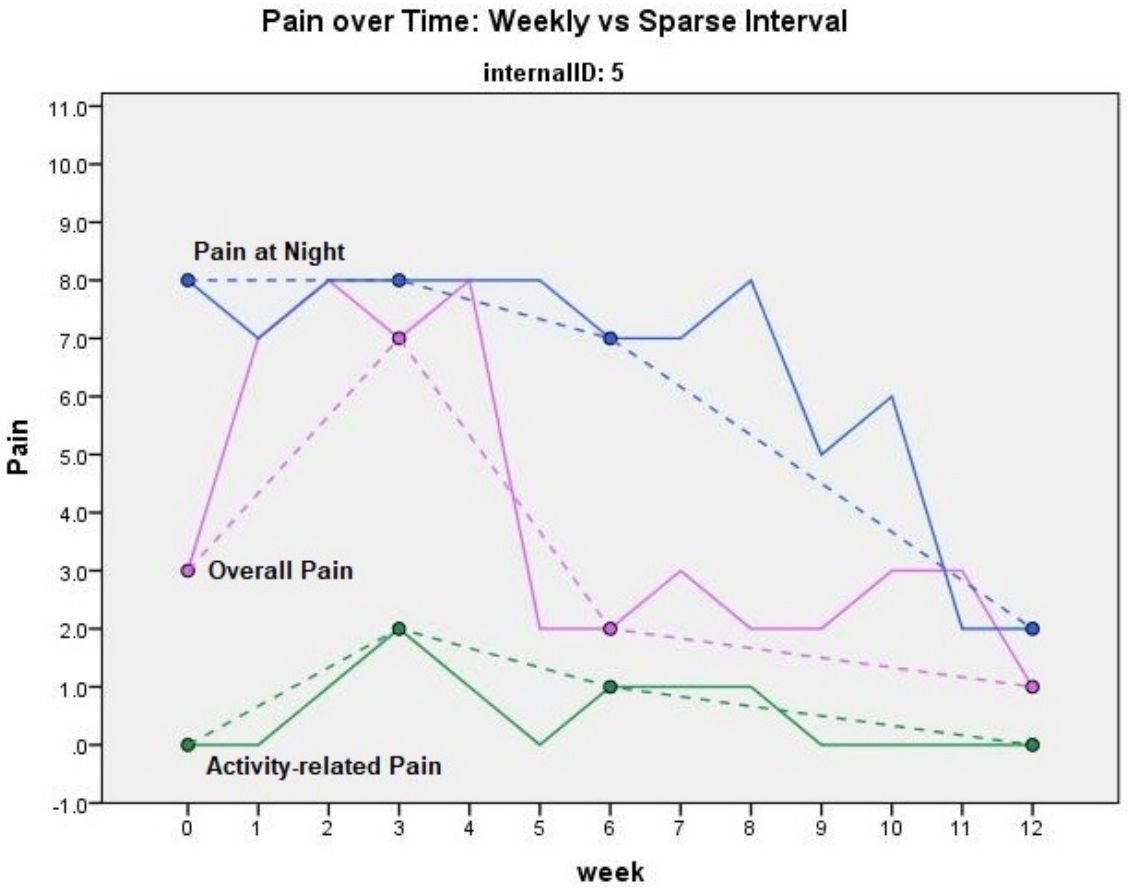


Figure 4.8: Pain Trajectory

The remaining pain trajectories are shown in Appendix B, and although different in patterns, have similar results. While the sparse interval data in a small number of cases show a relatively acceptable view of the overall trend of pain, there are many worsening and recovering peaks that this overall trend does not cover. An implication is that when the treatment efficacy is considered, it may be more important to be able to look at a higher granularity such as the weekly interval data. This higher frequency data can be annotated with context factor data to understand what causes the spiking peaks that affect the overall recovery and worsening of pain. The context factor data may include information about the patient's activity, medicine intake, other treatments or conditions, visits to doctors, or simply the participant's natural lifestyle pattern that affects the course of pain and recovery. In considering that the majority of patients suffering from LE recover within a year, it may be acceptable to use this 'big picture view' using the sparse intervals. However, it is important

especially for patients that do not show this 'overall' recovering trend, to have more detailed pain trajectories in order for the adjustments to the treatment or pain management plans to be made.

4.5.2 Statistical analysis of environmental variables against pain

The second part of the analysis focuses on the correlations between pain and the collected environmental variables using a statistical linear mixed model with fixed and random effects. I consulted with three independent bio-statisticians, and fitted the model as presented below.

The model was fitted in two stages. The first model was fit with the interval being only a random effect, which meant that I made no assumption that pain may or may not increase or decrease over time. Table 4.3 illustrates the results of the model that was fitted.

Table 4.3: Linear Mixed Model with fixed and random effects (Goh et al., 2016)

Pain	Coef.	Std. Err	z	P > z	Min 95% Conf.	Max 95% Conf.
minTemp	-0.0218	0.0257	-0.85	0.398	-0.0723	0.0287
maxTemp	0.0055	0.0148	0.37	0.710	-0.0235	0.0345
humidity	0.9893	0.5470	1.81	0.071	-0.0827	2.0615
activity pain (2)	-0.9510	0.2981	-3.19	0.001	-1.5354	-0.3666
pain at night (3)	0.3706	0.1458	2.54	0.011	0.0847	0.6565
intercept	3.453	0.7581	4.56	0.000	1.9674	4.9393

The results suggest that for the participants included, pain level is not associated with temperature or humidity. I note that the average activity-related pain is 0.95 units lower than the reported overall pain, and that the average pain experienced at night is 0.37 higher than the overall pain. For the second stage, I extended the model in Table 4.3 by including the interval as a fixed effect, and obtained the results illustrated in Table 4.4.

The second model fitted shows that pain decreases across the intervals (over time) as I expected. The results suggest that activity pain is normally lower than overall pain, and that pain experienced at night is typically higher than overall pain.

Based on the results from the two models fitted, there is no association between temperature or humidity with the pain experienced. The participants show a general recovery over time. Currently, to the best of my knowledge, environmental conditions such as the variables studied in this section are not traditionally included in this

Table 4.4: Linear Mixed Model with fixed and random effects including interval (Goh et al., 2016)

Pain	Coef.	Std. Err	z	P > z	Min 95% Conf.	Max 95% Conf.
minTemp	-0.0498	0.0324	-1.54	0.124	-0.1134	0.0136
maxTemp	0.0086	0.0154	0.56	0.573	-0.0215	0.0388
humidity	1.0198	0.7770	1.31	0.189	-0.5031	2.5428
interval	-0.1403	0.0338	-4.15	0.000	-0.2066	-0.0739
activity pain (2)	-0.9510	0.2981	-3.19	0.001	-1.5354	-0.3666
pain at night (3)	0.3706	0.1458	2.54	0.011	0.0847	0.6565
intercept	3.8145	0.8838	4.32	0.000	2.0822	5.5469

area of research. They are typically studied as part of the contributing factors of the original injury, and not as part of the recovery phase.

4.5.3 Analysis of the exit questionnaire

The third stage of analysis used the data collected using the exit questionnaire. The exit questionnaire sought to understand the participants' preference between using online or paper questionnaires, and reasons why they selected that option.

I found that 79% of the participants used online questionnaires, with 7% a mix of online and paper questionnaires. There were six reasons for not using online questionnaires: i) no internet access; ii) no personal computer or tablet; iii) there were other technical issues that occurred; iv) was not always at the computer; v) did not like completing online surveys; and vi) too busy to complete online questionnaires.

Of the participants that did use online questionnaires, the main reasons why they used them was that it was convenient, faster and easier to complete, when compared to completing paper based questionnaires. Some participants reported that it was lesser hassle as it did not require them to mail out questionnaires regularly. Others mentioned that they liked the weekly reminders as it prevented them from forgetting to complete the questionnaires. A minority of participants said they completed them online as it was environmentally friendly, and because there was guided content.

I also polled participants on which medium they were likely to complete future studies on, and 91% reported that they preferred online questionnaires. Therefore, I can conclude that using online questionnaires is preferred among participants.

The following section will outline our findings from the results obtained, based on discussions with our clinical collaborators.

4.6 Findings

The use of technology has allowed for this type of higher frequency data collection to take place. The traditional way to collect data would be to use paper questionnaires, and provide participants with reply paid envelopes for them to mail the completed questionnaires back to the researchers. This has always been a limitation of these kinds of clinical trials and medical studies, where the cost of data collection (and subsequent data entry) increases with the amount of data and the frequency of the intervals. Thus it has always been mostly infeasible to collect more granular data, especially when it increases the burden of response on the participants.

This study has demonstrated that technology is an enabler for the HFDC approach, and that the higher frequency data can identify interesting fluctuations in the data that was previously unknown. Our clinical partners agree that for treatment efficacy, it is important to understand what causes those unexpected fluctuations. The contextual data that was collected in this study was not particularly useful in explaining the changes in pain, but the analysis and subsequent discussion show that with the right questions asked, it would be theoretically possible to resolve the reasons for fluctuating pain to contextual reasons.

I have identified some issues with the design of the data collection.

First, the specified intervals of data collection for the contextual data was not frequent enough. As this data was not collected in the same frequency period as the pain data, it became difficult to pinpoint what contextual reasons could have affected the course of pain that the participant experienced.

Second, there were problems with the phrasing of the questions. The questionnaire used three questions to elicit the pain intensity from the participant. These questions asked for the pain over the past 24 hours, which I believe to be inaccurate for our purposes, due to two main reasons: i) pain may fluctuate over the course of a single day, but this is unconfirmed as there are no such datasets with data at daily intervals to support this theory; and ii) the accuracy of patient recall is a factor in the report as the participant is more likely to report pain 'last remembered' than in the 'last 24 hours'. Similarly, the environmental data collected was over the period of 24 hours, in order to match the intervals specified for the questions on pain intensity. This is not accurate as I am unable to understand the surrounding conditions at the time point when the patient experienced pain.

Third, participants were able to complete a missed questionnaire later, or in bulk by attending a session with the doctors in person. This recollection based completion of the questionnaires impacts the accuracy of the data, and therefore I had to exclude this from our analysis.

The result of these three issues is that the design of the questionnaires did not elicit an exact or accurate response, and if the goal of the study is to obtain an understanding of pain and its contextual reasons, then it would be best to ensure this data is as 'real-time' and as accurate as possible, in order to for the reported contextual data to be meaningful. I am unable to provide a firm recommendation towards 'how often should the data be collected' for pain data collection, but it would be more meaningful if the questions were tailored towards 'your pain now' than 'in the past 24 hours'. Similarly, the other questions that ask for contextual information needs to be close to real-time to avoid patient recall issues, and to allow the data to be as accurate as possible. It is much easier for a participant to report what they are feeling at that point in time, versus what they thought they felt a while ago. This means that the design focus of the questionnaires should be about the changes in pain experienced by the patient, as they experience it.

The necessity of close to real-time data collection introduces new burdens on the participant, so the design of the questionnaires and system should focus on preventing the participant from thinking that it is 'troublesome' or 'time consuming' to complete. Furthermore, validated questionnaires that elicit contextual reasons for pain experiences happening in real-time do not currently exist. There currently are some paper based pain diaries to collect pain intensity and medicine intake, but does not elicit any contextual reasons of pain. Further work is required to design such questionnaires for data collection.

Through our discussions with our clinical partners, I believe that collecting context around pain experiences is the correct path forward in furthering research in understanding the nature of pain. Such context could potentially identify reasons, or risk factors that affect pain. The data I have collected supports Olson (2014)'s theory that pain experiences are individualistic and that no two patients would probably experience the same pain pattern. The higher frequency data allowed the identification of interesting patterns, peaks and recovery periods that were previously unknown.

Finally, as reported, participants preferred the use of online to paper questionnaires. This was due to the convenience, ease of use and the ability to complete a questionnaire faster online (versus paper). These are also considerations for designing questionnaires to be used online; e.g. the design should enable convenience and a fast completion time of questionnaires.

4.7 Chapter Summary

This chapter has outlined the first case study on tennis elbow, that was designed as a proof of concept and to obtain some preliminary data to support the proposed HFDC approach. I have shown that the use of online technology enables a higher frequency data collection (HFDC) approach, and that this could provide more informative results.

I have instantiated a HFDC approach on an existing clinical study, adjusting the collection of key pain data variables from a 3-weekly interval to a weekly interval. The data collected demonstrates that there is value in collecting data at a higher frequency as it increases the granularity of data. I have identified what previously would have considered 'outliers' in the pain trajectory, but are actually important points that could affect efficacy of treatment and overall perception of the pain experience by the patient. Our clinical partners concluded that those new fluctuations identified in the pain trajectories are of interest and warrants further study. The data suggests that there is a need to further develop questions in collecting the data for the 'correct' context factors, and that the answer to this may lie within the patient's lifestyle patterns.

Through the evaluation and reflection of the study design, I identified three main issues that lie within the questionnaire and study design that affect the quality of the data collected, and the usefulness of contextual data. These issues guided a revision of our design guidelines and helped shape the next case study.

The next chapter will discuss the second case study in detail, including the background and motivation, study design and protocol, system design and development, the data analysis methods used, and provide a discussion of the results and findings.

Chapter 5

Study: Chronic Low Back Pain

This chapter contains the second case study that I designed from the ground up. This case study is designed to explore the impact of using a higher frequency data collection (HFDC) approach, as well the impact and usefulness of integrating the patient's context into the analysis of chronic low back pain. I build onto the foundation from the previous case study detailed in Chapter 4, where it was shown that the HFDC approach at weekly intervals identified new fluctuations that were previously unknown. The data collected thus far suggests that pain has a fluctuating nature and that there is potential that the existing data collection methods at sparse intervals does have the capability to capture the pain experience correctly. I discuss some key points learnt from case study one (CS1) in Section 5.1. This case study will address (in conjunction with CS1), the two research questions and their sub-questions using chronic low back pain as its context.

I have organised this chapter into the following sections: The chapter begins with a discussion on learning from CS1 in Section 5.1. Section 5.2 will provide the background and motivation, with Sections 5.3 and 5.4 outlining the study design and protocol, as well as the system design and development respectively. I discuss the data analysis methods used for CS2 in Section 5.5, followed by results and discussion in Section 5.6. Finally, I outline the findings from this case study in Section 5.7, and conclude the chapter with a summary in Section 5.8.

5.1 Learning from case study one

CS1 provided a pilot study to demonstrate the viability of the HFDC approach, with the potential that I could collect additional contextual data without increasing the response burden of the participants. In this study, I increased the data collection frequencies for the key pain data, which allowed us to obtain a more detailed view of

their pain trajectory. I also outlined some issues that were identified with CS1 in Chapter 4. This section outlines some key points that I have learned from CS1 that was applied to the design of case study two (CS2).

I found that the weekly interval for data collection of both contextual and pain data was insufficient. Although the weekly interval for the pain data provided a higher granularity to the pain trajectory, I did not know if the pain at a weekly average was sufficient in providing an accurate view of the pain experience using the pain trajectory. The contextual data was collected at monthly intervals, which made it difficult to connect contextual reasons for changes in pain to the actual pain data. Therefore in this case study I needed to ensure that the key contextual variables were aligned to the same data collection interval as the pain data. I also designed the collection intervals in CS2 to be daily, with the option to provide additional reports of pain. The goal was to encourage the participants to use the system's daily pain report format as a diary, and complete the pain reports when they felt that their pain had changed. I would have used the 'report only when you feel a change in pain' approach, but during my discussions with the domain experts, I found that this would not be statistically useful. Therefore, in order to have a daily baseline value that can be statistically tested, it was necessary to also maintain the standard daily reports at a similar time period (e.g. at a selected reminder time).

The wording of the questions used became a large issue as the existing questionnaires relied on reports of worst pain over a period of time. This is due to the inherent nature of contextual data, which is aligned to the present or a time-specific event. If I were to collect contextual data at a single point for a duration of time, i.e. for the last 24 hours every week; it would require the participant to provide a running time sheet of events or activities that they did, which could be construed as an invasion of the participant's privacy. I resolved this issue in the design of CS2 by collecting contextual data around the pain event being reported, with the questions framed in the case of the pain being reported at that point.

In CS1, there were multiple questionnaires used every reporting interval that were relatively long to complete. I found that this can impact the participant willingness to complete the study, as it is time consuming. In cases such as CS1 where the participant is receiving a benefit in return for completing the questionnaires, i.e. treatment, it may not be an issue. However, when the goal is to study the pain experience and the participant does not receive any obvious benefit other than the added knowledge from self-monitoring of their own pain, I found that it is difficult to recruit sufficient participants that will complete the study. Even with CS1, the main clinical trial is still ongoing as they have not achieved a sufficient number of

participants that complete the full study. I resolved this in CS2 by ensuring that one of the design focuses is on the time required to complete the questionnaires.

5.2 Background and Motivation

Chronic low back pain (cLBP) is defined as pain that persists beyond three months (Merskey, 1986), that is "localized to the anatomic area below the posterior ribs and above the lower margins of the buttock" (Borenstein, 1996, pg. 439). Patients suffering from cLBP are typically not expected to recover quickly over an extended period of time. cLBP is a chronic, ongoing condition that can be classified into two classes: i) Specific, and ii) Non-Specific. Specific refers to cLBP that has an attributable cause or condition, whereas non-specific refers to cLBP that cannot be resolved to a specific cause of the pain (Savigny et al., 2009). Most low back pain is of the non-specific class, with a recent review identifying this to be at about 90% of cLBP sufferers (Maher et al., 2016). cLBP is a global health problem, as it is currently the leading chronic contributor towards disability (Hoy et al., 2014). In Australia alone, it is estimated that one in five of the population suffers from persistent pain, costing about $34 billion to the economy every year (Pain Management Research Institute, The University of Sydney, 2014). Therefore, cLBP is an expensive condition that is of great interest to medical researchers.

Currently, there are two main approaches to studying cLBP within the medical field: i) identifying contributing or risk factors, and ii) exploration of medication or treatments. The majority of these studies focus on a single factor and assess if there is a relationship between the factor and cLBP. These studies typically conduct population level or randomized cohort studies to find correlations, much like any other typical medical study relying on statistics. In recent research, it has been suggested that no two patients' would experience the same pain (Olson, 2014). This potentially has a large implication, as it means that there would never really be a population level result if every individual patient experiences pain differently.

Clinical trials within the space of cLBP use standardized measures to determine the outcome. Table 5.1 shows a sample of the registered clinical trials in the Australian New Zealand Clinical Trials Registry during the period of 2015 to 2017 for low back pain, and their respective data collection time intervals for pain data. Medical or treatment clinical trials use primary outcomes such as a comparison of the efficacy of x versus y against placebo, or a comparison of the participant abilities, i.e. stretch, bend, participant function, from pre to post treatment. As expected, pain data is collected using a rating scale for pain intensity (i.e. NRS, VAS) or a questionnaire

(i.e. BPI, LRS). These studies typically collect pain data at sparse intervals, such as weekly, six or eight weekly.

Table 5.1: Representative selection of cLBP pain data collection frequency in Clinical Trials between 2015 and 2017

ACTRN	Type	Time Interval	Pain Instrument
ACTRN12615001193561	Medication	Baseline, Month 6	BPI (pain score)
ACTRN12616000624482	Treatment	Baseline, Post-intervention (immediate)	BPI (pain score)
ACTRN12617000636358	Treatment	Baseline, Month 1, 3, 6, 9, 12	NRS
ACTRN12617000142336	Treatment	Baseline, Week 12, 26, 52	NRS
ACTRN12616000735459	Treatment	Baseline, Week 2 follow up	NRS
ACTRN12615000714583	Treatment	Baseline, Week 8	NRS
ACTRN12615000189527	Treatment	Baseline, Weekly for 6M, Month 12	NRS
ACTRN12617000317392	Treatment	Month 3	NRS
ACTRN12616001649404	Medication	Once weekly	NRS
ACTRN12616000017426	Medication	Pain average at 14 days	NRS
ACTRN12616000888460	Treatment	Week 2, 6, Month 3, 6	NRS
ACTRN12617000074392	Treatment	Baseline, After first intervention, Month 1, 3, 6	VAS
ACTRN12615000958583	Medication	Baseline, Day 90 and Month 6, 9, 12	VAS
ACTRN12615001298505	Treatment	Baseline, Month 1	VAS
ACTRN12616001719426	Treatment	Baseline, Month 1, 2, 3	VAS
ACTRN12617000505303	Treatment	Baseline, Post-intervention (immediate)	VAS
ACTRN12616001661460	Treatment	Baseline, Week 10, 20	VAS
ACTRN12615001270505	Treatment	Baseline, Week 2, 4, 6, 8, 10, 12	VAS

I believe that the frequency of data collection, as well as the reliance on population level metrics to study pain is potentially a problem if pain has an individualistic nature. A recent review in the Lancet on low back pain identified that researchers do not really know much about pain, and that the existing medication and treatments have very low, or wide range of effects (Maher et al., 2016). The same review identified that one of the key limitations of the existing pain management methods is that there are only generic treatments for cLBP that have low to modest effect sizes in clinical trials. The authors conclude by stating that it is critical to develop an understanding of low back pain phenotypes in order to directly target causes of cLBP and the consequent disabilities.

Therefore in this case study, I designed the data collection to collect frequent data in order to explore the use of patient context for chronic pain, using online and mobile technologies. I describe the study design and protocol in the next section.

5.3 Study Design and Protocol

The study was conceived as an exploratory data collection study. I received ethics approval for this study from the Monash University Human Research Ethics Committee (Project # CF16/2009 - 2016001014). The study ran over a period of two months, following participants for a total of 33 days. I recruited participants from past participants and volunteers from the School of Public Health back study list who have consented to future contact. I ran the study in two stages, a pilot stage and the main stage. The pilot stage allowed us to run the study with a small amount of participants and revise the questionnaires and design of the system based on the initial user feedback. The main stage was where the majority of the remaining participants were contacted and recruited.

During the study design and planning phase, I had to design the study from ground up, which included the questionnaires for data collection, as there has not been any prior precedents of a study that used a HFDC approach with contextual instruments, and contextual questionnaires for cLBP did not exist. The questionnaires formulated this way used both validated questions and instruments, along with new questions designed to collect information about the context of pain from the participants. I selected the intervals of daily and weekly for the questionnaires to be designed. Due to the fact that the questionnaires were to be completed daily, I needed to ensure that the questions were short and did not take too much time to complete, while giving enough flexibility and depth in understanding the context around the pain experience.

The process of designing the questionnaires began from identifying variables and contextual attributes that would be collectable using a mobile-enabled web application. I used the descriptive context model discussed in Chapter 2 (Goh et al., 2015), and identified context categories and their relevant measures that would be possible to collect. The design of the questionnaires were finalised through two phases between the researchers and domain experts: i) negotiations on the data that I wanted to collect versus the data that the domain experts felt was useful; and ii) discussions on how best to frame the question in order to collect useful data. I also discussed and agreed upon the intervals for the questionnaires in the same manner. I designed the exit questionnaire to have two variants that depended on the status of the participant. There was one for participants choosing to opt-out, or drop out of the study, as well as one for participants that completed the study.

The pain questionnaires collected data on pain intensity using the NPRS, as well as contextual variables that were identified by a contextual model of chronic pain (Buchbinder et al., 2011; Goh et al., 2015). Figure 5.1 shows the contextual variables

collected from the study. The variables were selected to obtain a contextual understanding of what the participant was doing (activity), and what their surroundings were like (environment). To keep the questionnaires completable in a very short period of time, I moved some questions over to the weekly questionnaire, such as the questions on medication, changes in work and changes in treatment (over the last week).

Measure	Context Category	Baseline	Daily	Weekly
Pain intensity	Pain	X	X	
Trajectory - Recovery			X	
Type of change in pain		X	X	
Age	Demographics	X		
Gender		X		
Height		X		
Weight		X		
Education Level		X		
Marital Status		X		
Employment Status		X		
Country		X		
Suburb		X		
Type of work	Employment	X		X
Changes to work situation				X
Physical Maintenance (Exercise)	Physical	X	X	
Current Activity		X	X	
Independent Living	Disability			X
Vices (Smoking)	Medical	X		
Vices (Alcohol)		X		
Current medications				X
Treatment services	Treatment	X		X
Weather	Environment	X	X	
Relative Humidity		X	X	
Wind Chill		X	X	
Wind		X	X	
Air pressure		X	X	
Temperature		X	X	
Precipitation		X	X	
Min / Max Temperature (Day)		X	X	
Distance of (Variance) Min / Max Temperature		X	X	

Figure 5.1: Contextual Variables for CS2

The final version of the study protocol specified four questionnaires, two of which collected daily and weekly pain data. I selected the interval of 31 days (plus baseline for 32 days) to capture a full month of data. The other two were exit questionnaires

that were administered at the completion of the study. The exit questionnaire aimed at eliciting user experience, in terms of what they liked or did not like in the study, and what they felt about the pain trajectory graph displayed to the users on the dashboard. I also asked participants that dropped out of the study the reason for doing so. These exit questionnaires were anonymised and was sent on the 34th day after beginning the study, via email and administered using Google Forms. A copy of all the questionnaires used is attached in Appendix C. I show an overview of the frequencies of the questionnaires used in this study in Table 5.2. The contextual mapping for the data is shown in Figure 5.1.

I wanted to provide a mechanism for participants to report on their pain at any time, in addition to the regular interval reports. Therefore, I requested participants to complete ad-hoc reports (using the daily report format) when they perceive a change in pain. I believe that it is better for participants to make reports as soon as possible, in comparison to recall-based reporting where the participant may not have an accurate recollection of the events and pain experienced.

Table 5.2: Questionnaire Frequency

Questionnaire	Frequency
Baseline report	Day 0
Daily reports	Every Day for 31 days
Weekly reports	Every 7 Days for four weeks
Ad-hoc daily reports	Upon perceived change in pain, uses daily report
Exit questionnaire	Day 33

The study was planned to begin with a pilot run, contacting 100 potential participants with a sign-up of 14 users in order to work out any potential problems and kinks in the system. This also allowed us to make final changes to the design and questionnaires, based on the feedback provided on an ongoing basis from the users.

Data was collected using an online, mobile-accessible secure data collection system that was custom built for this purpose. The system provided a view of the last seven days of pain reports as a pain trajectory that was featured on the user's dashboard upon logging into the system. The system sent daily reminders at a self-selected time of either 6am, 12pm or 6pm via email to the participant.

The next section will provide an overview to the design and development of the system used in CS2.

5.4 System Design and Development

The system was developed using guidelines from CS1 outlined in Chapter 3, with a stronger focus on the mobile experience as it was expected most participants would use some form of a mobile device to access the system daily. Some further considerations for security of the data was to ensure that the data was stored and accessed via secure means that met organisational policies and legal requirements. I found that there can be a significant amount of time spent in this step to work out those requirements stemming from organisational policies, along with legal requirements. I also identified that it required a certain amount of expertise in developing, and setting up the correct server and accesses in implementing and testing the systems.

Users self-registered on the system through a registration process that showed them the explanatory statement and consent form, which concluded with the registration of an account for use on the system. They were sent a confirmation email with their password upon successful registration. The users were required to log in to complete the questionnaires, as shown in Figure 5.2. Once a user had logged on, they would be sent to the user dashboard shown in Figure 5.3. The dashboard had two main elements, the seven day pain trajectory plot that showed the user their last seven days of reported pain, along with the questionnaires listed on the bottom half of the screen. The users were only shown questionnaires that were due, which were the daily questionnaire and weekly questionnaire. Figure 5.4 and Figure 5.5 show clipped views of the daily and weekly questionnaire. I requested that study participants complete additional daily questionnaires - 'ad-hoc' reports when they felt that there was a change in their current pain. The ad-hoc reports used the same daily questionnaire, with the exception that the text displayed on the home page indicated that it was an ad-hoc report.

One difference from CS1 is that I did not build in fully featured administration functionalities as the system was designed to require very little administrative oversight, and the study did not allow offline completion of the questionnaires using paper forms. The administrator's dashboard was primarily used to keep track of user completion status and activity, as seen in Figure 5.7 and Figure 5.6. It was primarily used to check which users had fallen behind on their daily reporting, so that I could send them an email at the end of each week to check if there were any problems.

The following section will discuss the data analysis strategy for this case study.

Figure 5.2: User Login

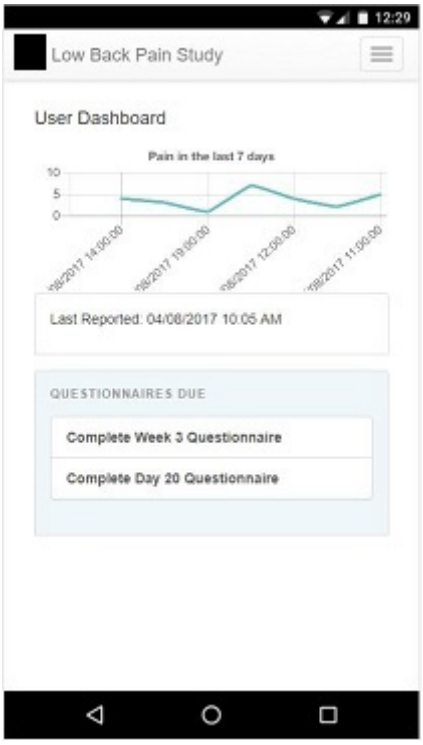


Figure 5.3: User Dashboard

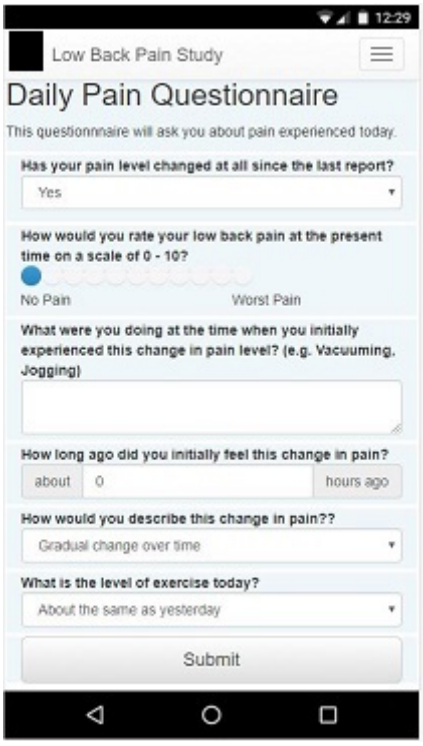


Figure 5.4: Daily Questionnaire

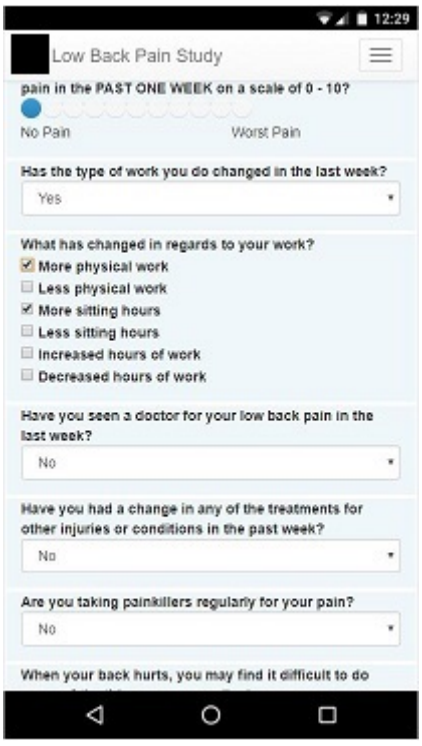


Figure 5.5: Weekly Questionnaire

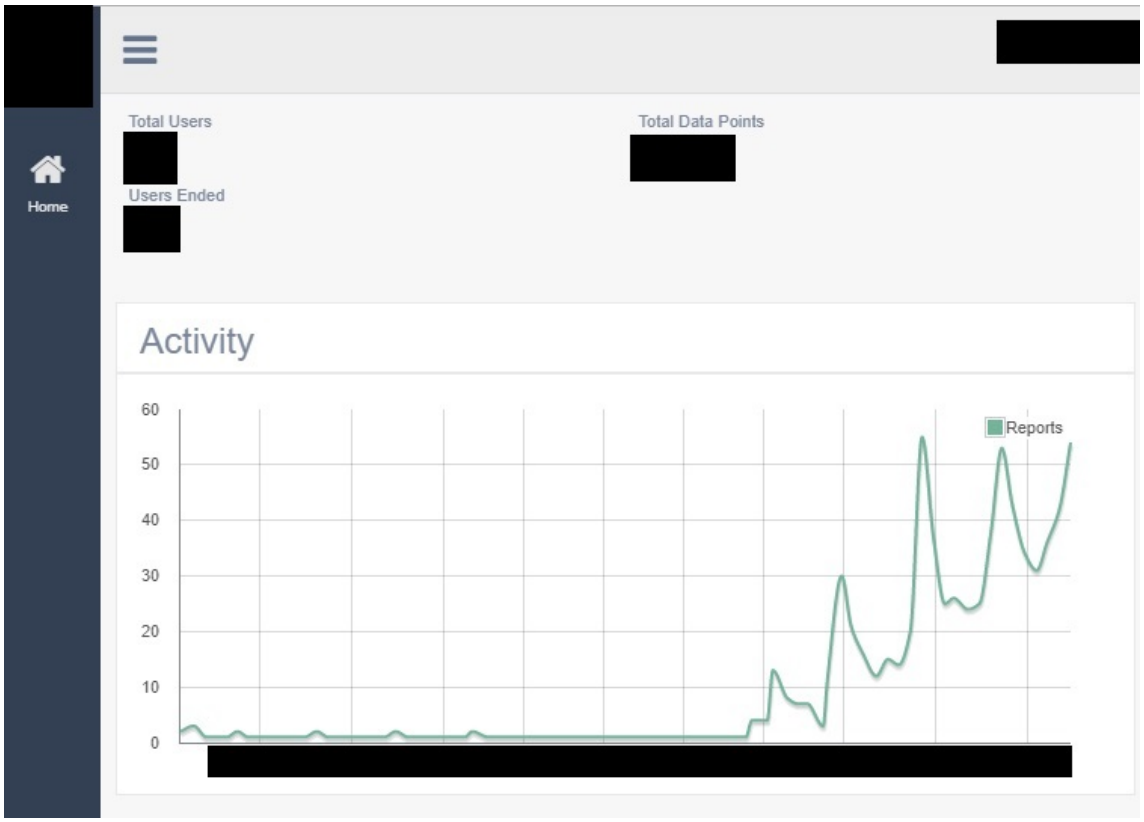


Figure 5.6: Admin Activity View

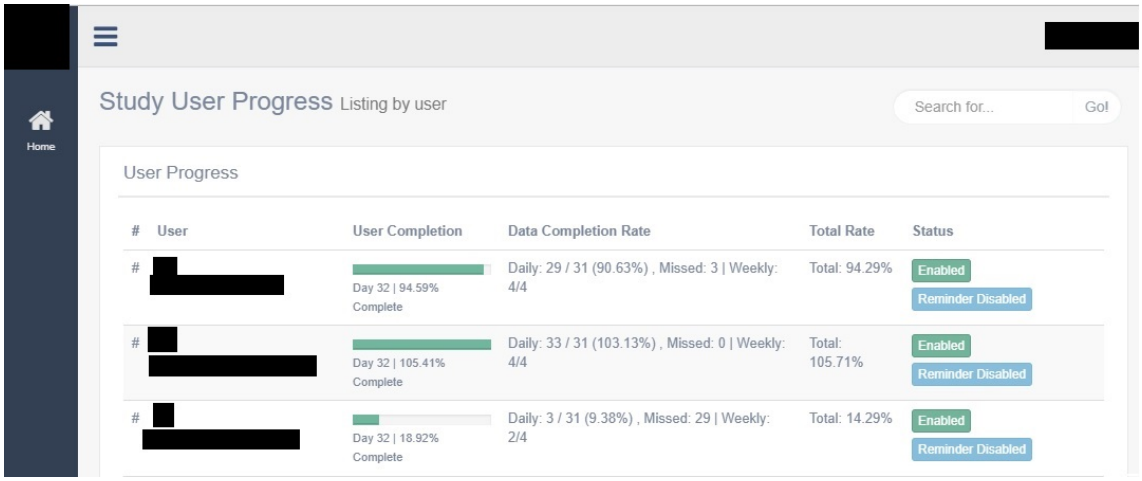


Figure 5.7: Admin Status View

5.5 Data Analysis

I designed the data analysis to be carried out in five stages. I used 'traditional' statistical models in stage one to determine if there were any correlations or patterns of interest. The statistical methods used are the general linear regression models, linear mixed-effects models, as well as descriptive statistics and pearson correlation tests. The first stage was aimed at exploring statistical correlations within the data between environmental variables and pain reported.

The second stage conducted comparative analysis for the generated pain trajectories for the two intervals: i) overall, i.e. weekly; and ii) sparse, i.e. one month. I use the sparse interval as the representation of a typical medical study data collection frequency. By doing so, I am able to derive an Area Under Curve (AUC) value for both trajectories, which is computed by calculating the total pain intensity for each period of time identified by the full pain trajectory over one month. I computed the total AUC of both sparse and overall pain trajectories, and compared the values. If the overall pain AUC was larger than the sparse data AUC, it would mean that there would be an underestimation of the actual pain experienced; with the opposite being an overestimation of the actual pain experienced.

The third stage used descriptive analysis of the ad-hoc pain reports provided by the participants. The ad-hoc pain report approach is something novel to cLBP research, as typically studies use fixed intervals in their data collection protocols, with additional 'negative' reports where pain increases being recorded as adverse events. The numbers and frequencies of the ad-hoc reports provided would be an indicator for the willingness of participants to provided additional reports when they perceived a change in their pain. It also provides useful information on the context of changes in pain which is in addition to the regular daily reports being submitted.

The fourth stage focused on studying the impact that using such a system has on the participants. I used NVivo to perform qualitative thematic analysis (Fereday and Muir-Cochrane, 2006) to identify themes, and code the data collected from the questionnaire and the notes taken from phone and email contacts between participants and researchers. The thematic analysis was aimed at understanding the impact that using such a system has on the participant. I used open-ended questions in the exit questionnaire in order to capture the user experience.

The fifth stage involved designing a process for the contextual data to be meshed into the regular pain trajectory analysis conducted. Using the computed overall individual pain trajectories, I identified clinically significant changes in pain (defined as a positive or negative change that is greater than or equals to 2 on the pain intensity rating of 0 to 10), and annotated the reported activity or action from the relevant daily pain report. Following that, I am able to conduct a descriptive analysis of the annotated pain trajectories for any similarities, or common themes and patterns across the cohort and at the individual level. At this point, I also look at the demographical data to check for any identifiable patterns that are clustered around specific contextual factors such as employment (job function, role) or by activity reported.

The next section will report and discuss the results from the data analysis conducted.

5.6 Results and Discussion

I contacted 899 people in total via email, with 94 (10.5%) people signing up to the study. Of these 94, 5 participants dropped out during the study, giving a participation rate of (95%) of those who were recruited and a completion rate of 95%. I further refined the data collected by excluding participants that had substantial missing data, which resulted in a total of 62% in usable data from the cohort. I define substantial missing data as not having completed at least 3 of 4 weekly questionnaires, and not completing the first and last day reports for the daily questionnaires. The response rate for the exit questionnaire was 42.6% of the cohort.

5.6.1 Modelling environmental variables against pain intensity

The statistical analysis models were aimed at identifying correlations between environmental variables and pain intensity. I began by spending time exploring the fit of models using a variety of different variable combinations. I modelled temperature at the point of report, temperature variance since last report, minimum and maximum temperature over 3 hours, 6 hours, 12 hours and 24 hours, wind speed, atmospheric pressure, wind chill, variance of atmospheric pressure since last report against daily pain reported. I did not find any significant correlations at population level when modelling any of these variable combinations, but there were some significance shown at the individual level. I discussed these with the medical domain experts and some biostatisticians to confirm the validity of the models and decided to use two types of models in our final report, which are the linear mixed effects and generalised linear regression models. I also ran correlations using Pearson correlation with two-tailed tests but did not find any significant correlations at the population level, which agrees with existing research.

I fitted two linear mixed effects models over the cohort using daily pain as the dependent variable, and environmental effects (temperature, pressure, wind speed) as fixed effects. I specified the user as the group cluster variable. The first model shown in Figure 5.8 shows slight significance at p=0.05 for pressure using the type II chi-square tests.

I extended the model by further grouping users by the day interval, as shown in Figure 5.9. Once again, only pressure shows slight significance at p=0.05.

The results from the two models suggest that atmospheric pressure may correlate with pain at times, but there are no other significant findings from the statistical model.

```
Model A:

Linear mixed model fit by maximum likelihood  ['lmerMod']
Formula: dailyPain ~ temp + pressure + windspeed + (1 | user)
   Data: data

     AIC      BIC   logLik deviance df.resid
  3925.5   3954.6  -1956.7   3913.5      949

Scaled residuals:
    Min      1Q  Median      3Q     Max
-3.6949 -0.6404 -0.0098  0.6178  3.3886

Random effects:
 Groups   Name        Variance Std.Dev.
 user     (Intercept) 3.749    1.936
 Residual             2.954    1.719
Number of obs: 955, groups:  user, 59

Fixed effects:
             Estimate Std. Error t value
(Intercept) 10.991343   3.376137   3.256
temp        -0.012512   0.014020  -0.892
pressure    -0.006323   0.003143  -2.012
windspeed   -0.052508   0.028257  -1.858

Correlation of Fixed Effects:
          (Intr) temp   pressr
temp      -0.330
pressure  -0.995  0.273
windspeed -0.856 -0.127  0.879

Analysis of Deviance Table (Type II Wald chisquare tests)

Response: dailyPain
           Chisq Df Pr(>Chisq)
temp      0.7965  1    0.37216
pressure  4.0475  1    0.04424 *
windspeed 3.4530  1    0.06314 .
---
Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
```

Figure 5.8: Linear mixed effects model A

```
Model B:

Linear mixed model fit by maximum likelihood  ['lmerMod']
Formula: dailyPain ~ temp + pressure + windspeed + (day | user)
   Data: data

     AIC      BIC   logLik deviance df.resid
  3925.0   3963.9  -1954.5   3909.0      947

Scaled residuals:
    Min      1Q  Median      3Q     Max
-3.7134 -0.6412 -0.0372  0.6075  3.4593

Random effects:
 Groups   Name        Variance  Std.Dev. Corr
 user     (Intercept) 4.4290854 2.10454
          day         0.0008559 0.02926  -0.46
 Residual             2.8869127 1.69909
Number of obs: 955, groups:  user, 59

Fixed effects:
             Estimate Std. Error t value
(Intercept) 10.945895   3.369604   3.248
temp        -0.010533   0.014401  -0.731
pressure    -0.006313   0.003138  -2.012
windspeed   -0.054678   0.028309  -1.931

Correlation of Fixed Effects:
          (Intr) temp   pressr
temp      -0.327
pressure  -0.995  0.272
windspeed -0.851 -0.140  0.874

Analysis of Deviance Table (Type II Wald chisquare tests)

Response: dailyPain
           Chisq Df Pr(>Chisq)
temp      0.5349  1    0.46454
pressure  4.0465  1    0.04426 *
windspeed 3.7305  1    0.05343 .
---
Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
```

Figure 5.9: Linear mixed effects model B

I also fitted generalised linear regression models for each participant (on an individual level). The full model results are attached in Appendix D. The models show that some participants have slight significance at p=0.05 or p=0.001 level with either temperature, pressure or wind speed. I believe that given more data, I will be able to find that some participants' pain are affected by different environmental factors, but the sample size available is too small to draw any conclusions of that type.

5.6.2 Modelling sparse and frequent intervals for pain experience

I computed the total user pain experience for each user for two intervals: i) baseline and follow up at one month, and ii) daily over one month. I calculated the differences, along with range, difference and variance in pain experience reported. The results for this are presented in Figure 5.10, with the full data sheet available in Appendix E. Variance was computed using the absolute difference between maximum and minimum pain, difference was computed using the absolute difference in pain reported at baseline and at the one month follow up. The data presented shows the degree of difference in the pain experience (AUC) of the two intervals. I found that more than 60% of the cohort had a greater than 30 point difference in pain experience, with the worst difference being 169 points over. This indicates that a one month interval for pain intensity is not indicative of the actual pain experienced for the majority of the cohort.

		Difference ($\Delta_{T=T1M}$Pain)		
	Experience ($\Delta_{\sum x}$Pain)	High (7-10)	Medium (4-6)	Low (0-3)
Variance (σ^2Pain)	High (7-10)	1.7% H 1.7%M	1.7% H 1.7%M	5.1% M 8.5% L
	Medium (4-6)		3.4% H 1.7% M	1.7% H 20.3% M 18.6% L
	Low (0-3)			1.7% H 18.6% M 13.6% L

Figure 5.10: Variance, Range and Difference in Pain Experience Reported

I continued by plotting the pain experience for the two intervals, and a selection of these are shown in Figure 5.11, with the remaining shown in Appendix F. On the graphs, the sparse interval is shown as a single blue line spanning the x-axis, with the full data shown as a shaded area on the same axis. The AUC values are printed on the middle space of the graph. I found that most of the participants have higher or lower pain experience than the projection based on the sparse interval line. In this study, all participants were taking medication at regular intervals. One potential implication is that most of the participants would have been either over or under medicating as their pain fluctuates. I can conclude that the traditional data collection intervals at baseline and a one month follow up do not capture the actual pain experienced by the participants.

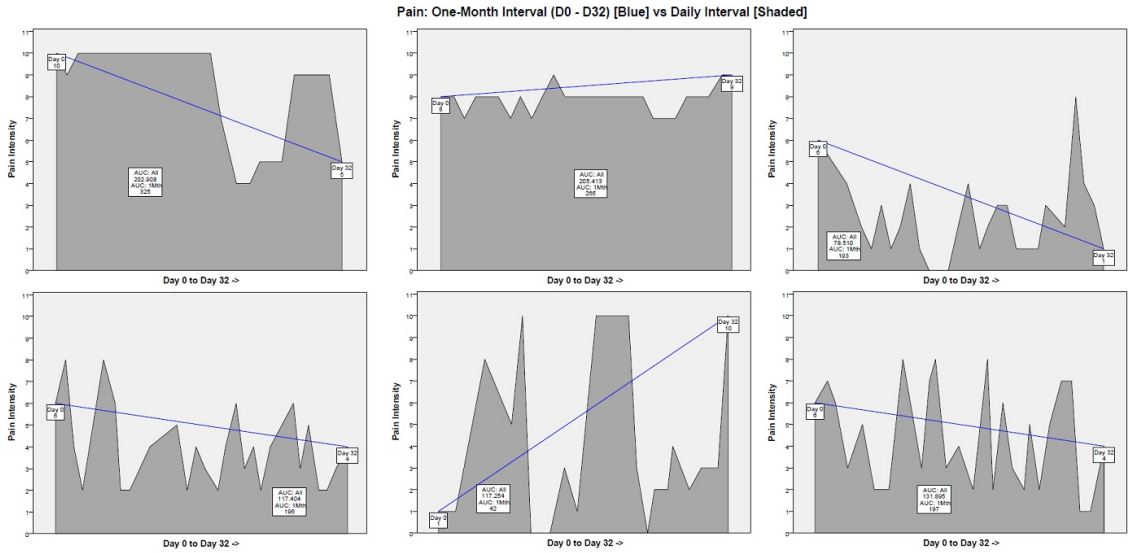


Figure 5.11: Graphs of Pain Experience (AUC) Interval I vs II

5.6.3 Modelling activity against pain intensity

The daily reports also asked participants about what they were currently doing at the point when they felt the change in pain. I extracted this data from the daily pain reports along with the pain intensity and computed the delta of pain intensity to determine which reports were for a clinically significant change in pain. I analysed the data and extracted a set of reported causes that affect pain positively or negatively at a significant level. The reported causes identified are presented in Table 5.3. There needs to be further work done to study if these reported causes actually affect pain.

Table 5.3: Reported causes of changes in pain

Change in pain	Reported causes
Recovering pain	standing / stretch after prolonged sitting, taking pain relief, resting, gym, walking, sitting, stretching
Worsening pain	prolonged sitting, construction work, gardening, at work (unspecified), sleeping / waking up, cleaning, walking, painting, weightlifting, strength training, carrying heavy load while walking, doing chores, laundry, prolonged driving, weighted step-ups

5.6.4 Effects of the ad-hoc reporting approach

I were interested in finding out the effect of asking participants to provide ad-hoc reports when they felt a change in their pain intensity. These ad-hoc reports are additional daily pain reports that were completed outside of the regular daily report. I found that 71.2% of the cohort provided ad-hoc reports, with each participant in that cohort providing an average of 5.6 reports. The reports were split evenly over reports of worsening, recovering and no change in pain at 28.8%, 33.5% and 37.7% respectively. I believe this to be an indicator that participants are more willing to provide such additional information on their pain, as well as report on perceived changes in pain when it is not time consuming to do so, and if there is some sort of perceived benefit from doing so. It is also interesting to note that the majority of the reported causes of changes in pain from the previous section shown in Table 5.3 come from the ad-hoc reports.

5.6.5 Qualitative Thematic Analysis of impact & user experience

I conducted qualitative thematic analysis on the data from the exit questionnaire and notes of the contacts between the participants and researchers, as described earlier in this chapter. To better understand and represent the themes relating to the impact and user experience that was found throughout the data, I classified these into common themes. I found that there were four main themes that pertained to: i) self-management of pain; ii) user experience; iii) questionnaire design; and iv) compliance. Further sub-themes emerged from each main theme, as shown in Table 5.4. The results described here have been published previously in Goh et al. (2017).

Table 5.4: Thematic Analysis Themes

Main Theme	Sub-Themes
Self-Management of Pain	Monitoring of Pain over Time
	Awareness of cLBP
	Self-Reflecting Behaviour
User Experience	Usability and Accessibility
Questionnaire Design	Question Response Granularity
	Daily Diary Response Format
Compliance	Issues with responding to questionnaires
	Missing Data

I discuss the findings using the four main themes identified from the thematic analysis of the questionnaire data and notes taken during the study in this section.

Self-Management of Pain

The theme for self-management of pain relates to the ability of participants to self-manage or understand their own pain. This includes enabling the monitoring of their own pain, increased awareness and enabling self-reflecting behaviour with guided contextual questions.

Most participants described the ability to monitor their own pain levels useful, and one such participant mentioned liking the ability to "note(-ing) the status of my back pain systematically". The pain trajectory graph shown on the dashboard allowed the monitoring of their own pain over time, and they could correlate and better remember what their pain was like at a previous reporting point. Another participant described it as "seeing the change over time" helped with their understanding on how their pain fluctuated and changed over time depending on what they did. It was also described as being "interesting to take note of my pain over the period and the changes ..." that the participant experienced. The ability to monitor their pain has also increased the participants' awareness of their own cLBP, as described in the next section.

The diary style where the participants "describe daily where the pain initiated from", combined with the 7-day pain trajectory graph allowed them to be more aware of the days that they did not experience much pain, and "enabled me to appreciate the good days more than I would ordinarily", or that it "helped ... realise my back pain isn't as bad as some days". There was also an increase in awareness of potential triggers of pain as participants identified some activities that they did that would cause an increase of pain, which was described as being "more aware of what activities aggravated or helped my back pain" and "... of what affects my pain". As the participants become more aware of their own cLBP, I observed some self-reflecting behaviour, as described in the following section.

Some participants experienced self-reflecting behaviour, with reports that it "made me take more care in what I did", and at the same time, "made me think about what I was doing to manage my back pain". Some participants also reported that being able to "describe daily where the pain initiated from" was something they liked about the system. Some participants also communicated via email or phone that they liked how they could "... confirm the pain I had was as I thought". Participants also commented that it was great as the system "drew my attention to the different levels of pain and gave me opportunities to do something proactive about them", and that "I could see what my back pain was and relate it to what I had been doing". On the other hand, there were participants with severe pain who commented that such systems were not so good as it made them "think about something I try very hard to ignore". Some participants that mostly experienced constant pain reported that it was not as useful, and made them think about the pain all the time.

User Experience

In discussing the user experience, I asked the participants to rate their experience on an 11-point scale from 0 to 10, with 0 representing 'Worst' and 10 representing 'Best'. The average experience rating was 7.2, with a median score of 8, with 60% of

respondents rating above the average score. I identified two themes within this area, the usability and the 'accessibility' of the system, which are discussed as follows.

The participants described the usability and accessibility of the system as a comparison between the use of online questionnaires and the use of paper questionnaires. I found that the 'accessibility' of the system was described by participants as the ability to 'access the system anytime, anywhere'. This is different to normal accessibility standards for web sites that refer to making content accessible for disabled people, or for areas with slow internet speeds (Caldwell et al., 2008; Bellevue College, 2017). Although current guidelines provide measures and recommendations to handle the accessibility for the disabled and areas with slow internet, the concept of ensuring that the system provided on the internet can be accessed 'anytime' and 'anywhere' is sidelined and not typically discussed. This may have been due to the normal expectation that web sites and web applications are generally 'always online'. Participants commented that the system was great as "the prompts where a good reminder". I observed that the perceived ease of use to the participants affected their willingness to use the system, with a majority of participants commenting that the system was "easy to use", "easy to complete" and "simple".

The system was available over the Internet, and accessible using a modern web browser such as Google Chrome. It had mobile views that allowed easy access using smartphones or tablets, which participants reported that they "liked being able to log in any time", and "(I) could use my iPad to access it as well". The data I collated suggested that the ability of the system to be accessible 'anytime, anywhere' plays a part in the users' intention to use a system. The researchers also received email and phone calls after the study to thank them for the opportunity to "let me know more about my actual pain", and in one case that "it did not always hurt as much as I thought".

Questionnaire Design

The questionnaires used in the system were designed using a participatory research approach in collaboration with clinicians. One of the objectives was to reduce the response load or burden of the participant when responding to these questionnaires. Therefore, I designed them to be short and guided diary styled using short questions that had specific selections, or short questions that would have open fields for answering.

During the first week of the study period, I had contact from participants regarding answering these questionnaires. There is a question that asks about 'how long ago did you experience this pain', and the answer field was for 'about x hours'. The researchers discussed this and decided to use a whole number result (i.e. 1 hour)

instead of decimals as I felt that no one would want to provide extremely accurate numbers (i.e. 0.33 hours). There were many participants that experienced errors as the system would not allow them to provide such accuracy, in the words of one participant that reported "couldn't submit and there was an error on the hour question that i put 1.56 hours on". I amended the question to read 'in whole numbers' instead to avoid confusion. I also recommend that future studies that design such form elements, include a label to provide an example for the format of the data to be input.

Participants also reported that the question responses did not offer enough granularity, such as "sometimes I couldn't exactly explain my pain", or "there was no way to describe the nature of the pain e.g. aching, stabbing, cramping, throbbing, ... using yes or no as alternatives is frustrating too because I don't know if I missed any", and "the information I could provide to explain the variances in pain to be too limiting". There needs to be further revision to the questionnaires used in expanding the way that I asked the participant on pain.

Some participants also reported that the questions were not very relevant or useful to their specific condition as there were "not enough expansive causes of back pain and associated pain", and for some participants that did not exercise on a regular basis or at all, "the exercise question was not relevant".

When asked about the use of the daily response format, participants were mostly positive and some reported "liking(d) that you had to do it every day", with participants being more aware and "... take more care in what I did", in terms of activities during the day. I was concerned about the burden of response on the participant in terms of the time required to complete the questionnaire. Therefore, I designed the questionnaire in a way that would allow the participants to complete it in a short amount of time, which was well appreciated by participants that stated "it was very easy, but would be better for the duration of the study to be shorter". The average daily response took about 48.18 seconds, or just under a minute.

Compliance

Compliance issues are broken down into two sub themes: i) issues to do with responding to the questionnaires; and ii) missing data from participants.

The most common issue I had were technical issues to do with the participant's Internet connection, with 15% of participants reporting this problem. Some participants reported that they had "initial log on difficulties" in the first week of the study, which stemmed from them not remembering their password that was provided during the registration process. The system was amended to also include their password in their welcome email for the participants' convenience. The other most common

report from participants was that they could not remember if they did report on time or if they forgot to complete it as the system did not give them an overview of the reports that were missing, as summed up by a participant: "I'm not sure if I did, I just can not be sure that I did not".

In terms of missing data, I identified five main reasons that participants reported as the reason to them not completing surveys, which were that "I forgot to complete the survey although I received a reminder", "was away on holiday", "too busy at work", "did not do it on the weekends" and "there was no change in pain". Participants that reported no change in pain found this style of daily reporting very tedious and of no benefit to them as they said that their pain does not fluctuate and that they are "not as sensitive to pain" after living with it for an extended period.

5.6.6 Contextual Analysis of pain intensity

As discussed earlier, a process to study contextual data for pain intensity does not exist. Thus, I designed a process to do so, and this section reports the result of the analysis conducted. The annotated pain trajectory shown in Figure 5.12 indicates the clinically significant changes based on the median pain experienced by the participant as points below and above the blue dotted lines. The annotations of activity and treatment are indicated in red and black text. I will discuss one such example here, and provide the remaining hand annotated graphs in Appendix G.

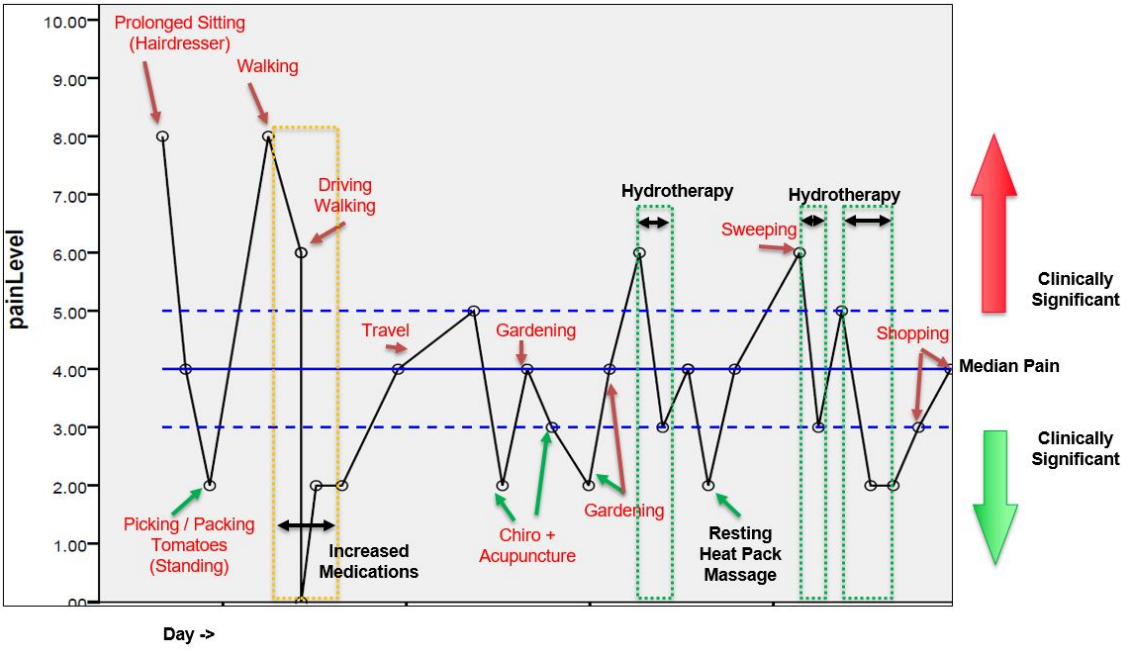


Figure 5.12: Sample Annotated Pain Trajectory

Using the pain trajectory plotted, I annotated activities and treatments that the participant has reported during their daily pain reports. This allowed us to identify activities that potentially have affected a change in pain, be it worsening or recovering pain.

For example, I can attribute the drop in pain level within the yellow box as a result of the participant having increased their medication dosage during that period. I can also attribute the fluctuations and decreases in pain level within the green boxes to hydrotherapy treatment sessions that the participant had begun attending. I found that the annotation of the pain trajectory with reported activities and additional contextual information about what the participant was doing at that point in time allowed us to understand some fluctuations shown on the pain trajectory. Given enough data, I believe that it would be possible to extrapolate a set of rules or identified risks that have been accompanied by increases in pain level for the individual. During discussions with the medical domain experts, I found that the annotated data was useful and has potential in driving future studies for the study of specific causes and risk factors.

5.7 Findings

This case study has allowed us to expand and build upon the initial work from the first case study outlined in Chapter 4. The use of technology here has allowed for different kinds of data to be collected, and combining the use of the descriptive contextual model and the use of an online, mobile-friendly data collection system has allowed us to identify and begin to open up new approaches to studying chronic pain conditions such as cLBP. The data shows that there are limitations to the existing data collection and analysis methods used by current clinical trials and studies, which include the inability to capture the patient's pain experience, as well as identify reasons to pain events experienced by the patient.

I acknowledge that there are limitations to the findings in this study, which include the sample size - which is not indicative of the population, but provides a small representation of the views from users of such a system. Although the sample size is small, the data collected thus far demonstrate that pain seems to be relatively individualistic, with participants of the study having different pain experiences. The statistical modelling done backs this up by not showing population level correlations, which matches results from other researchers' studies thus far. There are many considerations that need to be included when developing such a system, and through the design of the questionnaires that I have implemented in this study.

In terms of findings; first, the development of data collection instruments such as the daily questionnaire, has to use validated outcomes. However, where no such questionnaire exists for the measures to be collected, it is imperative that the work is done in an inclusive, participatory way that includes medical domain experts to ensure that data collected is able to be analysed in a meaningful manner.

Second, the technological platform that is used for implementation needs to be inclusive, and reflect real-world device and system use trends. The case study built a web-based mobile-friendly application in order to have a single unified site that can accommodate as many participants for a project of this time span. It would be best to have native applications for android and apple devices in order to increase the footprint of devices that will be willing to participate.

Third, based off feedback provided by the users, I find that it is critical to allow the systems' questionnaires to 'learn'. This means that it would be more engaging if the questionnaires allowed the participants to add options to questionnaires in the form of potential answers; as the feedback gathered identified that participants wanted to be more descriptive, or have different kinds of answers instead of using either an open field or an 'other' answer field.

Fourth, in studying chronic pain, there will inevitably be some participants or patients that distance themselves from pain as they have to live with it on a regular basis - care needs to be taken such that the questions, while driving self-reflective behaviour; do not harm the patients who do not wish to think about pain. This is especially true for protocols such as ours that ask for frequent pain reports. For example, one participant contacted us via phone near the conclusion of the study described how the pain was so bad that they usually avoid thinking about the pain and immerse themselves in work or other activities.

Fifth, I reinforce the finding published earlier in Goh et al. (2016) that participants do not always enter pain reports in a timely manner. As discussed previously, there were a lot of missing data reports attributed to forgetting to complete the pain reports on-time or at all, despite reminders being sent.

Sixth, I use the pain trajectory as a representation of pain experienced over time. The system provides a display of a seven-day pain trajectory to the participant on their dashboard, which seems to have helped with patient recall of their previous pain reports; which in turn seems to have made the data collected more accurate, based on feedback provided. It also played a part in encouraging self-reflecting behaviour, and allowing a better understanding of their historical pain. This impacts the data collection frequency as such data is really only useful depending on how often data is provided to it. These kinds of data display simply is only more useful at short

intervals such as daily, and additional ad-hoc reports that the participant provides when they experience changes in pain.

Seventh, building onto the previous point, there is a requirement for mechanisms in formalising the analysis and integration of ad-hoc pain reports into a standardized time-line. Other studies seem to ask questions that are 'valid' for a time-span, such as 24-hours, or 7-days. I observed that there were no validated methods for use in including non-time standardized data into the regular data analysis process for cLBP. The domain experts commented that for analysis purposes, the intervals between the data collected need to be somewhat consistent, i.e. reported at around the same time each day. I find that this is hard to ensure as the participants may not always report at the same time. When considering the ad-hoc reports, this increases the difficulty of ensuring consistent time intervals, but I leave this to future research in exploring how statistical analysis can be done for higher frequency data collected at irregular intervals.

Eighth, the usability of such a system requires further work - I found that most studies that review or elicit usability testing measures revolve around the Nielsen (1995) guidelines, and tend to use a similar set of usability attributes or variables in their model. Our results from this study agree with the existing usability models but align closer with Baharuddin et al. (2013)'s work where the user experience or 'usability' was heavily affected by the context in which the system was used for a specific task, or set of tasks. I found that the user experience was impacted by the environment, and the technology (e.g. iPad, android device, desktop computer, laptop) where the system was being used.

Ninth, the participation rate of 94 sign-ups from the cohort contacted does not reflect likely utility of such a system; given that I did not expect to get a modest participation rate from recruitment. The low participation rate may have been due to the lack of obvious medical benefit, but the important part is where I had 95% of the signed-up cohort complete the study. This implies that participants seemed to like using the system.

Tenth, the existing data collection methods and intervals employed by clinical trials in the cLBP space do not accurately capture the pain experience. The results from our study indicate that an average individual will either have an over or under estimated pain experience based on a one month follow up interval. I believe that this could be a reason why trials for medications and treatments do not always return a positive result, with majority of the medication trials returning a neutral, or weak effect size on the population. There needs to be further work to confirm this with a clinical trial.

Eleventh, although the statistical analysis from CS2 indicates that there may be some significant correlations at the individual level, I do not have enough data to explore it at a higher explanatory power. I believe that there needs to be further research studying the effects of the environmental conditions on pain, and further work to explore the inclusion of other kinds of context into statistical analysis.

Twelveth, I discovered during the pilot stage of CS2 that the participants tended to provide more accurate data than requested for. For example, one of the questions on the daily pain questionnaire asked the participant to provide an estimate of how long ago the change in pain occurred. The field provided had the words 'about ____ hours ago' shown, and it was expected that participants would simply round down or round up the time as they would not remember how long ago that the change occurred. The response from the pilot stage participants entirely the opposite to our expectation; I had complaints from the participants as they were trying to provide accurate numbers, i.e. 1.33 hours ago, or 0.25 hours ago, and the field did not support decimal number input. I amended the questionnaire to reflect that the number entry should be rounded to the nearest whole number. There is a need to ensure that the question also specifies the accuracy of the data field, which I have included in our recommendations for design guidelines.

Thirteenth, I found that the reports of pain using the ad-hoc approach seems to be useful in providing additional context to the pain trajectories plotted. This approach is novel to the cLBP space, and the majority of participants in this study seem to be willing to provide such data. There needs to be further work in developing this approach towards a validated means of including the data for statistical analysis.

Finally, for future studies that use a HFDC approach, it is still unknown if this approach increases the perceived reporting burden on the participant, given that the duration required to complete questionnaires is much shorter when compared to a traditional study in the same field. Future research needs to explore how to weigh the differences between the perceived reporting burden of the HFDC approach and measures to evaluate this.

5.8 Chapter Summary

This chapter has discussed the design, as well as the results and findings from the second case study. This study was designed from ground up in order to answer the research questions, which included understanding the impact of a HFDC approach, incorporating the patient's context in chronic pain, and understanding the impact from incorporating the patient's context. I used the findings from CS1 in

designing this case study, and through the ParDSM approach, designed a set of new questionnaires as instruments to elicit contextual data of pain from participants. I also implemented an ad-hoc reporting approach for additional daily reports by the participants when they perceive changes in their pain. The statistical analysis of the data did not return significant results, but this was expected due to the low amount of data available per individual. I reported on the eleven main findings that I have discovered over the course of this case study, and commented on potential areas for future research. The findings support our proposition that the HFDC approach will enable studying the patient context and improve the understanding of the patient's pain experience.

The next chapter will outline our findings in terms of the research questions specified in Chapter 3, provide some reflections towards current practice and conclude by listing our contributions in this thesis.

Chapter 6

Discussion and Reflection

In Chapter 4 and 5, I reported the results from two case studies that implemented the higher frequency data collection approach (HFDC). The HFDC approach is designed to provide a different socio-technical approach to studying chronic pain. The architecture for the HFDC approach provides a means for medical researchers to change or use a different set of methods in studying chronic pain, should they wish to do so. Based on the data and findings presented, domain experts agree that it is meaningful to consider the patient's context using our approach, and that such data could lead to better understanding of the pain experience. The HFDC approach has allowed us to obtain data of higher granularity, but raises more questions than it answers. I consider this to be a good outcome as the basic goal was to elicit and explore such issues in the problem space. This chapter will provide some discussion towards that, and review the findings and contributions that this work has made in answering the research questions described in Chapter 3.

I used the ParDSM approach to design and develop two exploratory case studies in a participatory manner with domain experts. The two case studies have been discussed along with their findings in Chapter 4 and 5, and this chapter begins by discussing the revision of the HFDC approach architecture based on our findings in CS1 and CS2.

This chapter is organised into six sections. Section 6.1 outlines revisions to the HFDC approach based on our findings. Section 6.2, Section 6.3 and 6.4 provides a discussion for the design of HFDC questionnaires, refinement of the context model, and contextual questionnaires for chronic pain. Section 6.5 discusses the impact of using the HFDC approach, followed by Section 6.6 on the impact from the incorporation of patient context in chronic pain. Section 6.7 discusses some other findings arising from this work. Section 6.8 will outline some reflections from our work, followed by a summary of this chapter in Section 6.9.

6.1 Revising the HFDC approach in chronic pain

Previously, I outlined an initial architecture for the HFDC approach in Chapter 3. Based on our findings, I was able to identify further detail and key components for the HFDC approach. I refined the design principles for the higher frequency data collection component to explicitly include the data collection frequency, among other design principles that are described in Section 6.2. The context model was refined based on further discussion with the domain experts and now reflects two levels of context: i) specific domain context; and ii) general domain context. I discuss the changes to the context model in Section 6.3.

I identified various analytical methods that can be used in the HFDC approach in Chapters 4 and 5, and designed a contextual analysis process for chronic pain, which I used in CS2 and outline in Section 6.6.

6.2 Designing HFDC questionnaires for chronic pain

In CS1, I worked with existing data collection instruments, modifying the data collection frequencies for key elements such as pain data in order to increase the granularity of the data available. This resulted in interesting pain trajectories being plotted from the data collected, which spurred interest from our clinical colleagues; in turn driving the ground-up development of new HFDC instruments in CS2. The design of CS1 began by conducting a study of existing data collection instruments - namely questionnaires, that domain experts were using for these kinds of studies. I identified questionnaires that would be normally mailed out to the study participants and studied their design. The majority of the work at this point was about converting the questionnaire on paper into digital form elements, that remained representative of the paper versions. This was important as the questionnaires were validated for use using specific query elements and wording. The instruments were then instantiated in real world studies, and evaluated by experts and study participants (users).

Based on the findings in the two case studies, I identified some considerations for design are described as follows:

Phrasing questions for clarity - In the HFDC approach, it is expected that the questionnaires used will be completed very regularly, at intervals of daily or less. It is important that the questions are phrased in a succinct manner that is easily understood. Italics and bold emphasis should be used to highlight key words within the question.

Simplify questionnaire logic - CS1 used a large variety of questionnaires, some of them more complex than others. I found that the original paper questionnaire provided sets of questions where the participant could answer one or more questions, but if they responded 'no' to a specific question, then the entire set of questions do not need to be completed. The logic of such questions should be simplified to ensure that it is easy to understand. For example, placing a yes/no question at the beginning before asking the participant to continue onto the rest of the set of questions will resolve complex logic. If a question consists of a large segment of optional and required input, the design and layout of the question should suggest this. For example, identifying required input using a red asterisk.

Validate data and check for errors - On paper forms, it is common for the data to be verified only during data entry. As I am using an online web application, I am able to perform validation of the data when the user types it in. It is strongly recommended to check the data entered for validity, be it within an expected range of values, or the type of input, i.e. email address format or time of day. The validation should occur on the client side to provide close to real-time response where possible.

Select contrasting colours - The system should make use of contrasting colours that are pleasing on the eye. I used simple colours such as black, grey scale and blue throughout the studies in a consistent manner. The colours used should ensure strong contrast between elements.

Identify input fields - Where input by the user is required, the field needs to be clearly identified. This can include the use of placeholder text or clear border for the input fields.

Paginate questions - Pagination is the splitting of a long questionnaire into multiple pages. Care should be taken to avoid forcing users to scroll down, instead using a 'next' button to go to the next page. I recommend grouping questions into logical sections or related areas. For example, questions asking the user what specific medication or treatments that they have been using or undergoing can be grouped together on the same page.

Selecting correct input interfaces - The design of a paper questionnaire tends to be somewhat different from a digital online version. For example, it is common to use check boxes instead of radio buttons, or a set of radio buttons for a list of items that the user has to select from. I recommend that for two-option questions, a radio button group is used; for three or more options, a drop down list should be used. If the question allows the user to select multiple options, then check boxes should be used. It is also ideal if an 'other' option field is available where able, so that the user is not forced into selecting one or the other options available.

Clearly identify data accuracy required - The question and accompanying data input field should clearly indicate the accuracy to which the data input is required. For example, 'hours ago' should also indicate either with an example or in placeholder text if decimals are expected or rejected.

Display errors - It is ideal to display errors as they are detected, in red text. If this is not possible, then the validation of the user input should be done before the submission of the form, or navigation on the form to the next page. The error should be clearly stated in a simple but obvious manner to the user.

I found that these guidelines worked well when being applied to conversion of the existing paper-based questionnaires into digital representations, but also to the design of new questionnaires from the ground-up, as I did in CS2. The questionnaires designed for CS2 aimed for an under 2 minute completion time, but there remains the question as to how many questions, or how far the length / duration of a questionnaire can be before users feel that it is time consuming to complete.

6.3 Modelling patient context in chronic pain

As discussed in Chapter 2, I began by studying existing models for chronic pain and identified how these models could be reclassified into contextual factors. I built up a model of variables that have been collected or considered in other research studies and classified them into contextual factors. I built a descriptive contextual model by considering and extending an existing chronic pain model designed to evaluate burden of chronic low back pain. The model describes ten contextual factors, along with some sample attributes; and is divided into two main domains. The top half in shaded circles contain specific domain contexts, and the bottom half in white circles contain general domain contexts. The model was shown to and evaluated by domain experts, and published by Goh et al. (2015). I used this model to guide and design the data collection approaches in both CS1 and CS2, and the data collected helped enhance and re-evaluate the design of the descriptive contextual model, as shown in Figure 6.1.

I refined the model by classifying sets of context factors into two categories: i) general domain context; ii) specific domain context.

I define general domain context as being context factors and variables that apply to the general domain of chronic pain. I outline the five context factors as follows:

Treatment - I define treatment as the information about the treatment that the patient is currently undergoing. This includes medication and other treatment, i.e. injections or physiotherapy. I find that this is typically collected in one of two ways:

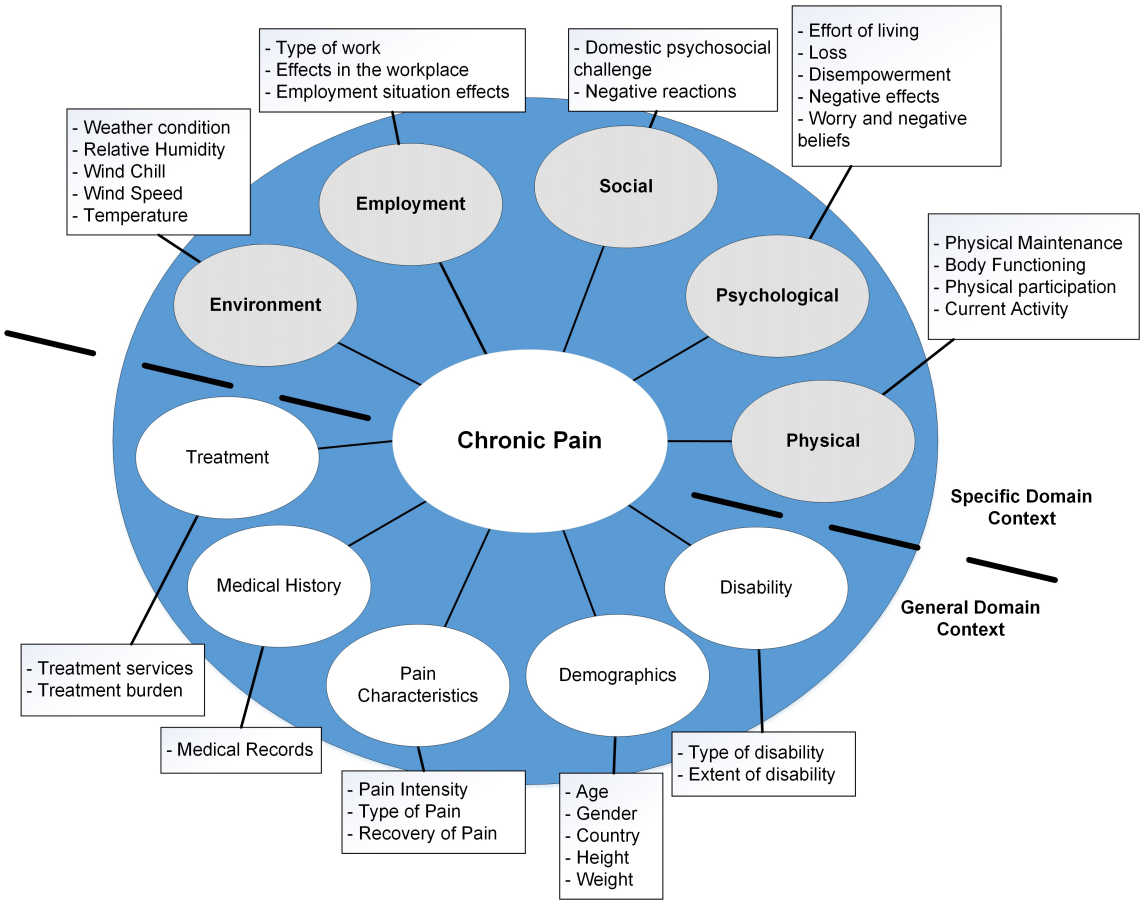


Figure 6.1: Descriptive Context Model

i) extracted from electronic health records; ii) questionnaires eliciting data about the current treatment that the patient is undergoing.

Medical History - I define medical history as the factor containing information on the patient's medical records and previous treatment history. This is usually provided by a government electronic health record, by hospital or patient owned records using a baseline questionnaire.

Pain Characteristics - Pain Characteristics is defined as the information about pain intensity or historical data of pain. In this thesis, I have collected this data using a pain scale, but it is also possible to use a score-based questionnaire to obtain the data.

Demographics - I define demographical data as the quantifiable statistics of the patient to a population. For example, patient age, gender, ethnicity, country or suburb. This category of data is collected using a baseline questionnaire.

Disability - Disability is defined as information about the patient's existing disabilities using a score based questionnaire such as the Roland-Morris Disability Questionnaire.

I define specific domain context as the context factors and variables that may not apply to every pain condition within the chronic pain domain. The five context factors are discussed below:

Environment - I define the environment factor as the data about the conditions that a patient is in. For example, temperature, wind chill, wind speed, wind direction, wind gust, air pressure, precipitation and relative humidity. This information is commonly correlated from a third party source (i.e. weather station or service) using an API, based on the location data provided by the user's device (i.e. using GPS tracking). I note that care needs to be taken not to store the location data permanently due to privacy concerns.

Employment - The employment factor is defined as the patient's occupation information. This includes the type of work, i.e. physical or office work, and other variables such as the effects on the employment situation and workplace. The data is collected using a questionnaire, and collected at baseline; with further information such as change in work or type of work to be collected at weekly intervals if it applies to that particular patient.

Social - I define social factors as the extent to which a patient interacts with other people. This contains variables such as psychosocial aspects at home, negative reaction about pain. This data can be elicited from social media using sentiment analysis, or using questionnaires at a weekly interval.

Psychological - Psychological category is defined as the psychological effects on the mind such as disempowerment, effort of living, negative mental effects, worries, life satisfaction, and depression. This data is collected using a questionnaire at a weekly interval.

Physical - I define the physical category as the exercise and other activities being carried out by a patient. For example, exercise amount, body functioning, participation in physical activities, and the current activity context. This data can be collected using questionnaires on the patient's activities, or using algorithms to extract activity classifications from accelerometer sensor data contained within mobile devices and wearable devices (i.e. fitness trackers).

I found that there are two main ways to implement the descriptive contextual model for chronic pain. First, the model can be used as a reference in collecting data from all ten contextual factors, which would allow a wide view and cover all aspects. This is expected to work only in an all-encompassing set of systems that includes patient records that feed into a clinical decision support system used by the doctors. Second, the model can be used to identify specific contextual factors for a medical study and

organise supporting data to fit the model during the design and data analysis phases of the study.

6.4 Designing contextual chronic pain questionnaires

The descriptive contextual model designed was used to identify contextual factors and guide the design of new questions in eliciting contextual variables for consideration in CS2. It was first necessary to identify a set of design goals and criteria that had to be considered when designing a contextual data collection instrument. I discussed and negotiated with domain experts in narrowing down a list of contextual variables and factors that could be collected, as well as design principles that would guide the design of the instrument. The instruments that were designed from this process were implemented in CS2 and evaluated by both users and domain experts. The users evaluated the system using an exit questionnaire designed to elicit thoughts on the system and the user experience. Findings from the exit questionnaire were fed back into the design criteria for the instruments.

The use of context requires a HFDC approach to be contextually useful. The contextual data collected at wide intervals did not contain explanatory power for the reasons behind fluctuating pain. Therefore, it is important that the design considerations for contextual questionnaires include the previously discussed items in Section 6.2. I outline some further design considerations for contextual chronic pain questionnaires based on our findings in CS2 as follows:

Historical pain trajectory - The historical pain trajectory of the patient should always be shown to aid recollection of their historical pain reports. I recommend the display of the last seven days of pain intensity plotted on a graph that is prominently visible.

Self-reflecting reporting style - The design of the questions should be short, and to the point. The phrasing should encourage or allow self-reflecting behaviour. For example, asking about what the patient was doing or is doing in terms of activity, i.e. running, walking, gardening.

Contextual questions - I recognise that not all context factors are relevant for every patient, so the design of the questionnaire should encourage and allow dynamic addition or removal of questions based on the answers provided. For example, if the user is known not to smoke, exclude smoking questions unless they indicated that they have begun smoking recently.

Allow additional options - Avoid using questions that contain a fixed option set. Always include an 'other' option that will prompt the user to provide a custom response where possible.

Encourage ad-hoc pain reporting - Consider the allowance of ad-hoc reporting of pain, which is the additional unscheduled reports of pain and context volunteered by the patient. This allows the collection of useful contextual pain data.

Design for quick completion - The questionnaire length should be designed in a way that a user is able to complete it in a very short period of time, i.e. under a minute. This applies to regular daily or more frequent pain reports. Weekly reports can be longer as it is not completed often.

Selection of questionnaire time period - The questions should share the same time period. For example if the question on pain asks for the pain over the last 24 hours, the remaining questions should also be focused on the same period. However, I recommend that for contextual questionnaires, the time period is 'now', rather than over a period of time. This encourages users to report more often about their perceived changes in pain.

Ensuring access to the system - I found that the users like the system simply because it is accessible at anytime, and anywhere via the Internet. The infrastructure supporting the system needs to be available and accessible over the internet at all times.

Regular reminders - Reminders should be sent to users regularly, based on the time period of the base pain data collection interval, i.e. daily pain reports have daily reminders. It is strongly recommended to negotiate a time for the reminder to be sent so that it is the most effective in ensuring the completion of the regular questionnaires by the patient.

Enable offline completion - The system implementing the approach should consider having offline completion of the questionnaire that is then synchronised to the server at a later time, to improve the user experience and compliance.

6.5 Eliciting impact of the HFDC approach

CS1 and CS2 implemented varying degrees of the HFDC approach, with the first study using weekly pain data and the second study using daily pain data. Based on our findings, I recommend that the collection of data happen as close to real-time as possible. This is due to the contextual data collected being time-sensitive and 'valid' for that report of pain. As discussed in Chapter 5, the analysis suggests that the

HFDC approach enables the generation of a more detailed and useful pain trajectory for each participant. I was also able to identify unknown and unexpected fluctuations of pain within the pain trajectories for most participants.

The pain data collected showed irregular fluctuations between the sparse intervals (i.e. weekly or monthly). These unknown irregular fluctuations have never been considered and thus overlooked, which suggests that the existing data collection frequencies used by clinical trials is insufficient.

In CS2, I plotted pain trajectories for the pain experience using the AUC measure. This allows us to obtain a theoretical 'total' sum of the pain experience that can be compared. I compared the difference in pain experience when using the data at: i) baseline to one month interval; and ii) daily intervals for a month. Our results show that in 81% of patients, there is more than 10% difference in the pain experience estimated by the one-month interval data when compared to the actual daily interval data.

There are two implications that I believe our results show.

First, the irregular fluctuations are not estimable and do not always have a regular pattern. In existing clinical trials, it is common to use sparse intervals of one month to determine the efficacy of treatment or medication for chronic pain. However, given that the pain varies over the course of the day, the data collected at such sparse intervals cannot be accurate in providing the actual effect sizes. This implies that the effect sizes calculated in analysis by clinical trials for treatment and medication is not representative of the actual pain experienced. The fluctuations of pain could also have had an impact on the efficacy of any treatment and medication being taken during that period of time. I recommend to study contextual reasons for fluctuating pain on a per-patient basis instead of at a population level.

Second, almost all of the cohort in CS2 were on some type of treatment or medication plan. The implication of the vast differences found in the pain experience could mean that the majority of patients are either over or under medicating. This assumes that the patient has weekly or monthly pain reports, or follow up reviews with a doctor to determine the amount of medication to be taken.

During our literature review, I found that the majority of existing medical instruments for data collection in chronic pain take a long time to complete due to their length. The HFDC approach requires that the data collection instruments do not take a long time to complete, or require a lengthy reading time. The majority of existing instruments do not meet these requirement, and there needs to be further work investigating this.

I find that the higher frequency data collection approach is cost prohibitive without the use of online data collection platforms. This consideration of cost includes the cost of printing, mailing, processing and data entry of responses for both the participant and researchers.

6.6 Eliciting impact of incorporating context into the HFDC approach

I identified some discoveries and issues with incorporating the patient's context in chronic pain. There were no data analysis methods that would work for these types of contextual data known to us. Therefore, I began by designing new ways to analyse and represent the contextual data. I studied how pain data was typically analysed. The primary method of visualising and studying pain is to use a pain trajectory, which is a graph of pain intensity plotted against time, and this represents the course of pain that a patient has had. I designed the following process to annotate and consider context for chronic pain through a series of discussions, trials and errors with domain experts. I present it as a set of eight steps:

1. Plot the pain trajectory. The pain trajectory must use real date and times instead of fixed 'period' intervals. This is to allow for an accurate rendition of the pain trajectory over time.

2. Identify data types. Separate the contextual data into statistical and descriptive categories. Descriptive data is data that typically is open-ended and requires coding, or 'describes' actions or activities that were taking place at the point of the pain report. Statistical data would include numerical forms and category based data that can be fitted into a statistical model, and can include coded descriptive data.

3. Fit statistical models for an individual patient. This allows the determination of any statistically significant factors. If there are statistically significant factors, identify these and set them aside.

4. Identify clinically significant changes in pain on the pain trajectory. This is defined as a positive or negative change that is greater than or equals to two on the pain intensity rating of 0 to 10.

5. Add additional descriptive information. Annotate the pain trajectory with the descriptive activity or action data for only the clinically significant points identified in Step 4.

6. Consider additional data for annotation. Based on the statistically significant factors from Step 3, further annotate the pain trajectory with this information.

7. Study the pain trajectory for similarities. It should be now possible to identify contextual reasons for the changes in pain based on the annotations. It is also possible to draft recommendations for the patient at this time to beware or avoid certain activities that seem to affect pain. In future updates (e.g. next month), consider if those activities have been avoided and if they are still impacting pain.

8. Extend findings to the cohort level. Identify similarities or common themes and patterns across the cohort.

The current process is still heavily reliant on manual analysis and I do not yet know how it can be automated to enable more efficient analysis, which I leave to future research. The integration of context in the analysis stage has elicited the following discoveries:

First, the context factors have provided some suggestions to the causes of worsening pain and recovering pain on the pain trajectories. These have been condensed into a set of potential causes as presented in Chapter 5, and demonstrates usefulness of the patient context. There needs to be further work in affirming and studying these causes.

Second, the annotations, along with the pain trajectory have confirmed that pain is mostly an individualistic experience that is affected by the patient's life patterns and other unknown factors.

Based on the findings and discussions, I recommend that specific contexts are always collected for each pain report, and I outline these in Table 6.1.

The following section will briefly discuss some findings that I discovered over this research work that require further study in future research.

6.7 Other findings from this work

Thus far, I have outlined our findings that relate to the research questions of this research in the sections above. However, as I have mentioned at the beginning of this chapter, there are more questions raised through the process of conducting this research, which I discuss in the section as follows.

The implementation of the HFDC approach has shown to be beneficial and has allowed for a higher granularity of data collected, with the resultant data analysis

Table 6.1: Context Factor Recommendations

Interval	Daily	Weekly
Recommended Variables	Pain Intensity Weather Temperature Humidity Pressure Activity Type of pain change Medication Location (Indoors/Outdoors)	Disability (RMDQ) Quality of Life Worst pain Intensity (7 day)
Conditional Factors	Work affect/effect Sleep affect/effect Vices (Alcohol, Smoking) Treatment changes	Psychosocial Factors Psychological Well-being

being richer and of great interest to the domain experts that I worked with. The first question is regarding the appropriate frequency of data to be collected - how often is enough? In CS1, I looked at collecting pain data at a weekly interval, only to realise that the contextual data is really only as useful as often it is collected; considering that contextual data will build a 'picture' of the context around the pain reports, I could say that for a weekly report, you would want a contextual 'picture' of the events around that week of pain. This is not very realistic because of various concerns, namely privacy and the burden on the patient reporting requirements. There are multiple constraints there, including the technology available in tracking activities, which is not sufficient in discretely identifying and differentiating between similar activities such as cycling and carrying heavy items or shopping. In CS2, I collected data at daily intervals, while asking the participants to also report when they perceived a change in pain. This mostly worked, except that I received feedback that some participants interpreted 'change in pain' to be negative, i.e. worsening pain, which meant that some participants did not report positive changes in pain, i.e. recovering pain. The implication is that some of the data is not 'complete' in the sense that I had 'missing' recovering pain reports from a small number of participants. The contextual data collected in CS2 was bundled into the daily pain report intervals, and were useful in providing a rough view of the participant's context at the point of the perceived change in pain. However, I are unable to tell if this is sufficient in providing an accurate and rich view of the 'context' around a pain event.

Second, one common issue in research as a whole is the topic of missing data. During CS1, I considered missing data within a single participant's reports beyond

a certain percentage to be 'incomplete' data and discarded the data collected from that participant for our purposes. If the participant had a low number of 'missing' data I interpolated over the duration based on the pain reports on either side. In CS2, I used a similar approach, discarding participant data if the amount missing was above a certain percentage. For the majority of participants, they had very few missing data points; rather - they had extra data points in the form of the ad-hoc reports that were provided as a result of 'unscheduled' changes in pain. Recall that I requested that participants provide ad-hoc daily reports if they had a perceived change in pain, and if they had already completed the daily report for that day. I found this to be exceedingly useful, as the majority of the activity data was recorded during these ad-hoc reports. This creates a problem in standard statistics used in this field, as it expects a fixed interval or time period in most statistical models that are used within chronic pain that I am aware of. It was not a problem at the wider data collection intervals as the questions used would ask for pain over a period of time. However, CS2 used questions asking for pain experienced now (or in the case of ad-hoc reports, when a change of pain was felt). The increase in accuracy meant that the data that was collected is typically not at equal intervals. I observed reports that were provided within the span of minutes, and as far as being hours or days apart from one another. There needs to be further work to study how a statistical model, or quantitative data analysis purposes can be designed to cope with irregular time-series data.

Third, feedback from participants in CS2 suggest that there may be a need to develop a 'self learning' questionnaire that will contextually include or exclude questions, responses and options based on the existing participant data. Analytically, this is a problem because you will not have standard responses over a period of time. In participant context, this is an issue because they may lose interest in completing the questionnaires as they feel that it is 'not of relevance' to them. There needs to be further work in studying how this could be achieved, or if some middle ground can be attained in order to increase participant willingness to continue a study; or simply just to figure out how such data can be utilised in a meaningful quantitative manner. The question also remains on how can I determine if a question becomes irrelevant for a participant. For example, if a participant indicates at baseline sign-up that they do not smoke or drink alcohol, is it still relevant to ask them that question at each report, or can I exclude it? What if they begin consuming alcohol or smoking at a later point during the study?

Fourth, the general usability of the questionnaire is assumed to be acceptable, without going to the extent of evaluation using standard usability measures. The design of the systems and instruments considered usability attributes and guidelines, and the

participant response indicates that it was mostly positive. During the system design for both CS1 and CS2, I found that while the literature describing usability principles was broad, it was lacking in that there was very little discussing applied measures for evaluation purposes in relation to the design of online, digital questionnaires. There needs to be further work studying and eliciting practical means for doing so.

Fifth, the participation rate for both CS1 and CS2 leaves much to be desired, with both studies reflecting low sign-up rates based on the number of patients that were contacted during recruitment. I expected a low participation rate due to the lack of obvious medical benefit, but I believe that further work studying the engagement, or even marketing of such research projects should be carried out in increasing the participation rate - what drives people to participate, or not to participate in research?

Sixth, at present I am unsure of the participant burden in terms of two measures: i) how does the research study affect their self-perceived 'burden' of the chronic condition; and ii) what is an acceptable duration for an online instrument to be completed? I attempted to ensure that the questionnaire did not probe too deeply for many details, and as a result designed the questions with short or field based answers to be as open as possible. I also aimed for a questionnaire design that allowed it to be completed within a very short period of time. Both result in certain measured compromises to be taken in regards to the depth of detail and number of questions that I could reasonably have on the data collection instruments. This was never a problem with the wide interval data collection method, as observed in the existing validated data collection instruments - even in chronic pain. Many of these instruments are multi page questionnaires that take an extended time to be completed, and some require professional assistance in the guise of a trained doctor, nurse or research assistant to be completed. I feel that there needs to be more work exploring an acceptable length and duration for a online questionnaire to be completed, especially if the questionnaire is to be completed at regular or frequent intervals.

Seventh, the instruments designed as a result of this study have not been formally validated. Although I use some validated measures in eliciting pain data, the remaining contextual measures are not commonly used, and have not been validated for clinical use. There needs to be further work exploring this, or simply a means to validate such contextual questionnaires where the instrument is designed for-purpose.

Eighth, technology has played a large part in this research. The entire premise of this work was based on the availability of technology that translated into enabling the HFDC approach using a secure, online, mobile-friendly platform. As I described in Chapter 2, I have not observed a large uptake in the use of such technology for similar

studies in chronic pain. In surveying the application landscape for mobile operating systems such as Android or iOS, there are many 'pain management' applications, and in general - 'eHealth' or 'Digital Health' applications, but there are no frameworks in place to ensure the quality and validity of advice, nor the safety of the data collected through these systems. I believe that this impacts the public 'view' of such applications, and as a result reduces the interest of potential participants in studies using such systems.

Thus far, I have discussed our findings for the research questions in this thesis. The next section covers our reflections on the current practice in medical research (clinical trials for cLBP) and development of such similar systems.

6.8 Reflection

This section provides a short reflection to current medical practice and recent research within the scope of this thesis.

6.8.1 Current medical practice

Recently, a paper published by Kongsted et al. (2017) discussed definitions of pain trajectory groups and subgroups that had ongoing fluctuations of pain using weekly measures of pain intensity over one year. I think that there would be potential in further research to apply the pain trajectory groups and subgroups from this paper to the data collected in this research to study the differences between the different classifications of cLBP in terms of the pain experience (AUC).

Existing practice in current clinical trials between 2017 - 2018 still utilise the same measures and time intervals for data collection that have been used prior to 2017. Although some studies use data collection intervals that refer to before and after the treatment itself, I do not yet know if the baseline reading at day 0, and the activities that the participant were doing before the treatment has an impact on the efficacy of the treatment itself.

Within the cLBP field, a majority of observed research do not utilise technology to its full potential in data collection. The opportunity that I utilised in this research to demonstrate the potential of online and mobile technology in enhancing the ability to collect data is real, and under-utilised. Currently, the majority of 2017 - 2018 clinical trials utilise paper questionnaires that are administered via post or in person. Admittedly, a proportion of these are due to necessity as there are tests that only can be run in the hospital setting, and some are due to the fact that a doctor follow

up is needed. However, certain key self-reported data such as the pain intensity; which is often used as a primary measure to determine whether a drug or treatment is working, is not collected at the necessary frequency. I found that the ability of a single one month follow up, i.e. at baseline and subsequent one month follow up data collection, is not sufficient to describe the efficacy of a drug or treatment on a chronic condition. This is primarily due to the nature of pain, which seems to fluctuate quite a lot over the span of a single day. This thesis demonstrates that the technological aspect and capabilities allow more accurate and useful data collection using the HFDC approach. However, before I arrive at the point where it becomes easy to implement such a data collection system, further research needs to be done to answer all the uncertainties that I described above, as well as to develop a strong architecture of components that will aid system design and building towards a HFDC system.

6.9 Chapter Summary

This chapter has provided a discussion of the findings in this thesis, and refining the architecture for the HFDC approach. I discussed our findings in relation to the design of both HFDC and contextual pain questionnaires, and presented two sets of design principles. I discussed and elicited the impact of using the HFDC approach, and the consideration of context using the HFDC approach, which provided findings and answers to our research questions. The chapter also provided insight into other findings that arose during the progress of this research, and discussed some reflections to practice in terms of medical and development areas. The findings of this research provide a starting point for further work to continue in this slice of knowledge, and I have identified areas for future work to be done.

The next chapter will present the conclusion to this thesis, accompanied by our answers to the research questions. I identify the contributions that I have made towards knowledge, methodology and practice, and close with some future research directions.

Chapter 7

Conclusion

Chronic pain is a global health problem. Currently, researchers still do not understand the nature of pain, nor have they been able to identify the reasons for the occurrence of pain (Maher et al., 2016). Experts have concluded that the existing treatments and medications are not effective, as the clinical trials to prove efficacy have shown weak and ranging effect sizes on population level metrics (Maher et al., 2016; Buchbinder et al., 2018). Our review of the literature in chronic pain identified that there was a low adoption rate of technology used for data collection. Although there are studies that utilise some form of technology, be it sensors or data collection instruments, a majority of research including clinical trials in specific fields such as chronic low back pain, do not use technology in data collection. Instead, the traditional means of using paper questionnaires administered to participants via mail, telephone, or in-person was prevalent.

I also discovered that the data collection intervals of such studies tended to be at sparse durations, i.e. 3-weekly and 1-month follow up intervals. Research currently shows that pain has a fluctuating nature that tends to be individualistic (Olson, 2014). Therefore, I believed that there was a chance that the data collection measures and intervals currently in use, contribute to the inaccuracy of how I measure the pain experienced by a patient.

In psychological and behavioural sciences, context is used in studying the nature of a phenomena (Green et al., 2009). However, existing medical studies do not utilise context in studying chronic pain. Therefore, this thesis aimed to introduce a different medical approach to studying chronic pain by using advances in technology to overcome traditional limitations of data collection. I developed a participatory approach to design science, that I coined Participatory Design Science Methodology (ParDSM). ParDSM extended Peffers et al. (2007)'s design science research methodology with participatory components that were identified by McKemmish et al. (2012).

This research strengthened the concept of a problem-based research entry point and implemented ParDSM in developing the research design described in Chapter 3.

By incorporating lessons learnt in other fields of research, I developed a higher frequency data collection (HFDC) approach that incorporated the patient's context, and demonstrated using two exploratory case studies that there was potential in using such an approach to study pain. The HFDC approach utilised advances in online and mobile technology. The first case study (CS1) was designed as a proof of concept to test and demonstrate the HFDC approach in a real world clinical trial as an add-on analytical component. The second case study (CS2) was then designed from the ground up, based on what was learnt from CS1, in order to understand the impact that the HFDC approach had when the patient's context was incorporated. I discussed the results from both case studies in Chapters 4 and 5, with the overall findings provided in Chapter 6. The results of our research demonstrated the depth and difference the HFDC approach has on the data collection process.

7.1 Answering the first research question

The first main research question of the study was:

What can be learned from a higher frequency data collection approach in chronic pain?

I developed a set of core requirements to form an initial architecture to represent the HFDC approach, that was presented in Chapter 3. These requirements were identified based on a literature review of the existing works within the chronic pain space. The HFDC approach was used to design and implement CS1 and CS2, which allowed us to test the key design elements of the architecture. I integrated feedback from both domain experts and domain users in both case studies to formulate the final revision of the architecture that was presented in Chapter 6.

I sub-divided the first research question into two further sub-questions:

How higher frequency data collection instruments can be designed?

What is the impact of a higher frequency data collection approach on chronic pain studies?

The following sub-sections will present our findings for these sub-questions.

7.1.1 How higher frequency data collection instruments can be designed?

This research question was addressed using an extensive literature review and analysis of data collection methods and instruments that were used in chronic pain research.

In CS1, I converted the existing data collection instruments used for the clinical trial into digital web versions. I developed and elicited an initial set of design guidelines that informed the conversion process. In CS2, I revised the guidelines through negotiations and discussions with domain experts, and included feedback provided by domain users. The result was a set of nine considerations for the design of HFDC instruments, which I summarise in Table 7.1.

Table 7.1: Summary of Design Considerations for Contextual Instruments

Design Principle	Summary
Phrasing questions for clarity	Question phrasing must be succinct and clear. Use italics and bold emphasis to identify key words within the question
Simplify questionnaire logic	The questions should be structured in a straightforward manner using simple logic
Validate data and check for errors	Ensure that the data is validated and check for incorrect input before processing
Select contrasting colours	Use contrasting colours that do not clash with one another
Identify input fields	Clearly identify input fields using a placeholder or borders
Paginate questions	Avoid scrolling and paginate long questionnaires
Selecting correct input interfaces	Ensure that the input type is selected correctly for the logic involved
Clearly identify data accuracy required	Always indicate the accuracy of the data input required
Display errors	Display errors as they are detected in red

7.1.2 What is the impact of a higher frequency data collection approach on chronic pain studies?

This research question was addressed using the evaluation data from CS1 and CS2 using exist questionnaires, and using the findings from the analysis discussed in Chapters 4 and 5.

The results of the analysis for both case studies identified irregular fluctuations in the pain trajectories plotted. The domain experts commented that these fluctuations were unexpected and of interest for further study. I found that the fluctuations are not estimable, and do not always present a regular pattern.

In the second case study, I computed the pain experience using the Area-Under-Curve (AUC) measure. In the cohort for CS2, 81% of participants demonstrated greater than 10% variance in the pain experience estimated by the one-month interval data when compared to the data captured for the daily intervals.

It is clear from our results that the sparse data interval is not an accurate representation of the pain experienced by the patient. This is a strong indication that the existing treatment and medication clinical trials are not collecting accurate data, and potentially reporting weak effects due to the inaccuracy.

I identified that the existing validated instruments being used are not suitable for the HFDC approach, as they are too lengthy to be completed on a frequent basis. There needs to be further work in validating shorter or abbreviated forms of the existing questionnaires; or to design new versions of them that elicit the same type of data using a short form.

7.2 Answering the second research question

The second main research question of the study was:

What can be learned from incorporating the patient's context in chronic pain?

The second research question uses the HFDC approach to incorporate the collection of the patient's context. This question is answered by sub-dividing it into three further sub-questions:

How to model the patient's context in chronic pain?

How data collection instruments that incorporate context can be designed?

What is the impact of incorporating the patient's context in chronic pain studies?

The following subsections will present our findings for these questions.

7.2.1 How to model the patient's context in chronic pain?

As discussed in Chapter 2, the patient's context is not something that has been studied in chronic pain. I found that there were no existing models of the patient context, therefore I conducted a literature review to identify data that has been collected by medical studies in chronic pain. I classified the data into contextual factors, and through a discussion and negotiation process with domain experts, revised the identified factors. I defined a descriptive contextual model for chronic pain in Chapter 6, which has ten contextual factors identified as follows:

- Treatment
- Medical History
- Pain Characteristics
- Demographics
- Disability
- Environment
- Employment
- Social
- Psychological
- Physical

I implemented varying degrees of the contextual model in both case studies. I recommend that the model is used in either identification of variables and corresponding context factors for the design of contextual studies, or as a reference to ensure that all aspects of the patient context is collected.

7.2.2 How data collection instruments that incorporate context can be designed?

The task of designing contextual data collection instruments for chronic pain was difficult as no such instrument, nor guidelines existed. Through the design and development of the second case study, I designed using a participatory approach, a set of contextual questionnaires that considered context at its core. I used the questionnaires in our implementation of case study two. The evaluation of the questionnaires were conducted using domain expert and user feedback in the form of an exit questionnaire. I elicited a set of considerations for the design of such data collection instruments based on the overall design process experienced, as well as the feedback obtained. These have been discussed in Chapter 6, and consolidated as a component in the overarching HFDC approach architecture. I present a summary of the considerations in Table 7.2.

Table 7.2: Summary of Design Considerations for Contextual Instruments

Design Principle	Summary
Historical pain trajectory	Display a pain trajectory that provides historical data for at least seven days to the user prominently
Self-reflecting reporting style	Design questions to enable self-reflecting behaviour
Contextual questionnaires	Encourage and allow contextual addition and removal of questions based on data collected
Allow additional options	Always include an 'other' option to allow custom responses
Encourage ad-hoc reporting	Allow additional unscheduled reports of pain and context by the patient
Design for quick completion	Design frequently used questionnaires to be completed in a short period of time
Selection of questionnaire time period	Design questions to use the same time period for reporting
Ensuring access to the system	The infrastructure supporting the system must be available and accessible online at all times
Regular reminders	Send reminders to users regularly. Negotiate the time for the reminder to be sent with the user
Enable offline completion	Consider allowing offline completion of questionnaires that is synchronised with the server at a later time

7.2.3 What is the impact of incorporating the patient's context in chronic pain studies?

I implemented varying degrees of both the HFDC approach and the incorporation of the patient's context in both case studies.

CS1 used weekly intervals to collect pain data, and irregular intervals for other context. The findings from CS1 show that contextual data needed to be time-matched with the intervals for pain data, and that weekly data collection intervals for context was not sufficient in providing explanatory power to the changes in pain identified on the participant's pain trajectory.

In CS2, I implemented daily and weekly intervals with different sets of contextual data for each questionnaire. This decision was taken as a result of the negotiation process between the researchers and the domain experts. I found that the data collection at the daily intervals was of greater use than the ones at the weekly intervals. The contextual data about the change in pain, such as the participant's activity was useful in explaining some of the significant fluctuations and patterns of pain, that was identified on the pain trajectory. I developed a process to annotate the pain trajectory using contextual data for analysis, which is discussed in Chapter 6. However, this process is still time consuming as it is done manually. It would benefit from further research to optimise and automate the process for speedier analysis.

The findings of the statistical analysis conducted for both case studies returned inconclusive results at a population level. In CS2, I also ran statistical modelling for individual sets of data, which showed varying levels of significance in different environmental variables for different participants. I am not able to draw conclusions from this due to the lack of data, but I recommend that future studies consider the modelling of individual participant data as it might lead to new findings.

The findings from the contextual analysis of pain intensity in CS2 also identified potential activities and treatments that had an impact on changes in pain. I am not able to conclude that these are contributing factors to pain, and leave it to future research. However, based on the usefulness of some types of context that I have collected in both case studies, I provided a recommendation for the collection of specific contexts and frequencies in Chapter 6. The recommended mandatory factors are summarised in Table 7.3.

Table 7.3: Summary of Context Factor Recommendations

Context Factor	Frequency
Pain Characteristics	Daily
Environment	Daily (Collected with Pain)
Physical (Activity)	Daily (Collected with Pain)
Treatment	Daily

I concluded that the contextual data must be collected as frequently as the pain data, and use frequent intervals in order to have explanatory power. I found that the use of contextual instruments explicitly requires a HFDC approach to be implemented using daily intervals.

7.3 Research Contributions

A list of the contributions made by this thesis was summarised in Chapter 1. This section provides a more detailed description of the contribution and significance of the research.

This research is the first work that incorporated the patient's context using a higher frequency data collection approach, which has provided new knowledge on the issues and limitations of the existing traditional data collection methods. The understanding of how existing variables collected by chronic pain studies can be viewed from a contextual point of view is captured in the descriptive contextual model that I designed and described in Chapters 2 and 6. This thesis elicited and refined the design principles that have been represented as major components in the

architecture for the higher frequency data collection approach, which is presented in Chapter 3 and 6. Throughout this thesis, I ensured that the research done was useful to the medical domain by using a participatory approach to design science. This research approach was developed into a formal extension of Peffers et al. (2007)'s DSRM model, and was defined in Chapter 3 as the Participatory Design Science Methodology (ParDSM). The results from the two exploratory case studies were expressed through the findings, and contributed unique insights into the fluctuating nature of pain, as well to future research directions for both medical and information systems researchers.

The following subsections provide a description of the contributions that this thesis makes to knowledge, methodology and practice.

7.3.1 Contributions to knowledge

Contribution to knowledge on the use of context for chronic pain research. This thesis contributed knowledge on the use of context in chronic pain research through the design and development of the first descriptive contextual model for chronic pain. The model provides a formal definition to the different contextual factors that were observed in existing chronic pain research. The contextual model provides the first step towards a contextual approach to studying chronic pain, and was published by Goh et al. (2015).

The findings from our case studies that implemented the model indicated that it is a requirement to collect data using a higher frequency data collection approach, in order for the contextual data to have explanatory power for the patient's pain experience. This research's use of the patient's context in chronic pain have led to some new perspectives on the use of environmental data, i.e. weather conditions. The statistical analysis conducted showed no significant correlations at population-level modelling. However, individual level models produced some correlations that require further study.

Contribution to knowledge on higher frequency contextual data collection for chronic pain. The architecture that was presented in Chapter 3 and revised in Chapter 6 represent the graphical formalisation of the higher frequency data collection (HFDC) approach that incorporated context for chronic pain. The architecture utilised mobile and online technology to overcome limitations of the existing paper-based data collection methods. This thesis is also the first to formalise an architecture for the HFDC approach.

The suitability of such an approach has been demonstrated using both case studies that explored the impact of using the HFDC approach to study the patient's context

in chronic pain. The advantages that were exposed through the use of such an approach were based on: i) the widespread usage of technology; ii) the availability of the internet; and iii) the strength of studying the context of a phenomena, i.e. context of pain, in order to understand its nature.

Experts agreed with the findings of our research that the HFDC approach that included the patient's context, provided insight into the contributing factors of pain, and produced pain trajectories that were accurate and representative of the pain experienced by the patient. The results from the analysis have also identified previously unknown fluctuations in pain that were not captured by traditional means of data collection. The findings were published by Goh et al. (2016) and Goh et al. (2017).

Contribution to knowledge on the understanding of pain. Currently, there is little that is understood about chronic pain, especially the non-specific variant that is not attributed to a cause. This thesis contributed to medical knowledge on the existing understanding of pain, by demonstrating through the use of the two case studies that pain has a fluctuating nature. The results of our research also supported existing theories that pain is an individual experience where no two patients may experience the same pain. The analysis conducted for the two case studies have also identified similarities in the overall patterns of pain, which may be classified in future research.

Contribution to knowledge on systems design for e-Health and medical contexts. This thesis contributed towards knowledge on systems design for both e-Health and medical contexts. Through the design and development process described in Chapters 3, 4 and 5 for both case studies, this thesis also provided a number of considerations for design for systems that collect sensitive medical data. The design principles were elicited using a reflection and iterative design process for both case studies. The evaluation results discussed in Chapter 4 and 5 also provide insight into factors that impact participants' willingness to utilise such systems, which was published by Goh et al. (2017).

Contribution to knowledge on the selection of data collection intervals for chronic pain. The thesis contributed knowledge through the review of existing literature, and exploration using two case studies on the data collection interval affecting the accuracy of findings for chronic pain. The literature review discovered that existing medical studies in chronic pain usually collect data at sparse intervals. The findings from the two case studies demonstrated that the selecting of sparse data collection intervals do not produce data that is representative of the actual pain experienced by a patient.

Chapters 4 and 5 discussed the comparative analysis conducted for data at sparse intervals versus frequent intervals at: i) weekly versus monthly; and ii) daily versus monthly. The findings produced show that the data collected at sparse intervals will result in severe over-estimation, or under-estimation of the actual pain experience for a given patient. The analysis and subsequent discussions provided represent this research's contribution towards knowledge on the importance of selecting correct data collection intervals for chronic pain. These findings have resulted in the identification of several future directions for research.

7.3.2 Contributions to methodology

Contribution to design science methodology. The research problem identified in this thesis resulted in the adoption of participatory components that were adapted from inclusive research design. The participatory components were critical to the success of this research due to the medical nature of the research problem. It was necessary to ensure that medical domain experts were equal participants throughout the research process, in order to guide and confirm the validity of the actions taken, and findings reported. This thesis contributes towards design science methodology, having proposed the Participatory Design Science Methodology (ParDSM) that has been defined in Chapter 3. This research also contributes towards design science knowledge through the implementation of ParDSM using two exploratory case studies.

Contribution to contextual analysis of pain trajectories. This thesis contributes towards contextual analysis of pain trajectories by presenting a novel approach that was developed in order to enable the analysis of contextual pain data. The process has been described in Chapter 5 and 6. The findings from the contextual analysis demonstrate the usefulness of this technique, which has been able to identify some reasons for the fluctuations on the pain trajectory.

7.3.3 Contributions to practice

Contribution to the design of higher frequency questionnaires for chronic pain. The design of the higher frequency questionnaires for use on online and mobile platforms using a participatory approach described in Chapters 3, 4 and 5 represent a contribution that this thesis has made.

The first case study converted paper based questionnaires into electronic forms, and the second case study designed higher frequency questionnaires from scratch. The design principles that were used for these processes were refined and described in Chapter 6, as well as in the responses to the research questions in this chapter.

Contribution to the design of contextual data collection for chronic pain. This thesis used a reflection process in the elicitation and refinement of design principles for the design of contextual data collection for chronic pain. The discussion provided in both case studies in Chapters 4 and 5, along with the discussion towards the refined design principles reflect the contribution that this thesis has made. The findings have also contributed towards the elicitation of a set of recommended context factors that should be collected, which has been described in Chapter 6.

7.4 Future Research

Based on our findings, I was able to identify some future research directions stemming from this work. Some of these have been spun off as new PhD projects in late 2017.

Currently, the main measure for activity that I have used relies on user input about their actions and activities. With the current advances in technology, it is possible to use skin-thin sensors to determine activity and the range of motion of a user. Some of these sensors have been used in activity and pedometer fitness devices, and there are some developed for use in medical contexts. One of the new PhD projects is studying the use of these sensors to automatically determine the activity and user posture.

As mentioned previously, further work needs to be done on the design and use of the contextual questionnaires in order for these to be valid for use in actual clinical contexts. Another PhD project is studying the design and use of such contextual questionnaires for mobile platforms in the medical space.

There is also potential in including context aware reasoning and recommender systems on the platform as it will allow the real-time determination and recommendation of activities or warning of potential risks as the user goes about their regular life. This could lead to improved, and personalised treatment plans and guidelines being available.

The process of annotating the pain trajectory with contextual data is a manual process. I would like to explore further on means of visualisation for pain trajectory and contextual information, in a way that is useful both to patients and the clinicians.

Through the literature review conducted, I found that there is potential in analysing contextual mood data. Psychological factors can play a part in affecting the user's perception of pain, and mood is one of the primary outcome measures that can be adapted contextually. This will be challenging as the existing methods are designed for long paper based questionnaires and not digital media. With the advent of social

media, it is possible to use content analysis of the user's social media accounts and comments posted to infer their mood.

Although I have provided recommendations on the collection of specific contexts of chronic pain, there needs to be further research into studying the contextual 'view' of pain, and to identify what appropriate frequencies are sufficient for different contextual factors.

Currently, when using an ad-hoc daily pain reporting method, I was advised that incorrect interpretations of statistical analysis may occur when using irregular interval data. Further work needs to be done to study how this problem can be mitigated, and how statistical analysis can be conducted for irregular interval data containing contextual features.

There is also an opportunity to elicit applied measures for evaluation in the relation to design of online digital questionnaires in a practical way.

From the two case studies, the participation rates based on the number of potential participants contacted is relatively low. I would like to see further work to elicit a theoretical model that describes the drive for potential participants to either participate or not participate in research. This would contribute strongly in designing a study that would have a higher registration and participation rate.

At present, I do not know what the participant burden is like in terms of: i) research study affecting self-perceived 'burden' of chronic condition; and ii) acceptable duration or length for the questionnaire. There needs to be further work to explore this in order to understand how much data can actually be collected reasonably.

Our review of the literature identified a large amount of applications that exist for mobile devices in pain management. There are no existing frameworks to evaluate or rate the quality and validity of advice provided through such applications, and I believe that there is an opportunity to conduct research in developing such a framework. The crux of this is that it may result in an increase of participants in case studies such as ours, due to the 'trust' factor.

Finally, there is potential in developing native mobile applications for both iOS and Android platforms, which will accompany the existing mobile web application. This will increase the penetration rate and allow us to study differences between reasons to use one over the other, and increase the means of access to the platform.

Appendix A

CS1 Questionnaires

This appendix contains the questionnaires used in the clinical trial for case study one.

A.1 Baseline questionnaire

RANDOMISED TRIAL OF TREATMENT FOR TENNIS ELBOW

BASELINE (INTERVIEW 1)

Demographics

Participant ID: | | | | | Date of Interview: .....

Email: .....

Gender: M F Age: .....

Height: ..... cm Weight: ..... kg

Highest level of education completed: Primary Secondary Tertiary

Marital status: Married/De facto Divorced/Separated/widowed Never married

Employment (fulltime/part-time etc.) and role: .....

Compensation (eg WorkCover): Yes No
History of diabetes: Yes No
History of elbow trauma: Yes No

Cause of tennis elbow as perceived by participant:.....
.....

Duration of symptoms:..... weeks/months/years
Dominant arm: Left Right Ambidextrous
Affected elbow: Left Right
Previous episode of same-sided elbow pain: Yes No
If yes: Number of episodes.....
Most recent previous episode (month/year of occurrence).....
Treatment for previous episodes (describe) .....

Previous treatment for current condition: None
Stretching exercises: Yes No
Acupuncture: Yes No
Chiropractic treatment: Yes No

RANDOMISED TRIAL OF TREATMENT FOR TENNIS ELBOW

Shock wave therapy:	Yes	No
NSAIDS:	Yes	No
Topical anti-inflammatories:	Yes	No
Ultrasound therapy:	Yes	No
Forearm brace:	Yes	No
Cross-frictional massage:	Yes	No
Local corticosteroid injections:	Yes	No

If yes: Date of most recent injection .....
How many? .....
Were they effective? .....
Duration of relief.....

Oral glucocorticoids:	Yes	No

If yes: Most recent date taken .....
Were they effective? .....
Duration of relief.....

Other treatments (please specify):.....
.....
.....

Sport and activities:

In the **past year**, indicate how many **hours per week** you did the following activities on a regular basis (regular means for at least three months):

Swimming	_____		
Water aerobics	_____		
Walking for exercise	_____		
Jogging	_____		
Cycling	_____		
Dancing	_____		
Strength/weight training	_____		
Aerobics	_____		
Gardening	_____		
Other (please specify)	_____	_____	hours per week
	_____	_____	hours per week

If you did not do any of the above activities please tick the box: ☐

RANDOMISED TRIAL OF TREATMENT FOR TENNIS ELBOW

Alcohol consumption:
Please tick as appropriate:

Never	☐
Sometimes	☐
Every day	☐

If 'Every day' please indicate the daily amount:

(2 or less glasses per day)	☐
(more than 2 glasses per day)	☐

Smoking:
Please tick as appropriate:

Never smoked	☐	
Ex-smoker	☐	Number per day = _____
Current smoker	☐	Number per day = _____

Current medications: *(if more room is needed, please turn page over and list on back)*

Name of medication:	Strength (mg)	Dosage (per day)
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

OFFICE USE ONLY

Stratification:

Radiologist and tear size:

☐	DC	< 6mm
☐	DC	≥ 6mm
☐	AL	< 6mm
☐	AL	≥ 6mm
☐	GL	< 6mm
☐	GL	≥ 6mm

A.2 Pain assessment questionnaire

RANDOMISED TRIAL OF TREATMENT FOR TENNIS ELBOW

Participant ID .....

Date .....

Visit (please circle) **BASELINE** **3 WEEKS** **6 WEEKS** **12 WEEKS** **24 WEEKS** **52 WEEKS**

OVERALL PAIN		PAIN AT NIGHT		ACTIVITY RELATED PAIN	
Indicate your WORST level of **overall elbow pain** over the past 24 hours by circling the appropriate number below		Indicate your WORST level of **elbow pain at night** over the past 24 hours by circling the appropriate number below		Indicate your WORST level of **activity related elbow pain** over the past 24 hours by circling the appropriate number below	
10	Worst imaginable pain	10	Worst imaginable pain	10	Worst imaginable pain
9		9		9	
8		8		8	
7		7		7	
6		6		6	
5		5		5	
4		4		4	
3		3		3	
2		2		2	
1		1		1	
0	No pain	0	No pain	0	No pain

Pain Assessment Numerical Scale, Version 1; Dated 04/12/2014
Page **1** of **1**

A.3 Cost and Consequences Questionnaire (Weekly)

RANDOMISED TRIAL OF TREATMENT FOR TENNIS ELBOW

PARTICIPANT ID: **DATE:**

COSTS AND CONSEQUENCES QUESTIONNAIRE

Please mark ☑ the circles and squares that apply – do not circle or cross out options.

Medications - check ☑ the circles and squares that apply

1a: Please indicate what **pain medications** (including over-the-counter medications and herbal supplements) you have taken **for any reason** in the past week. (*Mark ANY that apply*)

☑	Medication	Doctor's prescription?	How many tablets (or *ml*s for liquids) per day *OR* per week?
☐	I take no pain medications		
☐	Aspirin (e.g. Disprin)	O Yes, O No	☐ per day ☐ per week ___
☐	Paracetamol (e.g. Panadol)	O Yes, O No	☐ per day ☐ per week ___
☐	Codeine	O Yes, O No	☐ per day ☐ per week ___
☐	Paracetemol & Codeine mix (e.g. Panadeine, Prodeine)	O Yes, O No	☐ per day ☐ per week ___
☐	NSAID anti-inflammatories, e.g. Ibuprofen (Nurofen, Brufen), Diclofenac, Voltaren, Naproxen (Naprosyn), Indomethacin (Indocid)	O Yes, O No	☐ per day ☐ per week ___
☐	COX-2 inhibitor anti-inflammatories, e.g. Celecoxib (Celebrex), Meloxicam (Movalis)	O Yes, O No	☐ per day ☐ per week ___
☐	Supplements, e.g. fish oil, Glucosamine, Chondroitin Please specify: _____	O Yes, O No	☐ per day ☐ per week ___
☐	Any other pain medications or supplements? If so, please specify: _____	O Yes, O No	☐ per day ☐ per week ___

RANDOMISED TRIAL OF TREATMENT FOR TENNIS ELBOW

1b: Please indicate what medications (including over-the-counter medications and herbal supplements) you have taken in the past week to help with your **mood or sleep**. (*Mark ANY that apply*)

	Medication	Doctor's prescription?	How many tablets (or *ml*s for liquids) per day *OR* per week?
☐	I take no medications for help with mood or sleep		
☐	Fluoxetine (e.g. Prozac)	O Yes, O No	☐ per day __ __ ☐ per week
☐	Paroxetine (e.g. Aropax)	O Yes, O No	☐ per day __ __ ☐ per week
☐	Citalopram (e.g. Cipramil)	O Yes, O No	☐ per day __ __ ☐ per week
☐	Amitriptyline (e.g. Endep)	O Yes, O No	☐ per day __ __ ☐ per week
☐	Other? If so, please specify: _____ _____	O Yes, O No	☐ per day __ __ ☐ per week

1c: Please list **any other medications** (including over-the-counter medications and herbal supplements) you have taken in the past week **for any reason**. (*Mark ANY that apply*)

	Medication	Doctor's prescription?	How many tablets (or *ml*s for liquids) per day *OR* per week?
☐	I take no other medications for any reason		
☐	I also take: _____	O Yes, O No	☐ per day __ __ ☐ per week
☐	and: _____	O Yes, O No	☐ per day __ __ ☐ per week
☐	and: _____	O Yes, O No	☐ per day __ __ ☐ per week

RANDOMISED TRIAL OF TREATMENT FOR TENNIS ELBOW

Hospital Services

2. Have you visited an **accident & emergency department (A&E, or ED)** of a hospital for any reason in the past WEEK? (*Mark ONE*)

- ○ No
- ○ Yes
  - ↳ If so, please specify how many times? __ __

3. Have you been an **in-patient** (admitted to hospital overnight) in a hospital for any reason in the past WEEK? (*Mark ONE*)

- ○ No
- ○ Yes
  - ↳ If so, please specify how many times? __ __
  - ↳ Please estimate the total number of days stayed: __ __

4. Have you been a **day patient** (admitted to hospital for one day only, NO nights) in a hospital for any reason in the past WEEK? (*Mark ONE*)

- ○ No
- ○ Yes
  - ↳ If so, please specify how many times? __ __

5. Have you attended an **outpatient clinic** (for an appointment at a hospital but not admitted) in a hospital for any reason in the past WEEK? (*Mark ONE*)

- ○ No
- ○ Yes
  - ↳ If so, please specify how many times? __ __

Investigations

6. Have you had any of the following done for any reason in the past WEEK? (*Mark any that apply, excluding any done for this study)*

- ☐ Blood tests? please specify how many? __ __
- ☐ Urine tests? please specify how many? __ __
- ☐ X-rays / radiographs? please specify how many? __ __
- ☐ CT scans? please specify how many? __ __
- ☐ MRI scans? please specify how many? __ __
- ☐ Other procedures? If so, please specify:

  __

  ↳ please specify how many? __ __

RANDOMISED TRIAL OF TREATMENT FOR TENNIS ELBOW

Visits to Doctors in a community practice (not in a hospital or an outpatient clinic – report those in item 5):

In the past **WEEK (***other than* visit that were done as part of this study):

7. How many visits have you made to an **orthopaedic surgeon**? _ _

8. How many visits have you made to a **rheumatologist**? _ _

9. How many visits have you made to a **musculoskeletal doctor**? _ _

10. How many visits have you made to a **sports physician**? _ _

Medical or Surgical Procedures (in either a hospital, clinic, or community practice)

11. What procedures have you had **because of your tennis elbow problem** in the past WEEK (*other than* those that were for this study)? (*Mark ANY that apply)*

- ☐ A right elbow steroid injection
- ☐ A left elbow steroid injection
- ☐ Other injections? If so, please specify:

  _

- ☐ Other procedures? (Surgery, Massage, Physiotherapy, Chiropractic manipulation, Acupuncture)

  ? If so, please specify:

  _

RANDOMISED TRIAL OF TREATMENT FOR TENNIS ELBOW

Other Health Services

12. Please indicate if you have visited any of the following services in the past WEEK (other than those that were for this study) and if so, how many times and the cost per visit. (*Mark ANY that apply*) **DO NOT include any visits that were part of this study**.

	Mark any that apply:	Number of visits?	Cost to **you** per visit (if any) in dollars	How did you travel there? (car, taxi, public transport, other – please specify)	Distance (km)
GP	☐	_ _	$_ _		
Hospital	☐	_ _	$_ _		
Nurse (Specialist or practice)	☐	_ _	$_ _		
Physiotherapist	☐	_ _	$_ _		
Occupational therapist	☐	_ _	$_ _		
Osteopath	☐	_ _	$_ _		
Chiropractor	☐	_ _	$_ _		
Massage therapist	☐	_ _	$_ _		
Podiatrist	☐	_ _	$_ _		
Psychologist	☐	_ _	$_ _		
Rest home care / respite care	☐	_ _	$_ _		
Other, complementary, or alternative health care workers (e.g. Acupuncturist, Aromatherapist, Naturopath, Homeopath, Feldenkrais teacher, Alexander technique teacher, Herbalist, Traditional Chinese medicine practitioner, Spiritual leader)	☐	_ _	$_ _		

Community Services that come to your home

13. Please indicate if any of the following services have come to visit you in your home in the past WEEK and if so, how many times. (*Mark ANY that apply*)

	Mark any that apply:	Number of visits?	Cost to you per visit (if any) in dollars
Community or District Nurse	☐	_ _	$_ _ _
Other health visitor	☐	_ _	$_ _ _
Home help / Carer	☐	_ _	$_ _ _
House cleaner	☐	_ _	$_ _ _
Meals on wheels	☐	_ _	$_ _ _
Social worker	☐	_ _	$_ _ _
Day care / Rehabilitation	☐	_ _	$_ _ _
Helper from a voluntary organisation	☐	_ _	$_ _ _
Other	☐	_ _	$_ _ _

Aids and Adaptations

14. Have you purchased or been provided with aids.) to help with your tennis elbow problem in the past WEEK? (*Mark ANY that apply*). If yes, please state how much (if any) you had to pay personally for each category of item, in the past six months.

☐ No, none purchase or prescribed

☐ Tennis Elbow brace (orthosis): cost to you: $ _ _ _

☐ Other. If so, please specify: cost to you: $ _ _ _

_ _

_ _

RANDOMISED TRIAL OF TREATMENT FOR TENNIS ELBOW

15. Have you made adaptations to your home or lifestyle (more frequent taxi usage, stopping paid work, etc.) because of your health in the past WEEK?

- ○ No
- ○ Yes
  - ↳ If so, please indicate what adaptation(s) you have made and the estimated cost to you:

    _

    _

    _

Impact on Work

16. What is your source of income? (*Mark ANY that apply*)

- ☐ Wages / salary for paid work
- ☐ Self-employed
- ☐ Government superannuation / pension
- ☐ Income insurance / workers compensation insurance
- ☐ Living off savings or investments only (or primarily)
- ☐ Other – Please specify: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

17. Approximately how many hours of paid work did you do last week?

_ _ hours

18. How has your work been affected by your tennis elbow problem in the past WEEK? (*Mark if applicable*)

- ☐ I restricted or changed the type of work I did, because of my elbow
  - ↳ In what way? Please specify _ _ _ _ _ _ _ _ _ _ _ _ _
  - ↳ _

Personal and friends or family costs associated with your health

19. If there are other costs or consequences of your tennis elbow problem not already covered in the questions above, ***or*** if you have any comments you would like to share with us regarding any aspect of this study, please provide them below.

_ _

_ _

_ _

Thank you for filling in this questionnaire and participating in our study.

Please return your completed questionnaire promptly.

A.4 Cost and Consequences Questionnaire (4-Weekly)

RANDOMISED TRIAL OF TREATMENT FOR TENNIS ELBOW

PARTICIPANT ID: **DATE:**

COSTS AND CONSEQUENCES QUESTIONNAIRE

Please mark ☑ the circles and squares that apply – do not circle or cross out options.

Medications - check ☑ the circles and squares that apply

1a: Please indicate what **pain medications** (including over-the-counter medications and herbal supplements) you have taken **for any reason** in the past week. (*Mark ANY that apply*)

☑	Medication	Doctor's prescription?	How many tablets (or *ml*s for liquids) per day *OR* per week?
☐	I take no pain medications		
☐	Aspirin (e.g. Disprin)	O Yes, O No	☐ per day ☐ per week __ __
☐	Paracetamol (e.g. Panadol)	O Yes, O No	☐ per day ☐ per week __ __
☐	Codeine	O Yes, O No	☐ per day ☐ per week __ __
☐	Paracetemol & Codeine mix (e.g. Panadeine, Prodeine)	O Yes, O No	☐ per day ☐ per week __ __
☐	NSAID anti-inflammatories, e.g. Ibuprofen (Nurofen, Brufen), Diclofenac, Voltaren, Naproxen (Naprosyn), Indomethacin (Indocid)	O Yes, O No	☐ per day ☐ per week __ __
☐	COX-2 inhibitor anti-inflammatories, e.g. Celecoxib (Celebrex), Meloxicam (Movalis)	O Yes, O No	☐ per day ☐ per week __ __
☐	Supplements, e.g. fish oil, Glucosamine, Chondroitin Please specify: _____	O Yes, O No	☐ per day ☐ per week __ __
☐	Any other pain medications or supplements? If so, please specify: _____	O Yes, O No	☐ per day ☐ per week __ __

RANDOMISED TRIAL OF TREATMENT FOR TENNIS ELBOW

1b: Please indicate what medications (including over-the-counter medications and herbal supplements) you have taken in the past week to help with your **mood or sleep**. (*Mark ANY that apply*)

	Medication	Doctor's prescription?	How many tablets (or *ml*s for liquids) per day *OR* per week?
☐	I take no medications for help with mood or sleep		
☐	Fluoxetine (e.g. Prozac)	O Yes, O No	☐ per day ☐ per week __ __
☐	Paroxetine (e.g. Aropax)	O Yes, O No	☐ per day ☐ per week __ __
☐	Citalopram (e.g. Cipramil)	O Yes, O No	☐ per day ☐ per week __ __
☐	Amitriptyline (e.g. Endep)	O Yes, O No	☐ per day ☐ per week __ __
☐	Other? If so, please specify: _____ _____	O Yes, O No	☐ per day ☐ per week __ __

1c: Please list **any other medications** (including over-the-counter medications and herbal supplements) you have taken in the past week **for any reason**. (*Mark ANY that apply*)

	Medication	Doctor's prescription?	How many tablets (or *ml*s for liquids) per day *OR* per week?
☐	I take no other medications for any reason		
☐	I also take: _____	O Yes, O No	☐ per day ☐ per week __ __
☐	and: _____	O Yes, O No	☐ per day ☐ per week __ __
☐	and: _____	O Yes, O No	☐ per day ☐ per week __ __

2a. Has your use of **pain medications** changed in the past FOUR WEEKS? (*Mark ONE*)

- O Using much more
- O Using somewhat more
- O Using about the same
- O Using somewhat less
- O Using much less
- O Not applicable (I haven't used any for four weeks)

2b. Has your use of **dietary supplements** or **alternative medicines** changed in the past FOUR WEEKS? (*Mark ONE*)

- O Using much more
- O Using somewhat more
- O Using about the same
- O Using somewhat less
- O Using much less
- O Not applicable (I haven't used any for four weeks)

2c. Has your use of medications **for your mood or sleep** changed in the past FOUR WEEKS? (*Mark ONE*)

- O Using much more
- O Using somewhat more
- O Using about the same
- O Using somewhat less
- O Using much less
- O Not applicable (I haven't used any for four weeks)

Hospital Services

3. Have you visited an **accident & emergency department (A&E, or ED)** of a hospital for any reason in the past FOUR WEEKS? (*Mark ONE*)

- O No
- O Yes

  ↳ If so, please specify how many times? _ _

RANDOMISED TRIAL OF TREATMENT FOR TENNIS ELBOW

4. Have you been an **in-patient** (admitted to hospital overnight) in a hospital for any reason in the past FOUR WEEKS? (*Mark ONE*)

- ○ No
- ○ Yes
  - ↳ If so, please specify how many times? _ _
  - ↳ Please estimate the total number of days stayed: _ _

5. Have you been a **day patient** (admitted to hospital for one day only, NO nights) in a hospital for any reason in the past FOUR WEEKS? (*Mark ONE*)

- ○ No
- ○ Yes
  - ↳ If so, please specify how many times? _ _

6. Have you attended an **outpatient clinic** (for an appointment at a hospital but not admitted) in a hospital for any reason in the past FOUR WEEKS? (*Mark ONE*)

- ○ No
- ○ Yes
  - ↳ If so, please specify how many times? _ _

Investigations

7. Have you had any of the following done for any reason in the past FOUR WEEKS? (*Mark any that apply, excluding any done for this study)*

- ☐ Blood tests? please specify how many? _ _
- ☐ Urine tests? please specify how many? _ _
- ☐ X-rays / radiographs? please specify how many? _ _
- ☐ CT scans? please specify how many? _ _
- ☐ MRI scans? please specify how many? _ _
- ☐ Other procedures? If so, please specify:

  _

  - ↳ please specify how many? _ _

Visits to Doctors in a community practice (not in a hospital or an outpatient clinic – report those in item 6):

In the past **FOUR WEEKS (***other than* visit that were done as part of this study):

8. How many visits have you made to an **orthopaedic surgeon**? _ _

9. How many visits have you made to a **rheumatologist**? _ _

10. How many visits have you made to a **musculoskeletal doctor**? _ _

11. How many visits have you made to a **sports physician**? _ _

Medical or Surgical Procedures (in either a hospital, clinic, or community practice)

12. What procedures have you had **because of your tennis elbow problem** in the past FOUR WEEKS (*other than* those that were for this study)? (*Mark ANY that apply)*

- ☐ A right elbow steroid injection
- ☐ A left elbow steroid injection
- ☐ Other injections? If so, please specify:

  _

- ☐ Other procedures? (Surgery, Massage, Physiotherapy, Chiropractic manipulation, Acupuncture)

  ? If so, please specify:

  _

RANDOMISED TRIAL OF TREATMENT FOR TENNIS ELBOW

Other Health Services

13. Please indicate if you have visited any of the following services in in the past FOUR WEEKs(other than those that were for this study) and if so, how many times and the cost per visit. (*Mark ANY that apply*) **DO NOT include any visits that were part of this study**.

	Mark any that apply:	Number of visits?	Cost to **you** per visit (if any) in dollars	How did you travel there? (car, taxi, public transport, other – please specify)	Distance (km)
GP	☐	_ _	$_ _		
Hospital	☐	_ _	$_ _		
Nurse (Specialist or practice)	☐	_ _	$_ _		
Physiotherapist	☐	_ _	$_ _		
Occupational therapist	☐	_ _	$_ _		
Osteopath	☐	_ _	$_ _		
Chiropractor	☐	_ _	$_ _		
Massage therapist	☐	_ _	$_ _		
Podiatrist	☐	_ _	$_ _		
Psychologist	☐	_ _	$_ _		
Rest home care / respite care	☐	_ _	$_ _		
Other, complementary, or alternative health care workers (e.g. Acupuncturist, Aromatherapist, Naturopath, Homeopath, Feldenkrais teacher, Alexander technique teacher, Herbalist, Traditional Chinese medicine practitioner, Spiritual leader)	☐	_ _	$_ _		

Community Services that come to your home

14. Please indicate if any of the following services have come to visit you in your home in the past FOUR WEEKS and if so, how many times. (*Mark ANY that apply*)

	Mark any that apply:	Number of visits?	Cost to you per visit (if any) in dollars
Community or District Nurse	☐	_ _	$ _ _ _
Other health visitor	☐	_ _	$ _ _ _
Home help / Carer	☐	_ _	$ _ _ _
House cleaner	☐	_ _	$ _ _ _
Meals on wheels	☐	_ _	$ _ _ _
Social worker	☐	_ _	$ _ _ _
Day care / Rehabilitation	☐	_ _	$ _ _ _
Helper from a voluntary organisation	☐	_ _	$ _ _ _
Other	☐	_ _	$ _ _ _

Aids and Adaptations

15. Have you purchased or been provided with aids.) to help with your tennis elbow problem in the past FOUR WEEKS? (*Mark ANY that apply*). If yes, please state how much (if any) you had to pay personally for each category of item, in the past six months.

☐ No, none purchase or prescribed

☐ Tennis Elbow brace (orthosis) (off-the-shelf, not custom-made for you) cost to you: $ _ _ _

☐ Other. If so, please specify: cost to you: $ _ _ _

_ _

_ _

RANDOMISED TRIAL OF TREATMENT FOR TENNIS ELBOW

16. Have you made adaptations to your home or lifestyle (more frequent taxi usage, stopping paid work, etc.) because of your health in the past FOUR WEEKS?

- O No
- O Yes
  - ↳ If so, please indicate what adaptation(s) you have made and the estimated cost to you:

_ _

_ _

_ _

Impact on Work

17. What is your source of income? (*Mark ANY that apply*)

- ☐ Wages / salary for paid work
- ☐ Self-employed
- ☐ Government superannuation / pension
- ☐ Income insurance / workers compensation insurance
- ☐ Living off savings or investments only (or primarily)
- ☐ Other – Please specify: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

18. On average, how many hours of paid work did you perform *each week* over the past FOUR WEEKS?

_ _ hours

19. How has your work been affected by your tennis elbow problem in the past FOUR WEEKS? (*Mark ANY that apply*)

- ☐ I took time off work in the last month (*not including holidays or annual leave*) because of my elbow
  - ↳ How many days did you take off? _ _
- ☐ I worked fewer hours because of my elbow
  - ↳ How many hours less did you work? _ _ (☐ in total, or ☐ per week)
- ☐ I restricted or changed the type of work I did, because of my elbow
  - ↳ In what way? Please specify _ _ _ _ _ _ _ _ _ _ _ _ _
  - ↳ _

Personal and friends or family costs associated with your health

20. If there are other costs or consequences of your tennis elbow problem not already covered in the questions above, ***or*** if you have any comments you would like to share with us regarding any aspect of this study, please provide them below.

_ _
_ _
_ _
_ _
_ _

Thank you for filling in this questionnaire and participating in our study.

Please return your completed questionnaire promptly.

A.5 Assessment of Quality Of Life Questionnaire

RANDOMISED TRIAL OF TREATMENT FOR TENNIS ELBOW

The Assessment of Quality of Life (AQOL) Instrument

Participant ID: | | | | |

Date: _____/_____/_____

Visit (please circle): **BASELINE 3 WEEKS 6 WEEKS 12 WEEKS 24 WEEKS 52 WEEKS**

INSTRUCTIONS:

Please circle the **one** alternative that best describes you **during the last week**

INDEPENDENT LIVING:

1 Do I need any help looking after myself?
1. I need no help at all.
2. Occasionally I need some help with personal care tasks.
3. I need help with the more difficult personal care tasks.
4. I need daily help with most or all personal care tasks.

2 When doing household tasks: (For example, preparing food, gardening, using the video recorder, radio, telephone or washing the car)
1. I need no help at all.
2. Occasionally I need some help with household tasks.
3. I need help with the more difficult household tasks.
4. I need daily help with most or all household tasks.

3 Thinking about how easily I can get around my home and community:
1. I get around my home and community by myself without any difficulty.
2. I find it difficult to get around my home and community by myself.
3. I cannot get around the community by myself, but I can get around my home with some difficulty.
4. I cannot get around either the community or my home by myself.

SOCIAL RELATIONSHIPS

4 Because of my health, my relationships (for example: with my friends, partner or parents) generally:
1. Are very close and warm.
2. Are sometimes close and warm.
3. Are seldom close and warm.
4. I have no close and warm relationships.

5 Thinking about my relationships with other people:
1. I have plenty of friends, and am never lonely.
2. Although I have friends, I am occasionally lonely.
3. I have some friends, but am often lonely for company.
4. I am socially isolated and feel lonely.

6 Thinking about my health and my relationship with my family:
1. My role in the family is unaffected by my health.
2. There are some parts of my family role I cannot carry out.
3. There are many parts of my family role I cannot carry out.
4. I cannot carry out any part of my family role.

RANDOMISED TRIAL OF TREATMENT FOR TENNIS ELBOW

PHYSICAL SENSES

7 Thinking about my vision, including when using my glasses or contact lenses if needed:
1. I see normally
2. I have some difficulty focussing on things, or I do not see them sharply. *For example: small print, a newspaper, or seeing objects in the distance.*
3. I have a lot of difficulty seeing things. My vision is blurred. *For example: I can see just enough to get by with.*
4. I only see general shapes, or I am blind. *For example: I need a guide to move around.*

8 Thinking about my hearing, including my hearing aid if needed:
1. I hear normally.
2. I have some difficulty hearing or I do not hear clearly. *For example: I ask people to speak up, or turn up the TV or radio volume.*
3. I have difficulty hearing things clearly. *For example: Often I do not hear what is said. I usually do not take part in conversations because I cannot hear what is said.*
4. I hear very little indeed. *For example: I cannot fully understand loud voices speaking directly to me.*

9 When I communicate with others: (For example: by talking, listening, writing or signing)
1. I have no trouble speaking to them or understanding what they are saying
2. I have some difficulty being understood by people who do not know me. I have no trouble understanding what others are saying to me.
3. I am only understood by people who know me well. I have great trouble understanding what others are saying to me.
4. I cannot adequately communicate with others.

PSYCHOLOGICAL WELL-BEING

10 If I think about how I sleep:
1. I am able to sleep without difficulty most of the time.
2. My sleep is interrupted some of the time, but I am usually able to go back to sleep without difficulty.
3. My sleep is interrupted most nights, but I am usually able to go back to sleep without difficulty.
4. I sleep in short bursts only. I am awake most of the night.

11 Thinking about how I generally feel:
1. I do not feel anxious, worried or depressed.
2. I am slightly anxious, worried or depressed.
3. I feel moderately anxious, worried or depressed.
4. I am extremely anxious, worried or depressed.

12 How much pain or discomfort do I experience:
1. None at all.
2. I have moderate pain.
3. I suffer from severe pain.
4. I suffer unbearable pain.

A.6 Patient Rated Tennis Elbow Evaluation Questionnaire

RANDOMISED TRIAL OF TREATMENT FOR TENNIS ELBOW

Participant ID: ..... Date: .....

Visit: BASELINE 3 WEEKS 6 WEEKS 12 WEEKS 24 WEEKS 52 WEEKS

PATIENT-RATED TENNIS ELBOW EVALUATION

1 PAIN IN YOUR AFFECTED ARM											
*Rate the average amount of pain in your arm **over the past week** by circling the number that best describes your pain on a scale from 0 to 10. A **zero** (0) means that you **did not have any pain** and a **ten** (10) means that you had **the worst pain imaginable.***											
RATE YOUR PAIN: No pain											Worst imaginable
When you are at rest	0	1	2	3	4	5	6	7	8	9	10
When you are doing a task with repeated arm movement	0	1	2	3	4	5	6	7	8	9	10
When carrying a plastic bag of groceries	0	1	2	3	4	5	6	7	8	9	10
When your pain was at its least	0	1	2	3	4	5	6	7	8	9	10
When your pain was at its worst	0	1	2	3	4	5	6	7	8	9	10
A. SPECIFIC ACTIVITIES: *Rate the amount of difficulty you experienced performing each of the tasks listed below, over the past week, by circling the number that best describes your difficulty on a scale of 0 to 10. A **zero** (0) means that you **did not experience any difficulty** and a **ten** (10) means it was **so difficult you were unable to do it at all.***											
No difficulty											Unable to do
Turn a doorknob or key	0	1	2	3	4	5	6	7	8	9	10
Carry a grocery bag or briefcase by the handle	0	1	2	3	4	5	6	7	8	9	10
Lift a full coffee cup or glass of milk to your mouth	0	1	2	3	4	5	6	7	8	9	10
Open a jar	0	1	2	3	4	5	6	7	8	9	10
Pull up pants	0	1	2	3	4	5	6	7	8	9	10
Wring out a wash cloth or wet towel	0	1	2	3	4	5	6	7	8	9	10
B. USUAL ACTIVITIES: *Rate the amount of difficulty you experienced performing your **usual** activities in each of the areas listed below, over the past week, by circling the number that best describes your difficulty on a scale of 0 to 10. A **zero** (0) means that you **did not experience any difficulty** and a **ten** (10) means it was **so difficult you were unable to do that activity at all.***											
Personal activities (dressing, washing)	0	1	2	3	4	5	6	7	8	9	10
Household work (cleaning, maintenance)	0	1	2	3	4	5	6	7	8	9	10
Work (your job or everyday work)	0	1	2	3	4	5	6	7	8	9	10
Recreational or sporting activities	0	1	2	3	4	5	6	7	8	9	10

A.7 Perceived Recovery and Adverse Effects Questionnaire

PERCEIVED RECOVERY
Compared with the **how you felt before your injection**, how would you rate your elbow pain?
Please circle the number that best describes any change:

	A great deal worse	Moderately worse	A little worse	No change	A little better	Moderately better	A great deal better
My **pain** is now……	1	2	3	4	5	6	7

ADVERSE EFFECTS

Have you experienced any health issues (e.g. colds, migraines, stomach upsets, injuries etc.) since you last completed this survey?

- O Yes
- O No

If yes, please list below

_____

_____

_____

_____

Comments:

_____

_____

_____

_____

Perceived Recovery and AE questionnaire; version 1 dated 01/04/2014
Page **1** of **1**

A.8 Exit Questionnaire - online vs paper data collection

RANDOMISED TRIAL OF TREATMENT FOR TENNIS ELBOW

Participant ID .....

Date .....

Visit: 52 WEEKS

Online vs. Paper Data Collection

1. The questionnaires for this clinical trial were available in paper format or online. Which one did you use?

- ☐ Online questionnaires
- ☐ Paper questionnaires
- ☐ Mix of online and paper questionnaires

2. If you used the paper based questionnaires, why did you choose that (please tick one)

- ☐ no computer
- ☐ not familiar enough to fill it out online
- ☐ do not like to read and complete surveys online
- ☐ other (please describe)

3. If you used the online survey why did you choose that method? (E.g. more convenient, faster, less hassle, easier etc.)

.....

4. Which version would you use in the future?

- ☐ Online questionnaires
- ☐ Paper questionnaires

A.9 Depression Anxiety Stress Scale Questionnaire

DASS21 *Participant ID:* *Date:*

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

The rating scale is as follows:

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

1	I found it hard to wind down	0	1	2	3
2	I was aware of dryness of my mouth	0	1	2	3
3	I couldn't seem to experience any positive feeling at all	0	1	2	3
4	I experienced breathing difficulty (eg, excessively rapid breathing, breathlessness in the absence of physical exertion)	0	1	2	3
5	I found it difficult to work up the initiative to do things	0	1	2	3
6	I tended to over-react to situations	0	1	2	3
7	I experienced trembling (eg, in the hands)	0	1	2	3
8	I felt that I was using a lot of nervous energy	0	1	2	3
9	I was worried about situations in which I might panic and make a fool of myself	0	1	2	3
10	I felt that I had nothing to look forward to	0	1	2	3
11	I found myself getting agitated	0	1	2	3
12	I found it difficult to relax	0	1	2	3
13	I felt down-hearted and blue	0	1	2	3
14	I was intolerant of anything that kept me from getting on with what I was doing	0	1	2	3
15	I felt I was close to panic	0	1	2	3
16	I was unable to become enthusiastic about anything	0	1	2	3
17	I felt I wasn't worth much as a person	0	1	2	3
18	I felt that I was rather touchy	0	1	2	3
19	I was aware of the action of my heart in the absence of physical exertion (eg, sense of heart rate increase, heart missing a beat)	0	1	2	3
20	I felt scared without any good reason	0	1	2	3
21	I felt that life was meaningless	0	1	2	3

A.10 Pain free grip, Income and Insurance Questionnaire

RANDOMISED TRIAL OF TREATMENT FOR TENNIS ELBOW

Participant ID .....

Date .....

Visit: (please circle) BASELINE 12 WEEKS 52 WEEKS

MAXIMUM PAIN-FREE GRIP FORCE

Indicate whether Left or Right arm is affected. Record the results of three (3) trials with the elbow extended. Allow 20 second intervals between tests.

AFFECTED ARM L R	**UNAFFECTED ARM**
Maximum pain-free grip force (kg)	**Maximum pain-free grip force (kg)**
Trial 1	Trial 1
Trial 2	Trial 2
Trial 3	Trial 3
Maximum grip force (kg)	
Trial 1	
Trial 2	
Trial 3	

RANDOMISED TRIAL OF TREATMENT FOR TENNIS ELBOW

WORK AND HEALTH INSURANCE

1. Approximately, what is the hourly pay rate for your work? (*Round to the nearest dollar*)

$ _ _ _ per hour

OR If you don't know the hourly rate, what is your salary per year? (*Mark ONE*)

- ☐ Less than $20,000
- ☐ Between $20,000 and $40, 000
- ☐ Between $40,000 and $60, 000
- ☐ Between $60,000 and $80, 000
- ☐ Between $80,000 and $100, 000
- ☐ Between $100,000 and $200, 000
- ☐ over $200,000

2. Do you have any of the following? (*Mark ANY that apply*)

(mark ☑ the squares that apply to you, whether or not you must also pay a co-payment)

- ☐ Private Health Insurance – Hospital cover only
- ☐ Private Health Insurance with Extras
- ☐ No Private healthcare cover at all
- ☐ Other – Please specify: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

A.11 Blinding Success Assessment

RANDOMISED TRIAL OF TREATMENT FOR TENNIS ELBOW

BLINDING SUCCESS ASSESSMENT

Participant ID: | | | | |

Date: _____/_____/_____

Visit (please circle): WEEK12 WEEK 52

Please indicate with an **X** which of the following statements most applies to you:

- ☐ I think I had the glucocorticoid injection
- ☐ I think I had the autologous platelet rich plasma injection
- ☐ I think I had the saline (placebo) injection
- ☐ I am not sure what treatment I received

A.12 Medical Screening Form

RANDOMISED TRIAL OF TREATMENT FOR TENNIS ELBOW

Medical Screening Form

Office Use Only:
Eligible Y N
Participant ID: ……

Date: _____/_____/_____

Potential Participant Name: _____

Participant Contact Phone Number: _____

Age.: _____ Sex: **F** **M**

Referring Dr Name: _____

Referring Dr Phone: _____ Referring Dr Fax: _____

PLEASE MARK ALL BOXES (Shaded boxes indicate eligibility)	**Yes**	**No**
Aged 18-65 years:	☐	☐
Able to read and write in English:	☐	☐
Lateral elbow pain ≥6 weeks:	☐	☐
Local glucocorticoid injection in the previous six months:	☐	☐
Oral glucocorticoids in the previous three months:	☐	☐
Bilateral symptoms of lateral elbow pain:	☐	☐
Other elbow pathology:	☐	☐
Other elbow pathology specified:	☐	☐
Generalised inflammatory arthritis:	☐	☐
Concurrent shoulder pain:	☐	☐
Concurrent neck pain:	☐	☐
Wound or skin lesion on the lateral side of the affected elbow:	☐	☐

PLEASE MARK ALL BOXES (Shaded boxes indicate eligibility)	**Yes**	**No**
Neurological symptoms or signs in the affected arm:	☐	☐
Severe infection:	☐	☐
Malignancy:	☐	☐
Bleeding disorder:	☐	☐
Previous surgery to the elbow:	☐	☐

PLEASE FAX FORM ON 9508 1653 OR CALL 9508 1652

A.13 Reproducability Screening Form

RANDOMISED TRIAL OF TREATMENT FOR TENNIS ELBOW

Reproducibility Screening Form

Date: _____/_____/_____

Participant ID: _____

Name:.....

Address: .....
.....

Phone numbers: Home: ..... Work: .....
Mobile: .....

Screened by: _____

Name of current General Practitioner: .....

Address: .....
.....

Phone number:.....

REPRODUCIBILITY OF PAIN:

Please Mark with an X all those that apply

	Yes	No
Palpation of the lateral epicondyle and/or common extensor origin of the elbow	☐	☐
Gripping Resisted Wrist	☐	☐
Second or Third finger extension (dorsiflexion)	☐	☐
Potentially Eligible	☐	☐

Ultrasound screening date: _____/_____/_____

Note: Pain must be reproducible by two or more of the above criteria for potential inclusion

ELIGIBILITY AND CONSENT

	Yes	No
Participant eligible:	☐	☐
Unlikely to complete trial:	☐	☐

Reason unlikely to complete trial: .....

Participant given information sheet: ☐ ☐

Consent received:

- ☐ Did not consent [0]
- ☐ Consented [1]
- ☐ No consent form received [2]

Consent date: _____/_____/_____

A.14 Sonographer worksheet

RANDOMISED TRIAL OF TREATMENT FOR TENNIS ELBOW

Participant ID number: ☐☐☐☐

Sonographer:

Please perform ultrasound using the settings listed below (please tick to confirm)

No information about participant clinical history is to be obtained

Elbow (left or right): ……..

Settings: ***Gen MSK*** ☐ ***No zoom*** ☐ ***17Mhz transducer*** ☐ ***No standoff pad*** ☐ ***Preset CDI*** ☐

Tendon thickness: ..... mm

Degree of hypoechogenicity:
- ☐ **1. None* (0%)**
- ☐ **2. Scant (1-24%)**
- ☐ **3. Moderate (25-49%)**
- ☐ **4. Marked (50-74%)**
- ☐ **5. Severe (75-100%)**

Tear/s: **Yes / No**

If present: ..... (l) x ..... (w)
- ☐ **Superficial**
- ☐ **Intrasubstance**
- ☐ **Deep**

Degree of vascularity:
- ☐ **1. None* (0%)**
- ☐ **2. Scant (1-24%)**
- ☐ **3. Moderate (25-49%)**
- ☐ **4. Marked (50-74%)**
- ☐ **5. Severe (75-100%)**

Bony changes: **Yes / No**

Lateral Collateral ligament intact: **Yes / No**

***IF BOTH DEGREE OF HYPOECHOGENICITY AND VASCULARITY SCORE 1, PARTICIPANT IS TO BE EXCLUDED AND NO INJECTION IS TO OCCUR**

Appendix B

CS1 - Comparative Analysis of Pain Trajectory

This appendix provides a brief overview and description of the remaining pain trajectories plotted for the comparison of pain trajectory data between different intervals in case study one.

Figure B.1 shows a direct overlap between overall pain and pain at night. The participant reports no activity-related pain in this instance. The weekly data shows a gradually increasing fluctuating trend in the first eight weeks, before stabilising at their original pain level towards weeks 8 through 12. There is a significant fluctuation between weeks 5 and 8. The sparse interval data tells a different story, with the data showing an overall fluctuating pain around the original pain level of 2.

Figure B.2 shows similar trajectories reported for all 3 variables. This participant is experiencing moderate to severe pain for the bulk of the study. The weekly data shows a significant recovery to close to no pain in the first week, with the pain rebounding to worse levels in the second week. The pain then remains mostly constant with some minor fluctuations between weeks 3 and 6. The data at the sparse intervals tells a completely different story, with pain gradually increasing between weeks 0 and 3, then minor recovery and rebounding pain between weeks 3 and 6, with pain holding steady from week 6 onwards. The sudden drop and increase in pain over week 1 and 2 is of interest as it would have impacted the overall recovery for this participant.

Figure B.3 has a similar trajectory between overall pain and pain at night. The participant reported much lower pain experienced during activities (3-4 point drop). The weekly data shows an overall improving trend, with a worsening period between weeks 8 and 11 before recovering in week 12. The sparse interval data shows an overall improving trend with no worsening spikes for the full duration plotted. The

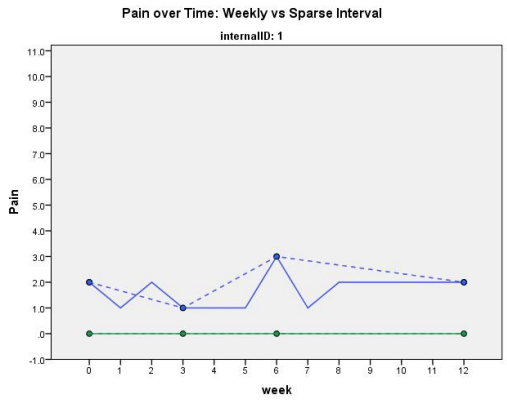


Figure B.1: Pain Trajectory

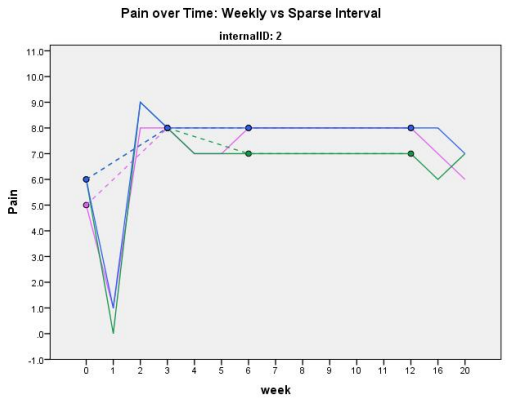


Figure B.2: Pain Trajectory

pain reported between weeks 8 and 12 are of interest as a quicker recovery could have been made if the treatment or pain management plan was adjusted based on the pain reported. This might have an impact on the time to recovery for the participant.

Figure B.4 shows an overall improving trend with some minor fluctuations during week 4. The weekly data shows a very unstable pain pattern as it has minor fluctuations throughout, with the exception of weeks 6 to 11 where there is slight stability of the pain experienced. The sparse data basically shows an overall improving trend, but fails to capture the peaks experienced at weeks 2, 4 and 9.

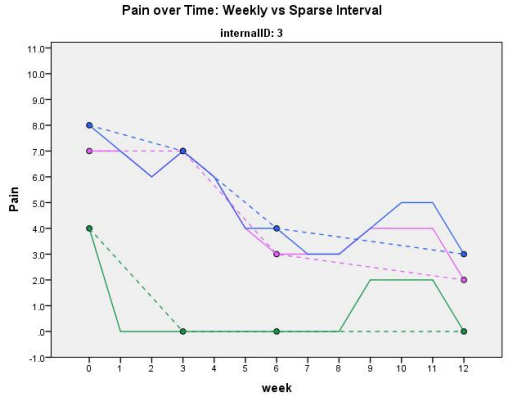


Figure B.3: Pain Trajectory

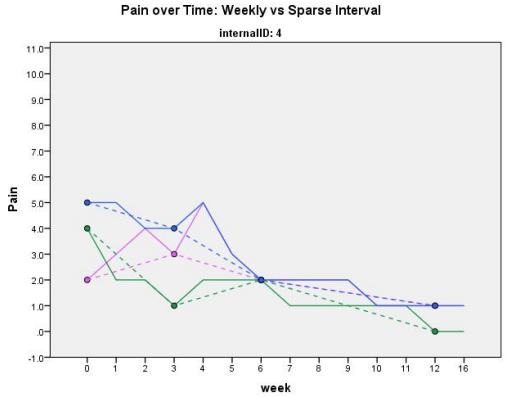


Figure B.4: Pain Trajectory

Figure B.5 has similar trajectories for all 3 variables. The weekly data shows an improving trend with some fluctuating pain over the weeks that do not really stabilise. The peaks observed at week 2 and 11 are of interest in this trajectory. The sparse interval data generally shows an improving trend after week 3, with some stability between weeks 3 and 6.

Figure B.6 shows worsening pain, followed by an improving trend over the course of weeks 3 to 12. The weekly data shows some lows between weeks 1 and 2, with

some peaks at week 5 and 7. The fluctuations caured here are not represented by the sparse interval graph, but the general outcome is captured.

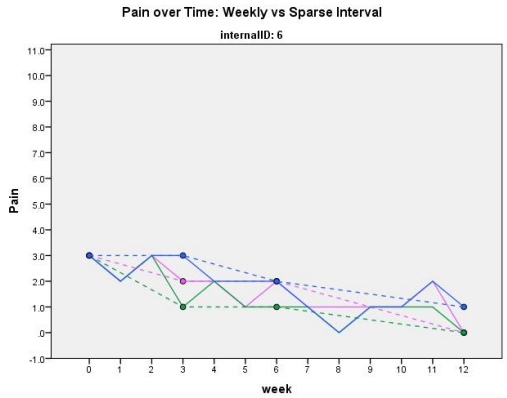


Figure B.5: Pain Trajectory

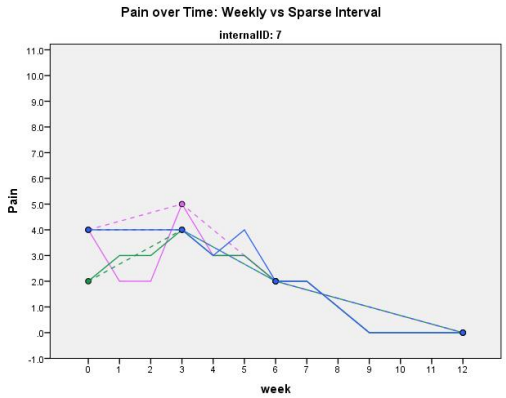


Figure B.6: Pain Trajectory

Figure B.7 shows an erratic pain trajectory that has major fluctuations through the weeks. The weekly data plotted shows three major fluctuations at weeks 1, 4 and 6, with some recovery at week 2 and 5. The sparse interval data simply shows an improving trend through the weeks, which is not representative of the weekly data.

Figure B.8 shows a mostly stable pain trajectory. The weekly data shows some recovery with rebounding pain that has recovery peaks at week 2, 4 and 7. The sparse data here simply shows a mostly stable pattern of pain. The overall pain plotted here overlaps with pain at night.

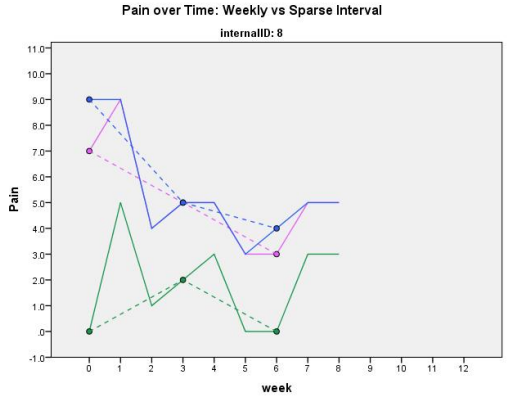


Figure B.7: Pain Trajectory

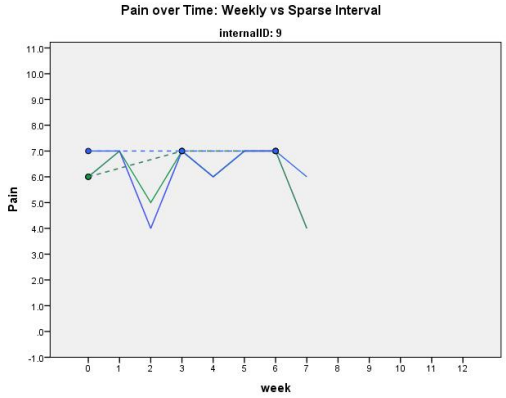


Figure B.8: Pain Trajectory

Figure B.9 shows an overall major recovery from severe pain before rebounding pain. The weekly data shows full recovery at week 2, before pain rebounds after week 4 to a minor level. The sparse data plot shows major recovery at week 3, followed by rebounding pain towards week 6 and beyond.

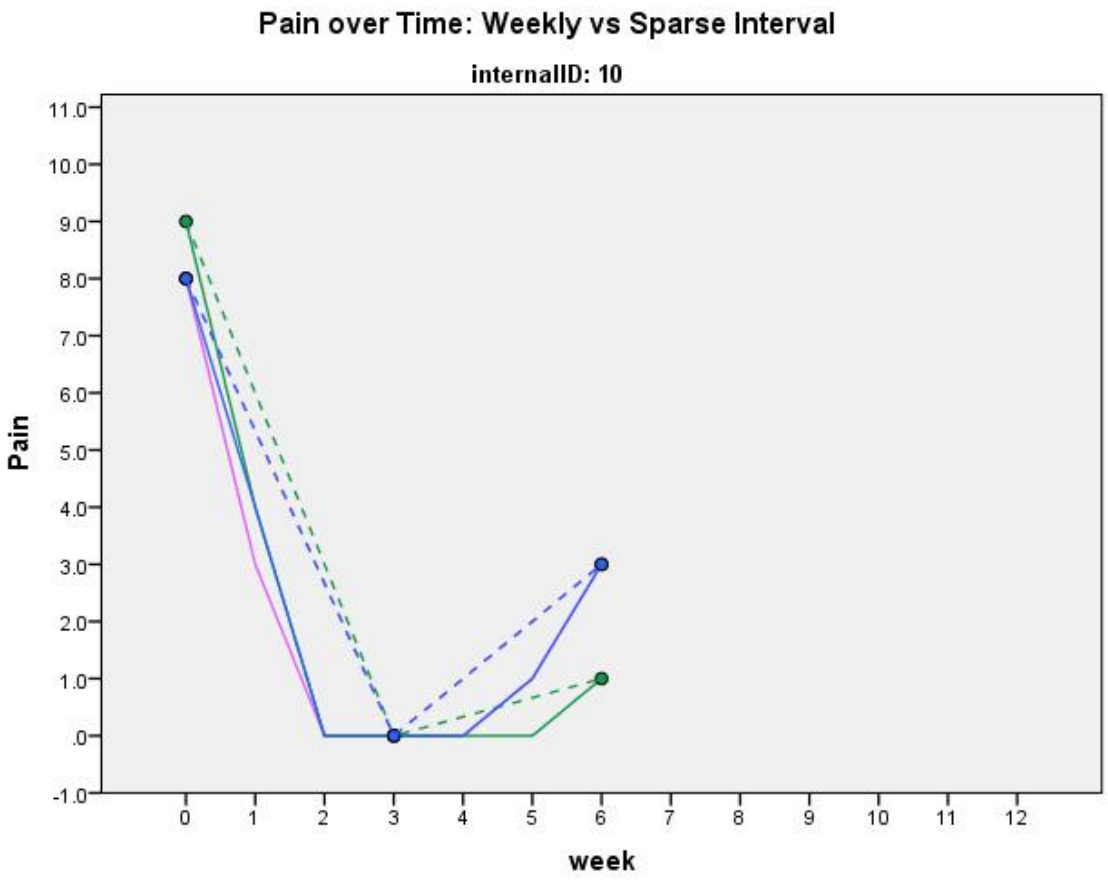


Figure B.9: Pain Trajectory

Appendix C

CS2 - Questionnaires

This appendix contains the contextual HFDC questionnaires developed for case study two. This appendix is organised into the following: Section C.1 contains the baseline questionnaire. Section C.2 contains the daily and ad-hoc pain questionnaire. Section C.3 contains the weekly questionnaire in two parts, and Section C.4 contains the exit questionnaire.

C.1 Baseline Questionnaire

Baseline Questionnaire

These are demographical and baseline questions.

1. Age
2. Gender
   a. Male
   b. Female
3. Height
   ____ cm
4. Weight
   ____ kg
5. Highest level of education completed
   a. Primary
   b. Secondary
   c. Tertiary
6. Martial Status
   a. Married / De facto
   b. Divorced / Seperated / Widowed
   c. Never married
7. Employment Status
   a. Full Time
   b. Part Time
   c. Casual / Sessional
   d. Not employed
   e. Other
8. Employment Role / Job
9. Suburb
10. PostCode
11. Any ongoing treatment or injuries?
12. Alcohol Consumption
    a. Never
    b. Sometimes
    c. Every day
13. Smoking
    a. Never smoked
    b. Ex-smoker
    c. Current smoker
14. What is your living situation?
    a. Living with family
    b. Living with friends
    c. Living alone
    d. Other
15. Would you prefer to receive reminders via email in the morning, afternoon or evening?
    a. Morning (6am)
    b. Afternoon (1pm)
    c. Evening (6pm)
16. How would you rate your low back pain at the present time on a scale of 0 – 10?
    [VAS Scale from 0 to 10]

C.2 Daily Pain Questionnaires

Daily Pain Questionnaire / Ad-hoc Pain Questionnaire

Notes: Participants are requested to respond to this questionnaire daily. They can opt to say 'no' to question 1, which concludes that day's survey. Reminders will be sent for the day itself, but if the participant misses one day they will not be able to do it on the following day.

1. Has your pain level changed at all since the last report?
   a. Yes
   b. No

   (If answer to Qn. 1 is Yes, continue with the rest of the questionnaire)
2. How would you rate your low back pain at the present time on a scale of 0 – 10?
   [VAS Scale from 0 to 10]
3. What were you doing at the time when you initially experienced this change in your pain level (e.g. Vacuuming, Jogging)?
4. How long ago did you initially feel this change in pain?
   About ____ hours
5. (If the change occurred at night (6PM – 6AM))
   Have you had problems sleeping recently (as compared to before this change happened)?
   a. Yes
   b. No
6. How would you describe this change in pain?
   a. Gradual change over time
   b. Sudden change
7. What is the level of exercise today?
   a. More than yesterday
   b. About the same
   c. Less than yesterday
   d. Did not exercise today
8. A snapshot of the current location data using the GPS will be taken to determine the current weather conditions.

C.3 Weekly Pain Questionnaires

MONASH University

Weekly Pain Questionnaire

The weekly questionnaire contains two parts. The first part is shown on this page, the second part contains the RMQ.

Notes: Participants are requested to respond to this questionnaire weekly. Participants are requested to continue with the daily pain report after this.

Part 1.

1. How would you rate your low back pain at the present time on a scale of 0 – 10?
   [VAS Scale from 0 to 10]
2. How would you rate your WORST level of low back pain in the PAST ONE WEEK on a scale of 0 – 10?
   [VAS Scale from 0 to 10]
3. How would you rate your AVERAGE level of low back pain in the PAST ONE WEEK on a scale of 0 – 10?
   [VAS Scale from 0 to 10]
4. Has the type of work you do changed in the last week?
   a. Yes
   b. No
5. (If answer to Qn. 9 is Yes)
   What has changed?
   - ☐ More physical work
   - ☐ Less physical work
   - ☐ More sitting hours
   - ☐ Less sitting hours
   - ☐ Increased hours of work
   - ☐ Decreased hours of work
6. Have you seen a doctor for your low back pain in the last week?
   a. Yes
   b. No
7. Have you had a change in any of the treatments for other injuries or conditions in the last week?
   a. Yes, started new treatment
   b. Yes, stopped or completed treatment
   c. No
8. (If answer to Qn. 7 is Yes)
   Please briefly describe the change in treatment, and include details of when this change happened.
9. Are you taking painkillers regularly for your pain?
   a. Yes
   b. No
10. (If answer to Qn. 9 is Yes)
    How many painkillers did you take in the last week?
    About ____ pills/tablets

Part 2.

Roland-Morris Low Back Pain and Disability Questionnaire

Instructions:
When your back hurts, you may find it difficult to do some of the things you normally do.
Mark only the sentences that describe you today.
You can mark the questions by tapping or clicking on the relevant checkbox.

- ☐ I stay at home most of the time because of my back.
- ☐ I change position frequently to try to get my back comfortable.
- ☐ I walk more slowly than usual because of my back.
- ☐ Because of my back, I am not doing any jobs that I usually do around the house.
- ☐ Because of my back, I use a handrail to get upstairs.
- ☐ Because of my back, I lie down to rest more often.
- ☐ Because of my back, I have to hold on to something to get out of an easy chair.
- ☐ Because of my back, I try to get other people to do things for me.
- ☐ I get dressed more slowly than usual because of my back.
- ☐ I only stand up for short periods of time because of my back.
- ☐ Because of my back, I try not to bend or kneel down.
- ☐ I find it difficult to get out of a chair because of my back.
- ☐ My back is painful almost all of the time.
- ☐ I find it difficult to turn over in bed because of my back.
- ☐ My appetite is not very good because of my back.
- ☐ I have trouble putting on my socks (or stockings) because of the pain in my back.
- ☐ I can only walk short distances because of my back pain.
- ☐ I sleep less well because of my back.
- ☐ Because of my back pain, I get dressed with the help of someone else.
- ☐ I sit down for most of the day because of my back.
- ☐ I avoid heavy jobs around the house because of my back.
- ☐ Because of back pain, I am more irritable and bad tempered with people than usual.
- ☐ Because of my back, I go upstairs more slowly than usual.
- ☐ I stay in bed most of the time because of my back.

C.4 Exit Questionnaires

Exit Questionnaire

Type 1: For participants opting out mid study (dropping out)

1. Why are you opting out of this study?
   i. Not Interested
   ii. Time Constraints
   iii. Technical Difficulties
   iv. Other _____

Type 2: For participants that have completed the study

1. What did you like about the study?
   _____

   1.1. Did you find the graph on the user dashboard page showing you the last seven days of pain reported useful?
   Yes / No

   1.2. Why?
   _____
2. What *didn't* you like about the study?
   _____
3. Is there anything that we can do to improve the study?
   _____
4. Did you miss any daily reports?
   Yes / No
   4.1. (If Yes) Why?
   a) There was no change in pain
   b) I forgot
   c) There were technical issues (i.e. no Internet)
   d) Other _____
5. Please rate your experience from 0-10.
   [Scale from 0-10]

Appendix D

CS2 - Statistical Modelling

This appendix contains the remaining results of the statistical modelling for case study two.

D.1 Statistical Models Results - Individual

This section contains the result of the statistical modelling at the individual level for case study two.

GLM result for user 17

Table D.1: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	145.2981	98.5121	1.47	0.1640
temp	0.1009	0.0938	1.08	0.3013
pressure	-0.1446	0.0971	-1.49	0.1602
windspeed	0.4935	0.2276	2.17	0.0492

Table D.2: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	1.16	1	0.2817
pressure	2.22	1	0.1364
windspeed	4.70	1	0.0301

GLM result for user 19

Table D.3: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	127.0747	136.4995	0.93	0.3738
temp	0.0904	0.0864	1.05	0.3198
pressure	-0.1152	0.1323	-0.87	0.4041
windspeed	-1.0880	0.3028	-3.59	0.0049

Table D.4: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	1.10	1	0.2952
pressure	0.76	1	0.3837
windspeed	12.91	1	0.0003

GLM result for user 20

Table D.5: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	16.2838	13.7220	1.19	0.2527
temp	0.0029	0.0499	0.06	0.9537
pressure	-0.0096	0.0130	-0.74	0.4713
windspeed	-0.0868	0.1277	-0.68	0.5062

Table D.6: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	0.00	1	0.9529
pressure	0.54	1	0.4607
windspeed	0.46	1	0.4964

GLM result for user 24

Table D.7: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	-53.2623	30.1978	-1.76	0.1012
temp	-0.0282	0.0307	-0.92	0.3751
pressure	0.0606	0.0294	2.06	0.0604
windspeed	0.0579	0.0881	0.66	0.5229

Table D.8: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	0.84	1	0.3584
pressure	4.23	1	0.0397
windspeed	0.43	1	0.5114

GLM result for user 25

Table D.9: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	117.1368	63.8683	1.83	0.0816
temp	-0.0725	0.0662	-1.10	0.2859
pressure	-0.1129	0.0623	-1.81	0.0850
windspeed	0.4782	0.1607	2.98	0.0075

Table D.10: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	1.20	1	0.2729
pressure	3.28	1	0.0700
windspeed	8.85	1	0.0029

GLM result for user 26

Table D.11: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	-7.8389	60.9140	-0.13	0.9012
temp	-0.0009	0.0566	-0.02	0.9883
pressure	0.0102	0.0593	0.17	0.8684
windspeed	0.0878	0.1377	0.64	0.5439

Table D.12: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	0.00	1	0.9879
pressure	0.03	1	0.8635
windspeed	0.41	1	0.5236

GLM result for user 28

Table D.13: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	17488.1369	43803.0703	0.40	0.7582
temp	-16.7081	42.5625	-0.39	0.7619
pressure	-16.7212	41.8707	-0.40	0.7581
windspeed	-19.9124	52.4278	-0.38	0.7689

Table D.14: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	0.15	1	0.6946
pressure	0.16	1	0.6896
windspeed	0.14	1	0.7041

GLM result for user 33

Table D.15: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	-10.7948	81.8261	-0.13	0.8961
temp	0.0058	0.1396	0.04	0.9669
pressure	0.0146	0.0792	0.18	0.8550
windspeed	-0.1057	0.2955	-0.36	0.7238

Table D.16: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	0.00	1	0.9666
pressure	0.03	1	0.8534
windspeed	0.13	1	0.7206

GLM result for user 34

Table D.17: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	-125.2227	40.6431	-3.08	0.0912
temp	0.1434	0.0603	2.38	0.1406
pressure	0.1228	0.0392	3.13	0.0886
windspeed	0.0508	0.0576	0.88	0.4709

Table D.18: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	5.65	1	0.0174
pressure	9.81	1	0.0017
windspeed	0.78	1	0.3778

GLM result for user 35

Table D.19: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	-17.6999	66.7458	-0.27	0.7945
temp	-0.1028	0.1454	-0.71	0.4903
pressure	0.0212	0.0634	0.33	0.7424
windspeed	0.5005	0.2369	2.11	0.0518

Table D.20: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	0.50	1	0.4794
pressure	0.11	1	0.7378
windspeed	4.46	1	0.0346

GLM result for user 36

Table D.21: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	2.2102	136.6008	0.02	0.9873
temp	-0.0020	0.1548	-0.01	0.9901
pressure	0.0010	0.1325	0.01	0.9940
windspeed	0.1501	0.3450	0.44	0.6706

Table D.22: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	0.00	1	0.9899
pressure	0.00	1	0.9939
windspeed	0.19	1	0.6635

GLM result for user 37

Table D.23: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	238.5643	185.6310	1.29	0.4210
temp	-0.1190	0.2162	-0.55	0.6796
pressure	-0.2273	0.1800	-1.26	0.4264
windspeed	-0.4003	0.5154	-0.78	0.5796

Table D.24: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	0.30	1	0.5819
pressure	1.59	1	0.2067
windspeed	0.60	1	0.4373

GLM result for user 39

Table D.25: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	-48.5685	53.4931	-0.91	0.3989
temp	-0.1117	0.0887	-1.26	0.2548
pressure	0.0591	0.0507	1.17	0.2882
windspeed	-0.6661	0.2115	-3.15	0.0198

Table D.26: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	1.59	1	0.2080
pressure	1.36	1	0.2440
windspeed	9.92	1	0.0016

GLM result for user 41

Table D.27: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	-1.1462	39.6814	-0.03	0.9771
temp	-0.1085	0.0625	-1.73	0.0913
pressure	0.0054	0.0387	0.14	0.8903
windspeed	0.0256	0.1271	0.20	0.8415

Table D.28: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	3.01	1	0.0828
pressure	0.02	1	0.8895
windspeed	0.04	1	0.8404

GLM result for user 43

Table D.29: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	-21.3124	17.6606	-1.21	0.2398
temp	0.0683	0.0718	0.95	0.3509
pressure	0.0252	0.0163	1.55	0.1349
windspeed	0.1814	0.1487	1.22	0.2346

Table D.30: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	0.91	1	0.3410
pressure	2.40	1	0.1213
windspeed	1.49	1	0.2223

GLM result for user 44

Table D.31: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	87.8597	52.0203	1.69	0.1151
temp	-0.1187	0.0548	-2.17	0.0493
pressure	-0.0798	0.0504	-1.58	0.1376
windspeed	-0.0844	0.1199	-0.70	0.4938

Table D.32: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	4.70	1	0.0302
pressure	2.50	1	0.1136
windspeed	0.50	1	0.4814

GLM result for user 47

Table D.33: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	3.5129	89.3461	0.04	0.9705
temp	0.0630	0.2302	0.27	0.7978
pressure	-0.0042	0.0856	-0.05	0.9636
windspeed	0.0268	0.2560	0.10	0.9216

Table D.34: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	0.07	1	0.7842
pressure	0.00	1	0.9612
windspeed	0.01	1	0.9165

GLM result for user 49

Table D.35: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	9.6695	109.3048	0.09	0.9306
temp	0.0769	0.0959	0.80	0.4346
pressure	-0.0072	0.1064	-0.07	0.9468
windspeed	0.0312	0.2931	0.11	0.9167

Table D.36: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	0.64	1	0.4229
pressure	0.00	1	0.9460
windspeed	0.01	1	0.9153

GLM result for user 50

Table D.37: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	-140.4219	128.1371	-1.10	0.2876
temp	-0.1519	0.1498	-1.01	0.3242
pressure	0.1458	0.1250	1.17	0.2588
windspeed	-0.2791	0.3294	-0.85	0.4080

Table D.38: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	1.03	1	0.3107
pressure	1.36	1	0.2436
windspeed	0.72	1	0.3969

GLM result for user 52

Table D.39: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	154.7455	184.7499	0.84	0.4904
temp	0.1643	0.3441	0.48	0.6801
pressure	-0.1482	0.1813	-0.82	0.4996
windspeed	-0.6761	1.1797	-0.57	0.6244

Table D.40: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	0.23	1	0.6330
pressure	0.67	1	0.4137
windspeed	0.33	1	0.5665

GLM result for user 55

Table D.41: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	23.4705	88.8189	0.26	0.8004
temp	-0.0363	0.1033	-0.35	0.7369
pressure	-0.0154	0.0856	-0.18	0.8630
windspeed	-0.0778	0.1281	-0.61	0.5661

Table D.42: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	0.12	1	0.7249
pressure	0.03	1	0.8571
windspeed	0.37	1	0.5438

GLM result for user 56

Table D.43: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	-27.9613	46.9962	-0.59	0.5614
temp	0.1166	0.0672	1.73	0.1048
pressure	0.0318	0.0462	0.69	0.5021
windspeed	-0.2281	0.1153	-1.98	0.0680

Table D.44: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	3.01	1	0.0829
pressure	0.47	1	0.4908
windspeed	3.91	1	0.0480

GLM result for user 57

Table D.45: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	72.6796	54.4677	1.33	0.2034
temp	0.0278	0.0876	0.32	0.7553
pressure	-0.0694	0.0535	-1.30	0.2151
windspeed	-0.2565	0.1307	-1.96	0.0700

Table D.46: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	0.10	1	0.7506
pressure	1.69	1	0.1941
windspeed	3.85	1	0.0498

GLM result for user 58

Table D.47: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	-37.3034	38.0366	-0.98	0.3339
temp	0.0286	0.0533	0.54	0.5954
pressure	0.0384	0.0369	1.04	0.3058
windspeed	-0.1053	0.0839	-1.26	0.2183

Table D.48: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	0.29	1	0.5918
pressure	1.08	1	0.2982
windspeed	1.58	1	0.2095

GLM result for user 59

Table D.49: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	-14.9146	43.0585	-0.35	0.7325
temp	-0.0915	0.0505	-1.81	0.0844
pressure	0.0192	0.0418	0.46	0.6498
windspeed	0.0750	0.0976	0.77	0.4510

Table D.50: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	3.28	1	0.0701
pressure	0.21	1	0.6451
windspeed	0.59	1	0.4425

GLM result for user 60

Table D.51: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	88.5710	60.0965	1.47	0.1541
temp	0.2057	0.1067	1.93	0.0662
pressure	-0.0853	0.0586	-1.46	0.1591
windspeed	-0.0775	0.1977	-0.39	0.6985

Table D.52: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	3.72	1	0.0538
pressure	2.12	1	0.1456
windspeed	0.15	1	0.6949

GLM result for user 62

Table D.53: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	7.0000			

Table D.54: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp		0	
pressure		0	
windspeed		0	

GLM result for user 64

Table D.55: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	6.4742	23.5003	0.28	0.7867
temp	0.0557	0.0440	1.26	0.2256
pressure	-0.0061	0.0229	-0.27	0.7939
windspeed	0.0991	0.1212	0.82	0.4264

Table D.56: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	1.60	1	0.2063
pressure	0.07	1	0.7903
windspeed	0.67	1	0.4136

GLM result for user 65

Table D.57: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	157.4000	91.9177	1.71	0.1148
temp	-0.1110	0.1036	-1.07	0.3068
pressure	-0.1484	0.0890	-1.67	0.1236
windspeed	-0.2094	0.1809	-1.16	0.2716

Table D.58: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	1.15	1	0.2839
pressure	2.78	1	0.0954
windspeed	1.34	1	0.2470

GLM result for user 70

Table D.59: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	-50.0341	34.3923	-1.45	0.2194
temp	-0.0999	0.0737	-1.36	0.2468
pressure	0.0523	0.0334	1.57	0.1925
windspeed	0.0398	0.0602	0.66	0.5448

Table D.60: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	1.84	1	0.1754
pressure	2.45	1	0.1174
windspeed	0.44	1	0.5087

GLM result for user 71

Table D.61: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	-1.0433	11.7196	-0.09	0.9313
temp	0.0482	0.0653	0.74	0.4811
pressure	0.0007	0.0112	0.06	0.9502
windspeed	-0.0286	0.1352	-0.21	0.8380

Table D.62: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	0.55	1	0.4600
pressure	0.00	1	0.9487
windspeed	0.04	1	0.8328

GLM result for user 73

Table D.63: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	-10.7953	28.5833	-0.38	0.7155
temp	-1.2425	0.1576	-7.89	0.0000
pressure	0.0299	0.0276	1.08	0.3110
windspeed	0.8935	0.1746	5.12	0.0009

Table D.64: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	62.18	1	0.0000
pressure	1.17	1	0.2794
windspeed	26.17	1	0.0000

GLM result for user 76

Table D.65: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	110.9406	62.6670	1.77	0.0912
temp	-0.1375	0.0733	-1.88	0.0748
pressure	-0.1020	0.0612	-1.67	0.1107
windspeed	-0.3138	0.0934	-3.36	0.0030

Table D.66: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	3.52	1	0.0608
pressure	2.77	1	0.0958
windspeed	11.29	1	0.0008

GLM result for user 77

Table D.67: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	16.2380	9.0722	1.79	0.0801
temp	-0.0121	0.0363	-0.33	0.7393
pressure	-0.0116	0.0084	-1.38	0.1732
windspeed	-0.1115	0.0743	-1.50	0.1405

Table D.68: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	0.11	1	0.7378
pressure	1.91	1	0.1666
windspeed	2.25	1	0.1337

GLM result for user 79

Table D.69: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	-99.9695	202.8963	-0.49	0.6397
temp	-0.3063	0.7058	-0.43	0.6795
pressure	0.1076	0.1959	0.55	0.6024
windspeed	0.5911	1.2964	0.46	0.6645

Table D.70: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	0.19	1	0.6643
pressure	0.30	1	0.5826
windspeed	0.21	1	0.6484

GLM result for user 81

Table D.71: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	4.1697	102.8530	0.04	0.9683
temp	0.1604	0.1837	0.87	0.3984
pressure	0.0006	0.1014	0.01	0.9954
windspeed	-0.2795	0.3747	-0.75	0.4690

Table D.72: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	0.76	1	0.3826
pressure	0.00	1	0.9954
windspeed	0.56	1	0.4557

GLM result for user 84

Table D.73: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	3.0000			

Table D.74: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp		0	
pressure		0	
windspeed		0	

GLM result for user 86

Table D.75: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	23.3569	106.6766	0.22	0.8311
temp	-0.0219	0.1576	-0.14	0.8922
pressure	-0.0183	0.1037	-0.18	0.8632
windspeed	0.1997	0.2730	0.73	0.4814

Table D.76: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	0.02	1	0.8894
pressure	0.03	1	0.8597
windspeed	0.53	1	0.4646

GLM result for user 87

Table D.77: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	-73.4778	174.3990	-0.42	0.6834
temp	0.2690	0.3076	0.87	0.4045
pressure	0.0728	0.1686	0.43	0.6760
windspeed	0.0345	0.7410	0.05	0.9639

Table D.78: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	0.76	1	0.3818
pressure	0.19	1	0.6659
windspeed	0.00	1	0.9629

GLM result for user 88

Table D.79: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	334.7724	149.5631	2.24	0.1111
temp	-0.3330	0.0996	-3.34	0.0443
pressure	-0.3146	0.1450	-2.17	0.1185
windspeed	-0.1168	0.2396	-0.49	0.6593

Table D.80: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	11.18	1	0.0008
pressure	4.71	1	0.0300
windspeed	0.24	1	0.6258

GLM result for user 91

Table D.81: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	43.8209	63.4883	0.69	0.5058
temp	0.1097	0.1167	0.94	0.3695
pressure	-0.0429	0.0624	-0.69	0.5077
windspeed	-0.0989	0.1781	-0.56	0.5908

Table D.82: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	0.88	1	0.3474
pressure	0.47	1	0.4921
windspeed	0.31	1	0.5785

GLM result for user 92

Table D.83: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	21.5320	39.4619	0.55	0.5924
temp	-0.0023	0.0524	-0.04	0.9648
pressure	-0.0202	0.0387	-0.52	0.6078
windspeed	0.0855	0.1150	0.74	0.4677

Table D.84: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	0.00	1	0.9643
pressure	0.27	1	0.6010
windspeed	0.55	1	0.4576

GLM result for user 93

Table D.85: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	-11.1652	83.3997	-0.13	0.8987
temp	0.2467	0.1126	2.19	0.0799
pressure	0.0140	0.0820	0.17	0.8714
windspeed	0.2899	0.2524	1.15	0.3027

Table D.86: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	4.80	1	0.0284
pressure	0.03	1	0.8647
windspeed	1.32	1	0.2507

GLM result for user 94

Table D.87: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	59.0405	109.7634	0.54	0.5956
temp	-0.0659	0.1244	-0.53	0.6013
pressure	-0.0522	0.1065	-0.49	0.6286
windspeed	0.1645	0.2843	0.58	0.5683

Table D.88: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	0.28	1	0.5964
pressure	0.24	1	0.6242
windspeed	0.33	1	0.5629

GLM result for user 95

Table D.89: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	67.7022	84.6723	0.80	0.4502
temp	0.0558	0.1536	0.36	0.7272
pressure	-0.0638	0.0844	-0.76	0.4744
windspeed	0.0833	0.2778	0.30	0.7729

Table D.90: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	0.13	1	0.7165
pressure	0.57	1	0.4498
windspeed	0.09	1	0.7642

GLM result for user 96

Table D.91: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	-107.1888	204.2701	-0.52	0.6160
temp	-0.2480	0.5870	-0.42	0.6853
pressure	0.1123	0.2068	0.54	0.6039
windspeed	0.4172	0.6774	0.62	0.5575

Table D.92: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	0.18	1	0.6726
pressure	0.30	1	0.5870
windspeed	0.38	1	0.5380

GLM result for user 99

Table D.93: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	-271.4263			
temp	-0.3853			
pressure	0.2746			

Table D.94: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp		0	
pressure		0	
windspeed		0	

GLM result for user 102

Table D.95: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	148.9863	85.8278	1.74	0.1166
temp	-0.1983	0.1101	-1.80	0.1051
pressure	-0.1371	0.0837	-1.64	0.1358
windspeed	-0.1289	0.2670	-0.48	0.6407

Table D.96: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	3.25	1	0.0716
pressure	2.68	1	0.1014
windspeed	0.23	1	0.6292

GLM result for user 106

Table D.97: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	-35.1513	88.2001	-0.40	0.7007
temp	0.0414	0.0788	0.53	0.6135
pressure	0.0364	0.0865	0.42	0.6852
windspeed	-0.1093	0.1278	-0.86	0.4171

Table D.98: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	0.28	1	0.5993
pressure	0.18	1	0.6742
windspeed	0.73	1	0.3922

GLM result for user 108

Table D.99: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	-20.3480	70.4894	-0.29	0.7744
temp	0.0882	0.1532	0.58	0.5683
pressure	0.0210	0.0686	0.31	0.7612
windspeed	-0.1963	0.2413	-0.81	0.4211

Table D.100: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	0.33	1	0.5649
pressure	0.09	1	0.7596
windspeed	0.66	1	0.4160

GLM result for user 109

Table D.101: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	-79.8103	101.3053	-0.79	0.4566
temp	0.0939	0.2005	0.47	0.6536
pressure	0.0788	0.0992	0.80	0.4527
windspeed	0.0635	0.1981	0.32	0.7577

Table D.102: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	0.22	1	0.6394
pressure	0.63	1	0.4266
windspeed	0.10	1	0.7483

GLM result for user 110

Table D.103: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	4.9463			
temp	0.2985			

Table D.104: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp		0	
pressure		0	
windspeed		0	

GLM result for user 112

Table D.105: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	-85.4746	111.7805	-0.76	0.4695
temp	0.0006	0.2146	0.00	0.9977
pressure	0.0902	0.1110	0.81	0.4430
windspeed	-0.3820	0.4146	-0.92	0.3875

Table D.106: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	0.00	1	0.9976
pressure	0.66	1	0.4163
windspeed	0.85	1	0.3568

GLM result for user 113

Table D.107: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	3.7857	0.6038	6.27	0.0000

Table D.108: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp		0	
pressure		0	
windspeed		0	

GLM result for user 114

Table D.109: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	37.3474	81.6437	0.46	0.6544
temp	0.1260	0.1474	0.85	0.4072
pressure	-0.0344	0.0802	-0.43	0.6743
windspeed	0.0769	0.1715	0.45	0.6606

Table D.110: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	0.73	1	0.3928
pressure	0.18	1	0.6678
windspeed	0.20	1	0.6537

GLM result for user 116

Table D.111: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	-96.4146	99.4450	-0.97	0.3576
temp	-0.2590	0.1505	-1.72	0.1192
pressure	0.1020	0.0971	1.05	0.3213
windspeed	-0.4454	0.5076	-0.88	0.4031

Table D.112: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	2.96	1	0.0851
pressure	1.10	1	0.2939
windspeed	0.77	1	0.3802

GLM result for user 118

Table D.113: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	285.7349			
temp	-0.1804			
pressure	-0.2683			
windspeed	-0.0638			

Table D.114: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp		1	
pressure		1	
windspeed		1	

GLM result for user 120

Table D.115: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	-175.2005	93.6701	-1.87	0.1582
temp	0.1550	0.3891	0.40	0.7170
pressure	0.1730	0.0893	1.94	0.1482
windspeed	-0.2326	0.1781	-1.31	0.2827

Table D.116: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	0.16	1	0.6903
pressure	3.75	1	0.0528
windspeed	1.71	1	0.1916

GLM result for user 121

Table D.117: Generalised Linear Model

	Estimate	Std. Error	t value	Pr(>|t|)
(Intercept)	73.4051	62.9097	1.17	0.2512
temp	-0.0161	0.0989	-0.16	0.8715
pressure	-0.0669	0.0611	-1.09	0.2810
windspeed	-0.3228	0.3401	-0.95	0.3491

Table D.118: ANOVA for Generalisd Linear Model

	LR Chisq	Df	Pr(>Chisq)
temp	0.03	1	0.8705
pressure	1.20	1	0.2735
windspeed	0.90	1	0.3426

Appendix E

CS2 - Datasheet

This appendix contains the datasheet described in Chapter 5 on modelling sparse and frequent intervals for pain experience.

A legend to the datasheet is provided in Figure E.1, with the datasheet divided onto two pages in Figure E.2 and Figure E.3.

Legend

Heading	Description
S/N	Internal Serial Number
1M ΔPain	Difference in Pain Intensity at 1 Month
Median Pain	Median pain intensity over 32 Days
Range of Pain	Range of Pain Intensity over 32 Days. Shown as Min-Max
AdHoc Rpt	Count of Ad-Hoc Pain Reports
Sched. Rpt	Count of Daily Pain Reports
AUC 1M	AUC (Pain Experience)for Day 0 and Day 32 (1 Month Interval)
AUC Full	AUC (Pain Experience) for Daily Interval over 32 Days
ΔAUC	Difference in AUC (Pain Experience)

Figure E.1: Pain Trajectory

S/N	1M ΔPain	Median Pain	Range of Pain	AdHoc Rpt	Sched. Rpt	AUC 1M	AUC Full	ΔAUC
54	-7	2	0-8	1	24	257	88.015	168.985
43	1	10	8-10	1	11	298	150.031	147.969
53	-1	6	3-8	0	16	263	145.053	117.947
7	-4	7	3-8	2	12	260	144.051	115.949
5	-5	2	0-8	0	26	193	78.51	114.49
2	-5	9	4-10	7	24	325	213.253	111.747
40	-2	6	4-9	0	24	262	169.925	92.075
56	2	0	0-6	5	20	134	48.298	85.702
8	-2	4	0-8	3	27	196	114.01	81.99
31	-3	0	0-3	2	21	96	14.921	81.079
36	-3	7	3-8	2	17	228	156.453	71.547
32	-2	6	3-6	20	23	196	126.26	69.74
22	0	6	3-8	0	28	231	162.495	68.505
46	-5	4	1-9	4	11	226	157.628	68.372
42	-2	1	0-3	3	30	97	34.519	62.481
27	1	7	6-7	0	16	199	137.655	61.345
4	1	8	7-9	1	27	265	205.413	59.587
18	-3	3	0-8	2	32	162	107.008	54.992
51	-2	2	2-4	4	29	130	75.856	54.144
17	-2	1	0-3	1	8	64	13.237	50.763
20	-1	4	0-5	0	20	131	80.878	50.122
10	1	4	2-8	9	30	199	150.373	48.627
45	1	4	2-5	0	22	133	88.57	44.43
13	0	6	5-7	0	24	231	191.102	39.898
37	-1	3	3-4	0	18	131	95.006	35.994
44	-1	5	1-9	8	27	197	174.722	22.278
52	0	8	8-9	0	12	264	241.931	22.069
48	3	5	3-8	3	26	135	118.643	16.357
6	0	3	2-3	0	30	99	83.737	15.263

Figure E.2: Datasheet for modelling sparse and frequent intervals for pain experience

S/N	1M ΔPain	Median Pain	Range of Pain	AdHoc Rpt	Sched. Rpt	AUC 1M	AUC Full	ΔAUC
35	0	7	0-9	2	25	231	220.004	10.996
47	1	2	2-3	0	11	67	56.947	10.053
24	0	2	0-4	12	27	66	57.669	8.331
11	2	3	1-8	3	26	101	95.105	5.895
9	0	2	2-4	1	18	66	63.865	2.135
30	0	2	2-3	0	26	66	64.654	1.346
14	1	2	0-5	12	31	67	66.168	0.832
33	1	3	1-6	21	25	67	67.855	-0.855
50	0	1	0-6	21	30	33	34.766	-1.766
49	0	2	1-4	4	29	66	71.803	-5.803
28	1	1	0-3	1	27	34	40.368	-6.368
12	0	2.5	1-5	0	6	66	73.604	-7.604
21	2	6	6-8	1	17	200	217.413	-17.413
26	1	4.5	2-8	6	24	133	153.881	-20.881
34	2	4	0-7	25	32	101	124.534	-23.534
58	-1	2	1-5	0	14	65	88.914	-23.914
59	1	4	1-9	21	24	100	125.839	-25.839
16	1	4	1-6	4	29	100	126.308	-26.308
55	0	4	2-7	6	23	99	127.553	-28.553
38	4	4	3-8	0	31	103	134.01	-31.01
41	0	1	0-4	1	19	0	31.51	-31.51
3	2	7	4-8	1	30	167	199.953	-32.953
23	1	1	0-5	1	18	1	35.033	-34.033
57	2	8	6-9	0	29	200	241.909	-41.909
29	2	4	0-6	1	28	68	110.511	-42.511
25	2	4	1-5	1	31	68	110.534	-42.534
15	3	6.5	3-9	6	30	135	188.119	-53.119
1	1	2	0-7	2	31	1	63.976	-62.976
19	9	3	0-10	3	22	42	124.364	-82.364

Figure E.3: Datasheet for modelling sparse and frequent intervals for pain experience (cont.)

Appendix F

CS2 - Modelling pain experience

This appendix contains the remaining graphs generated using SPSS 24. Each graph is a pain trajectory that plotted data from two intervals: i) sparse, D0 and D32; and ii) overall, daily for 33 days. The Area Under Curve (AUC) value is a representation of the total pain experience. I provide more information about this analysis in Chapter 5.

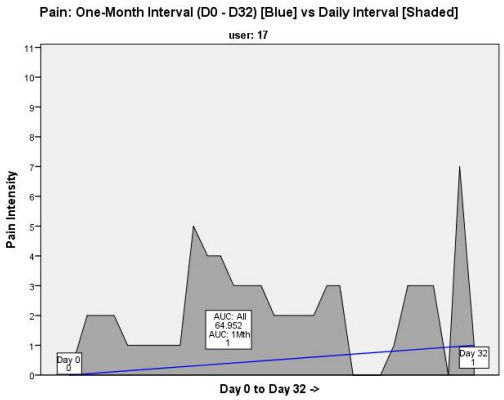


Figure F.1: Pain Experience over 1 Month

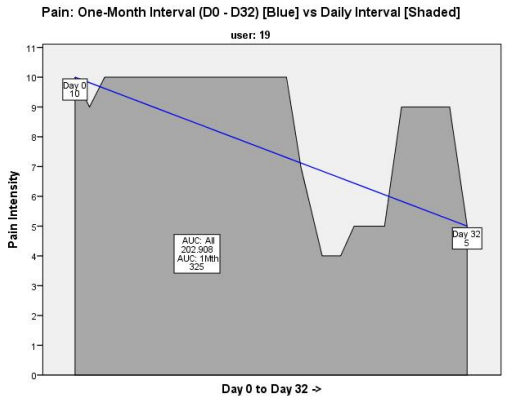


Figure F.2: Pain Experience over 1 Month

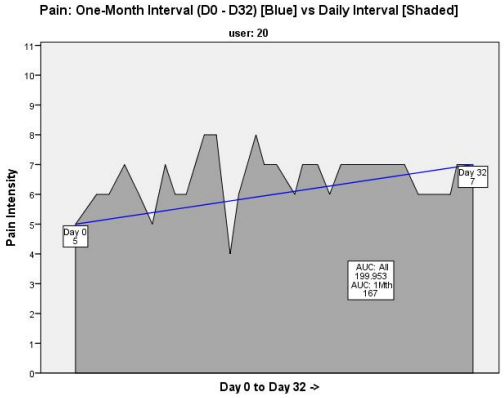


Figure F.3: Pain Experience over 1 Month

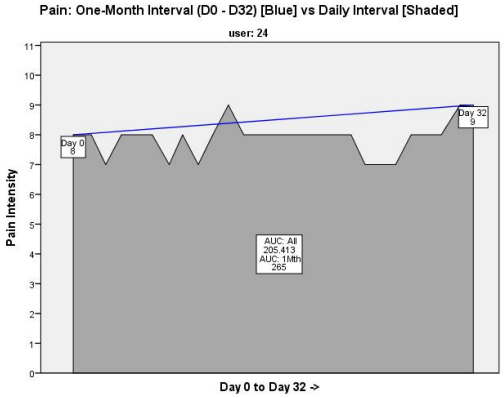


Figure F.4: Pain Experience over 1 Month

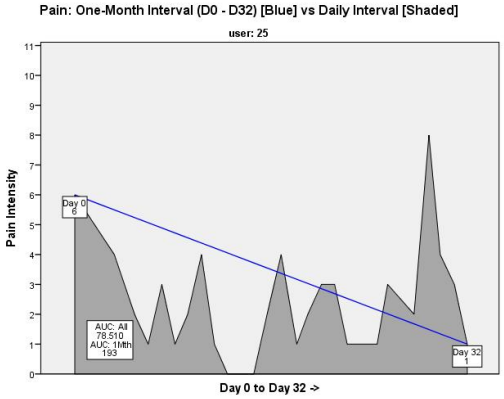


Figure F.5: Pain Experience over 1 Month

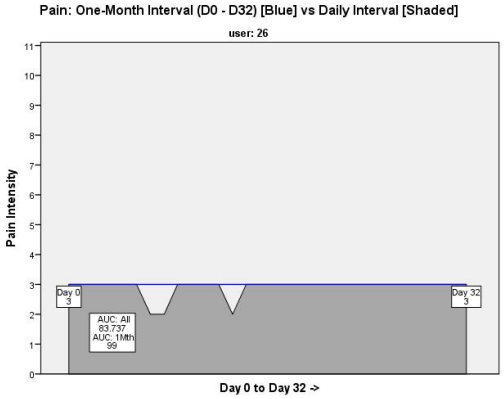


Figure F.6: Pain Experience over 1 Month

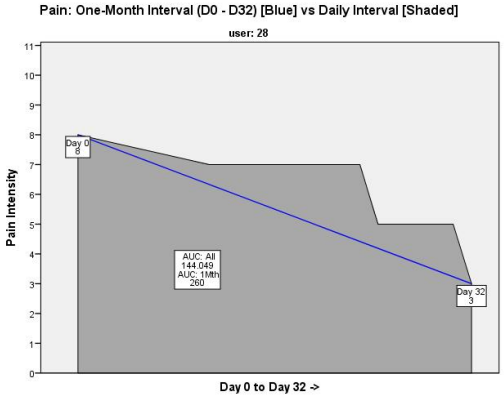


Figure F.7: Pain Experience over 1 Month

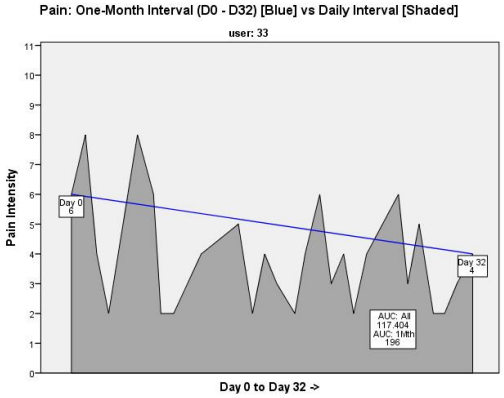


Figure F.8: Pain Experience over 1 Month

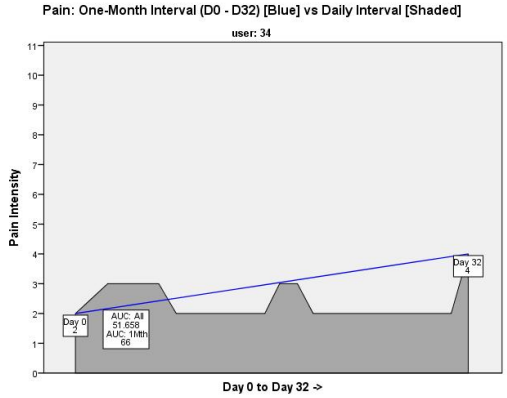


Figure F.9: Pain Experience over 1 Month

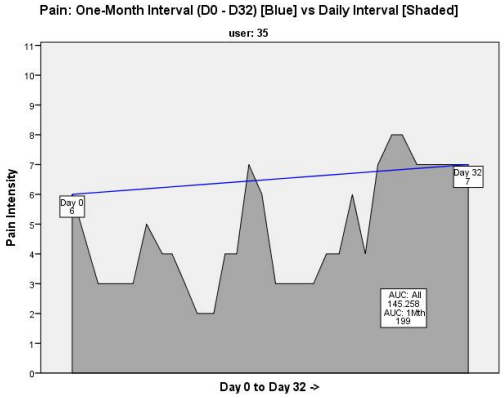


Figure F.10: Pain Experience over 1 Month

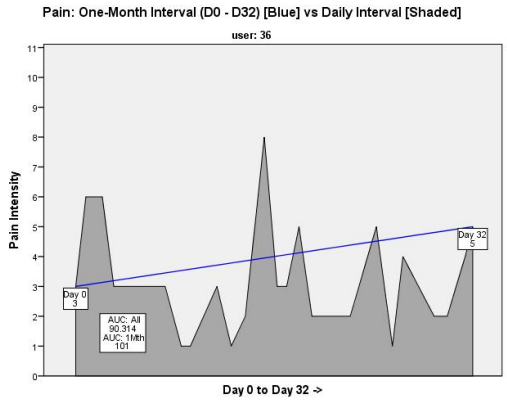


Figure F.11: Pain Experience over 1 Month

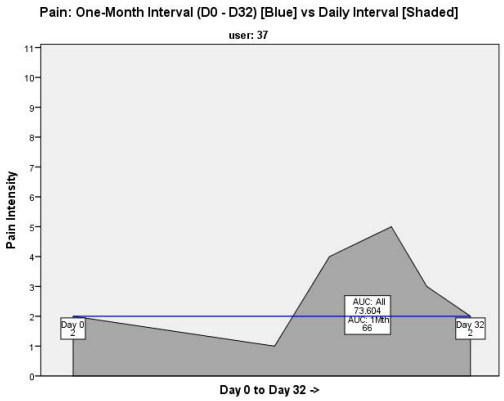


Figure F.12: Pain Experience over 1 Month

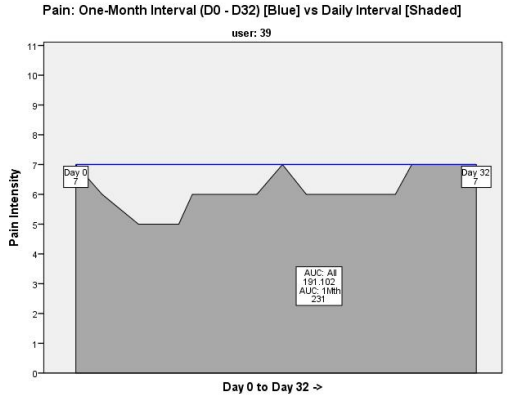


Figure F.13: Pain Experience over 1 Month

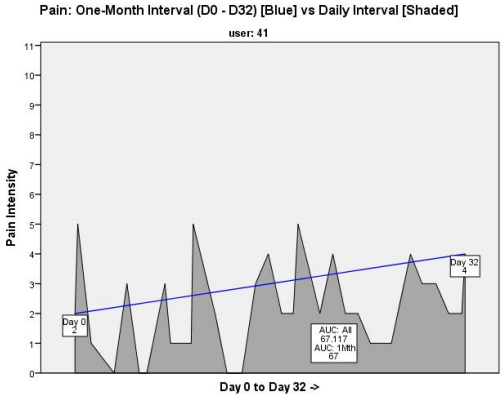


Figure F.14: Pain Experience over 1 Month

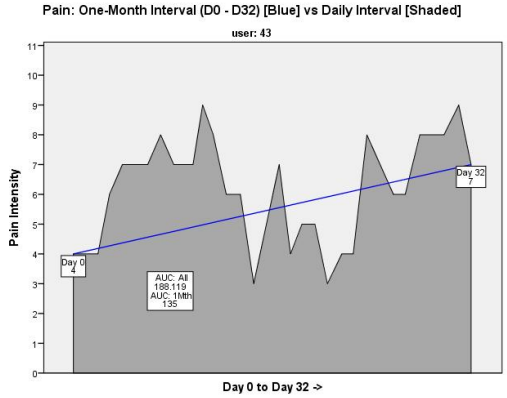


Figure F.15: Pain Experience over 1 Month

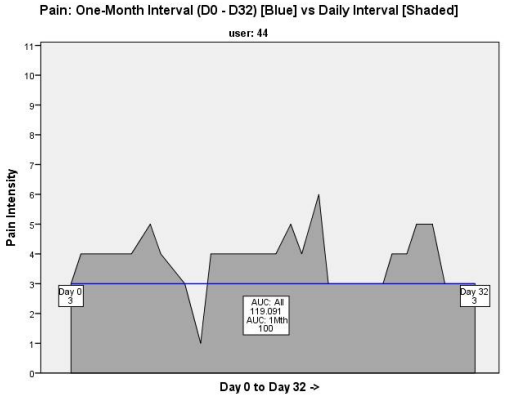


Figure F.16: Pain Experience over 1 Month

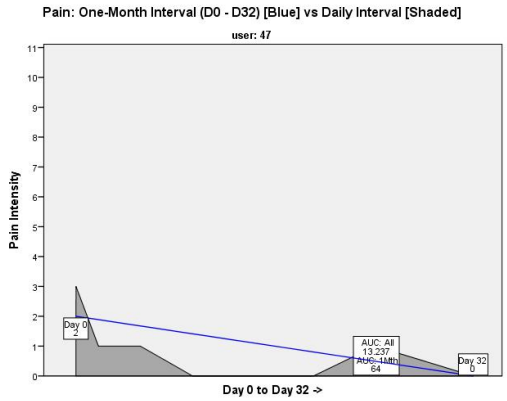


Figure F.17: Pain Experience over 1 Month

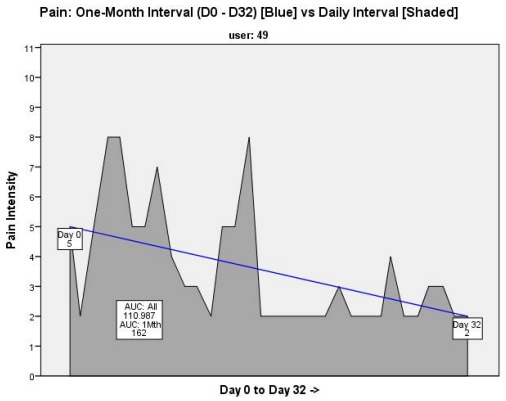


Figure F.18: Pain Experience over 1 Month

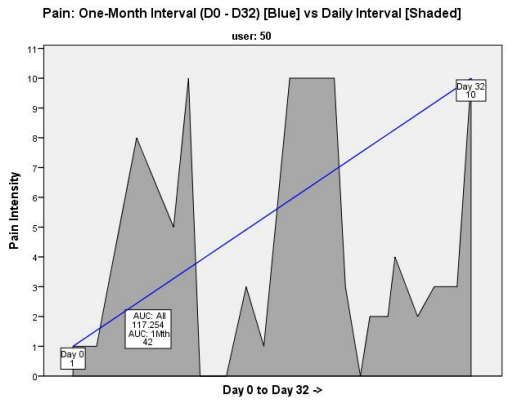


Figure F.19: Pain Experience over 1 Month

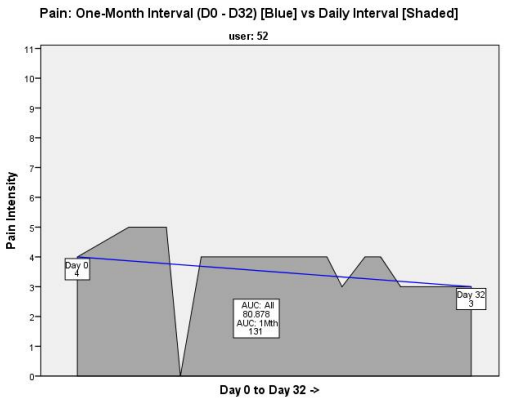


Figure F.20: Pain Experience over 1 Month

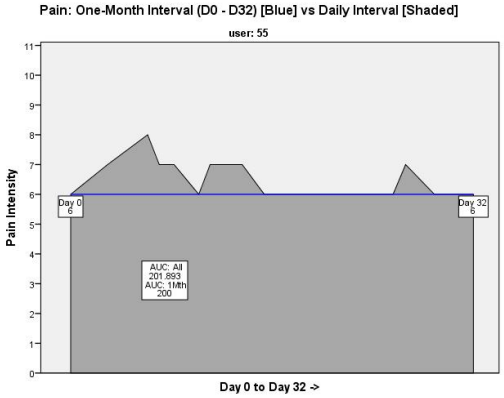


Figure F.21: Pain Experience over 1 Month

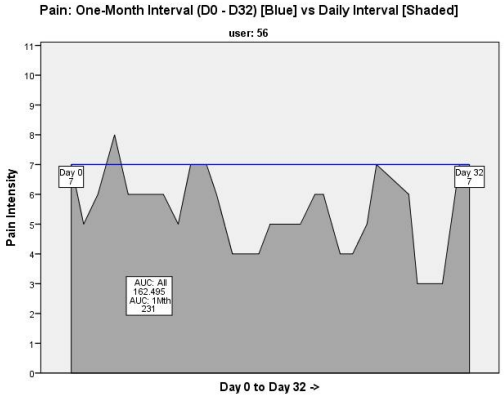


Figure F.22: Pain Experience over 1 Month

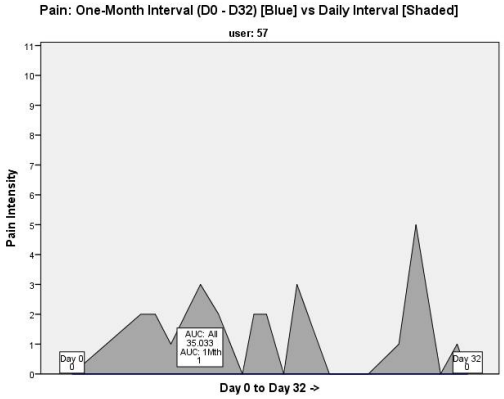


Figure F.23: Pain Experience over 1 Month

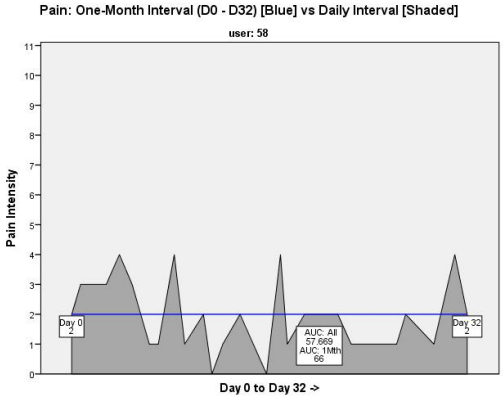


Figure F.24: Pain Experience over 1 Month

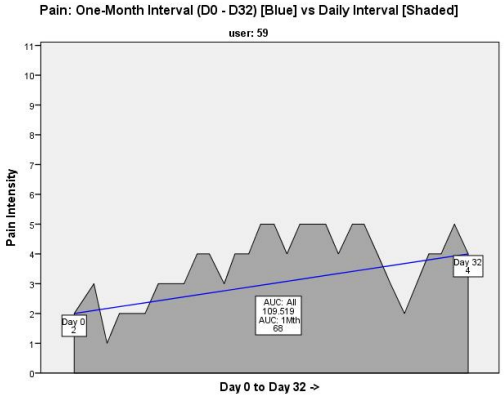


Figure F.25: Pain Experience over 1 Month

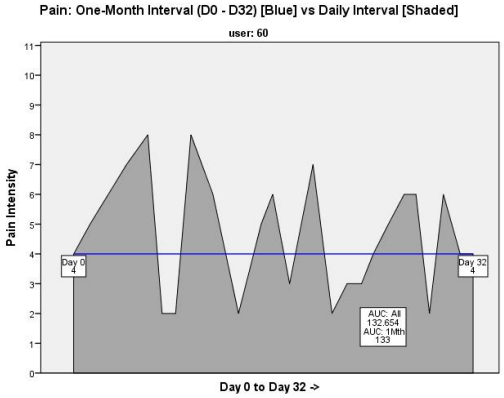


Figure F.26: Pain Experience over 1 Month

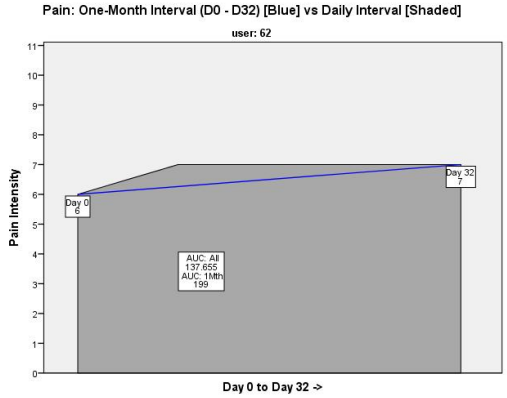


Figure F.27: Pain Experience over 1 Month

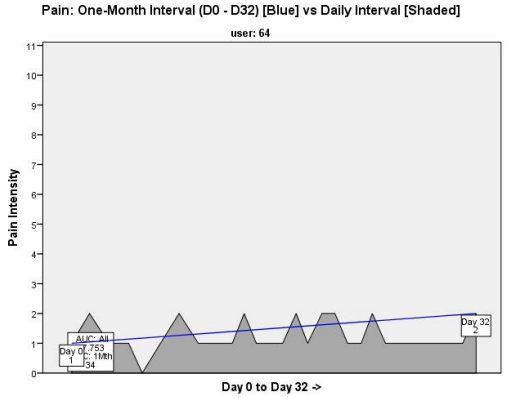


Figure F.28: Pain Experience over 1 Month

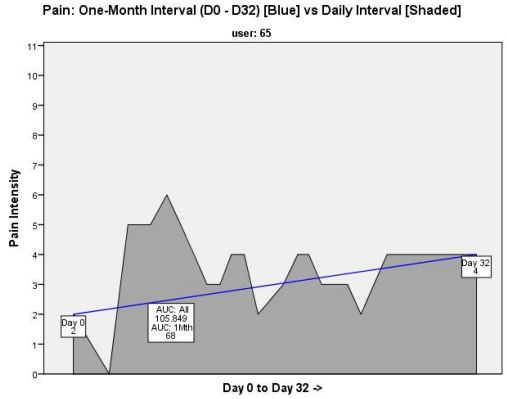


Figure F.29: Pain Experience over 1 Month

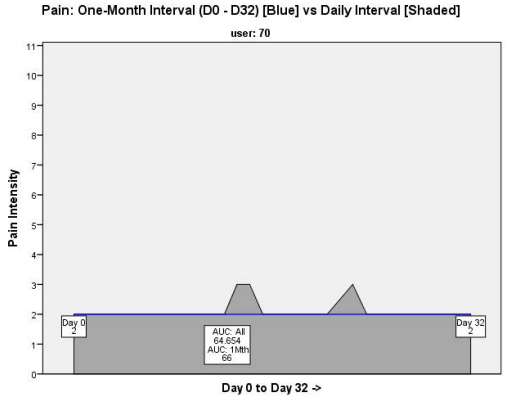


Figure F.30: Pain Experience over 1 Month

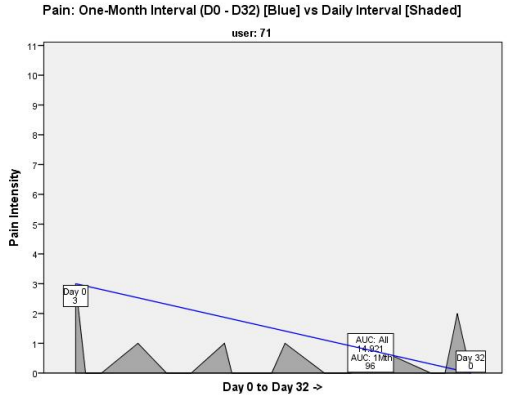


Figure F.31: Pain Experience over 1 Month

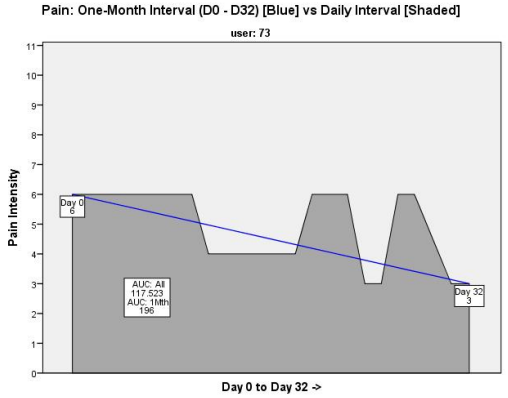


Figure F.32: Pain Experience over 1 Month

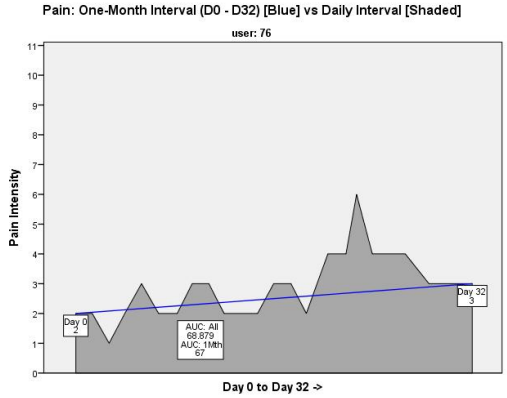


Figure F.33: Pain Experience over 1 Month

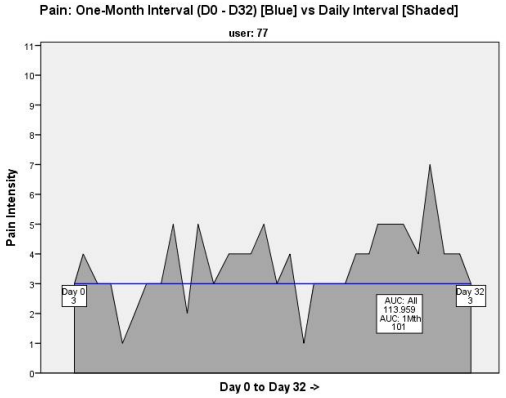


Figure F.34: Pain Experience over 1 Month

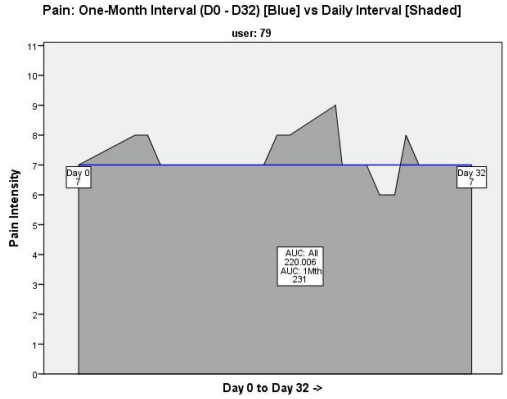


Figure F.35: Pain Experience over 1 Month

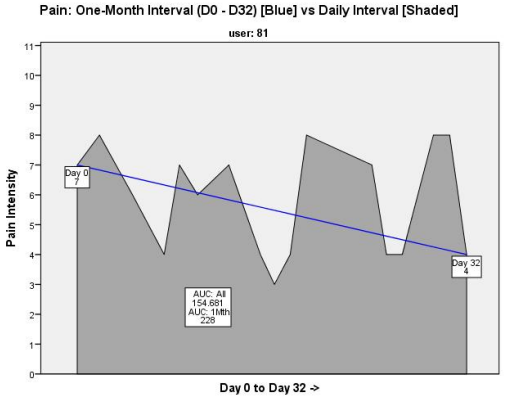


Figure F.36: Pain Experience over 1 Month

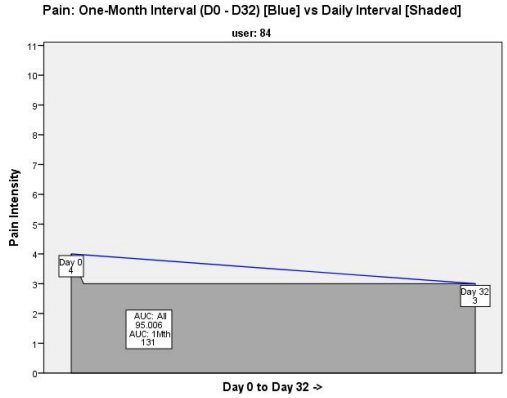


Figure F.37: Pain Experience over 1 Month

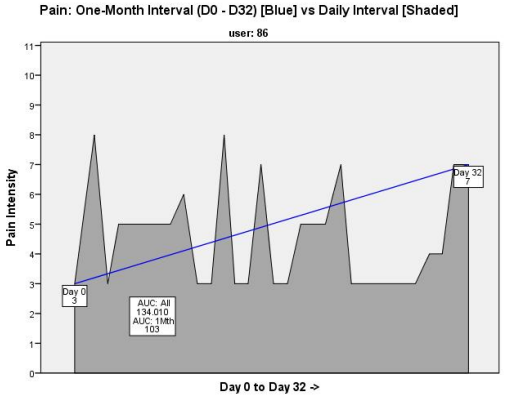


Figure F.38: Pain Experience over 1 Month

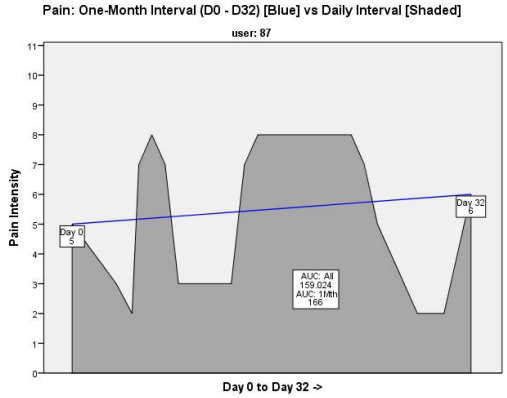


Figure F.39: Pain Experience over 1 Month

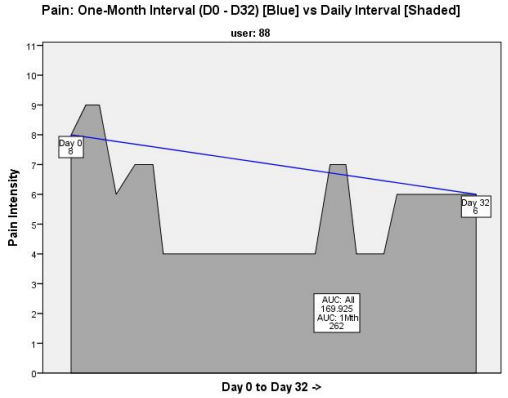


Figure F.40: Pain Experience over 1 Month

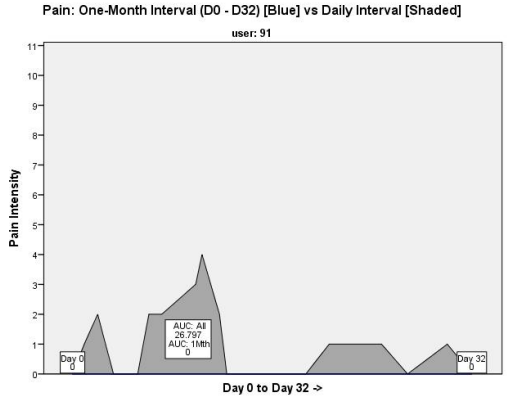


Figure F.41: Pain Experience over 1 Month

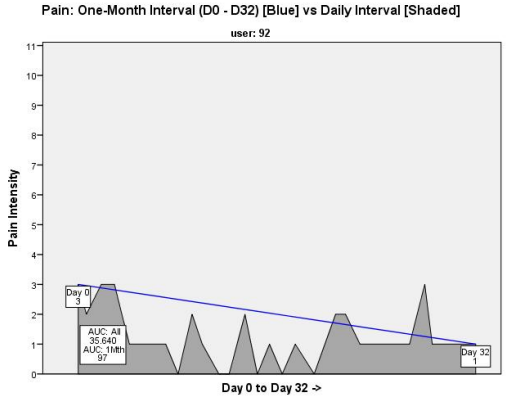


Figure F.42: Pain Experience over 1 Month

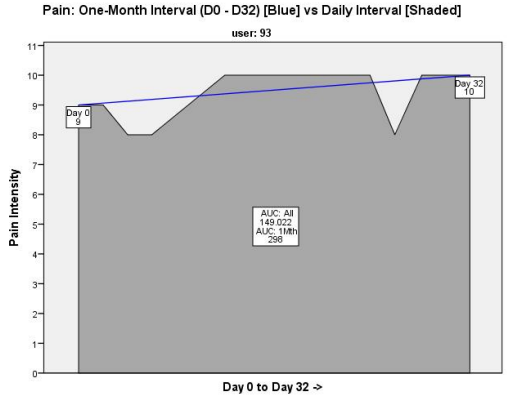


Figure F.43: Pain Experience over 1 Month

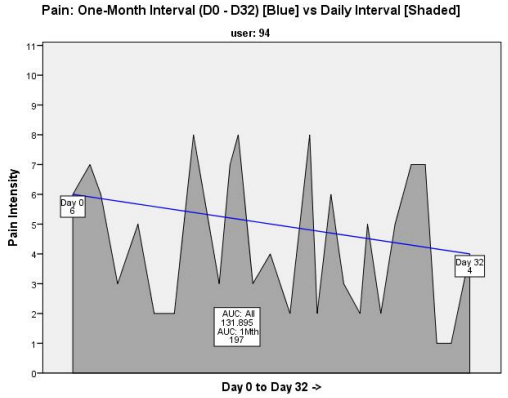


Figure F.44: Pain Experience over 1 Month

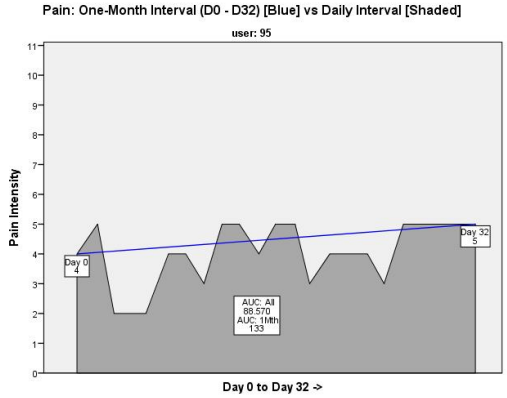


Figure F.45: Pain Experience over 1 Month

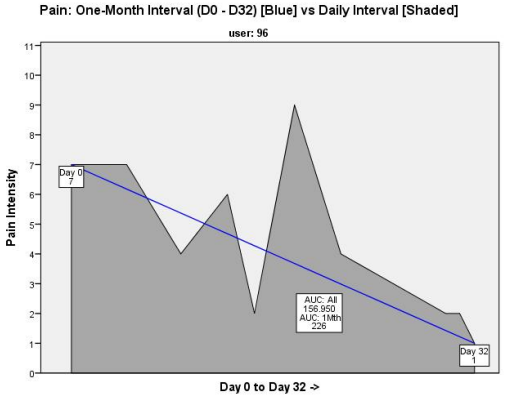


Figure F.46: Pain Experience over 1 Month

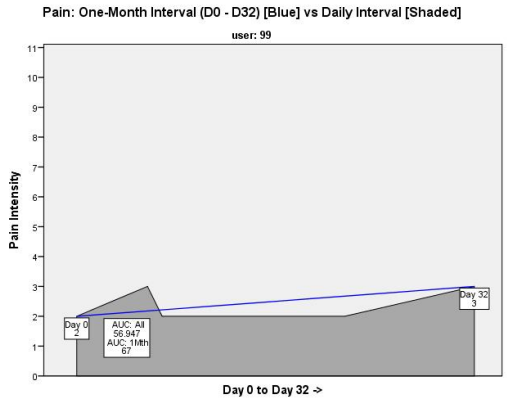


Figure F.47: Pain Experience over 1 Month

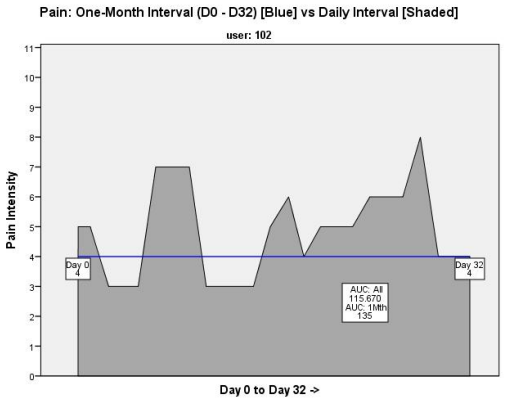


Figure F.48: Pain Experience over 1 Month

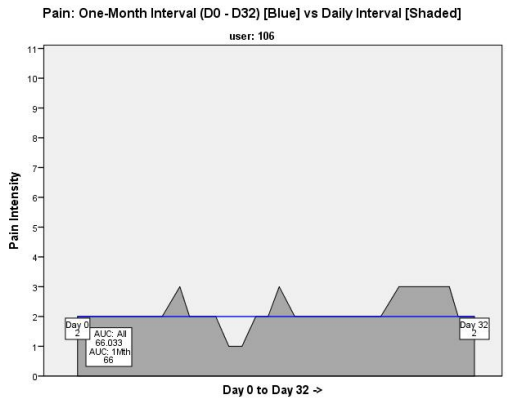


Figure F.49: Pain Experience over 1 Month

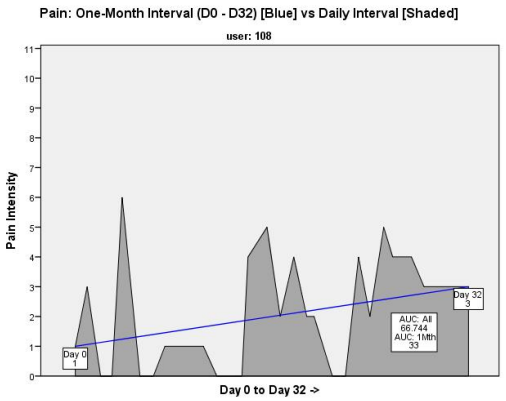


Figure F.50: Pain Experience over 1 Month

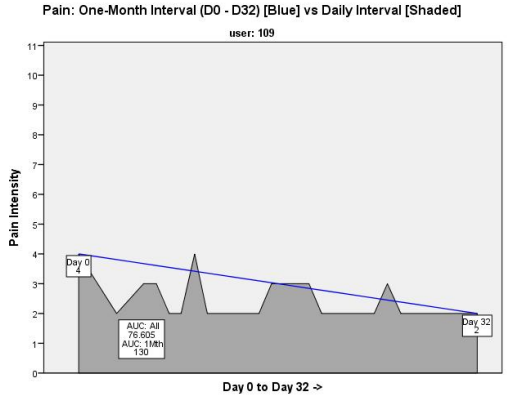


Figure F.51: Pain Experience over 1 Month

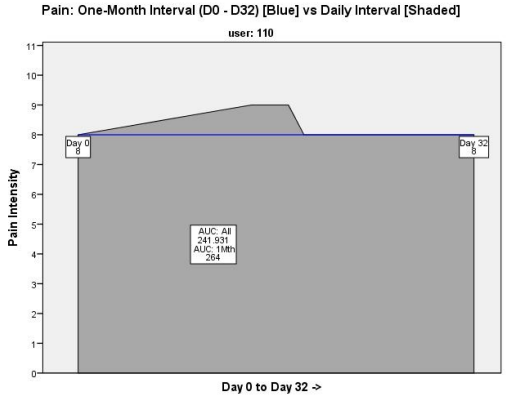


Figure F.52: Pain Experience over 1 Month

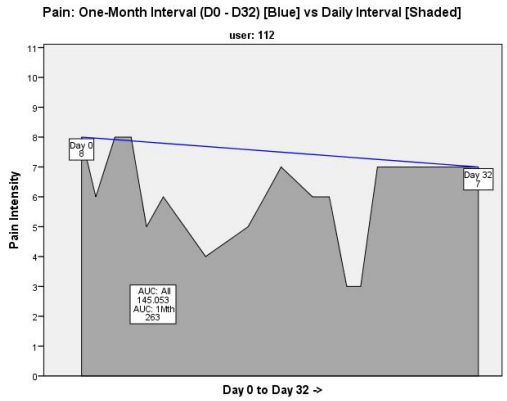


Figure F.53: Pain Experience over 1 Month

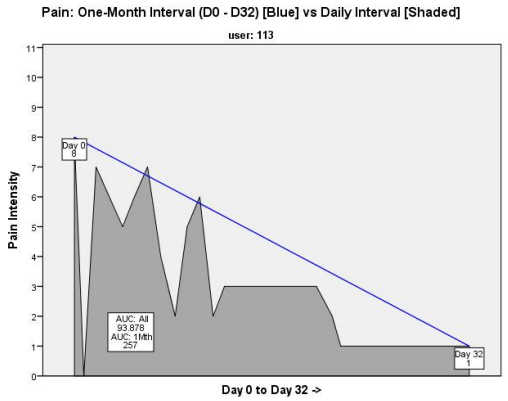


Figure F.54: Pain Experience over 1 Month

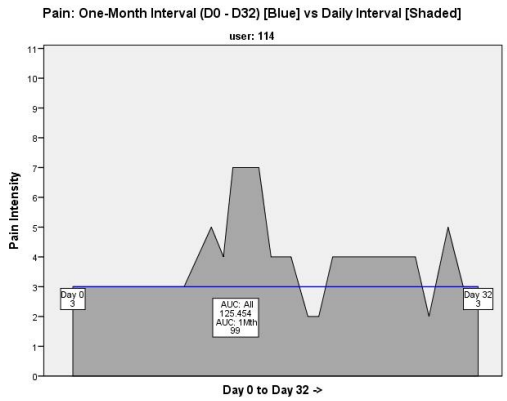


Figure F.55: Pain Experience over 1 Month

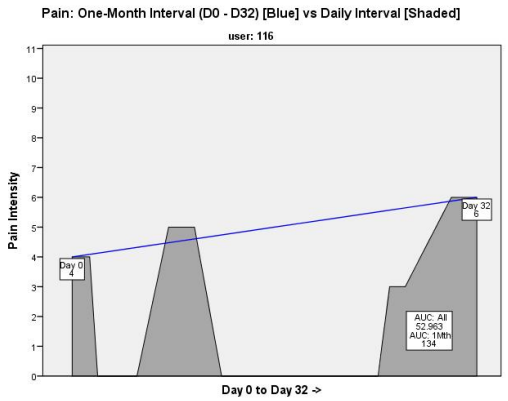


Figure F.56: Pain Experience over 1 Month

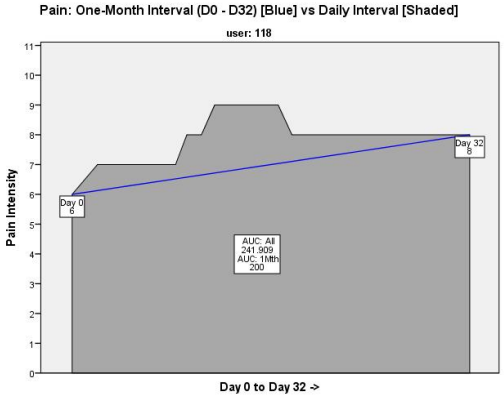


Figure F.57: Pain Experience over 1 Month

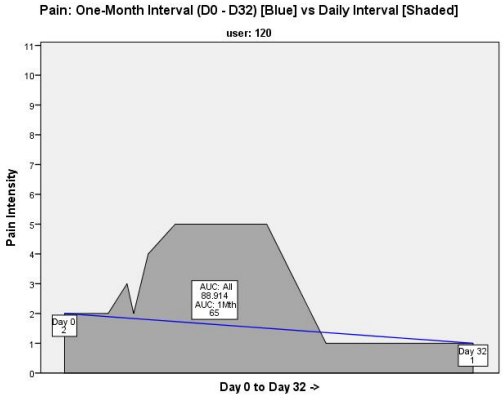


Figure F.58: Pain Experience over 1 Month

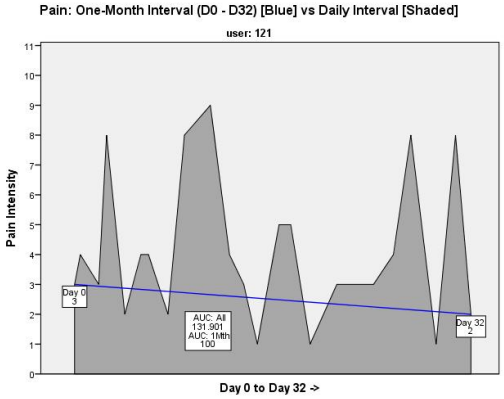


Figure F.59: Pain Experience over 1 Month

Appendix G

CS2 - Contextual Analysis of pain trajectories

This appendix contains the remaining hand-annotated pain trajectories. The pain trajectories were generated using SPSS 24. Each graph is a pain trajectory that represents the timeline of pain experienced by the participants. The horizontal line represents the median pain for the one month duration. Points on the trajectory that are above the top dotted horizontal line, and points below the bottom dotted horizontal line are significant changes in pain. I hand annotated the activities reported during each period, and include the pain experience calculation for reference. I provide more information about this analysis in Chapter 5.

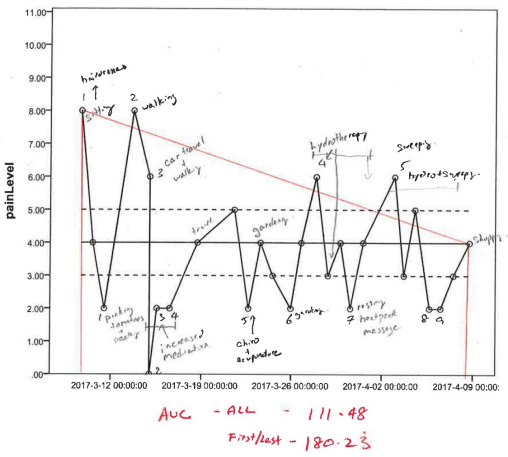
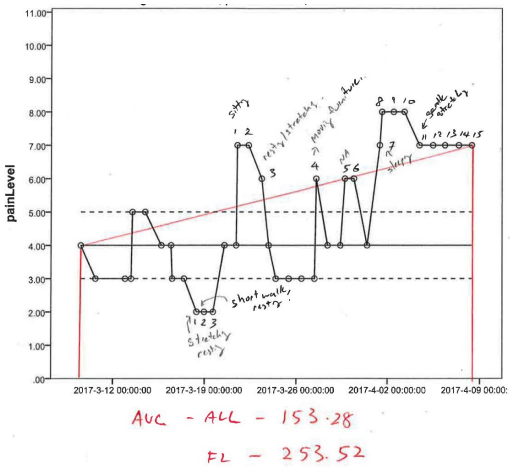


Figure G.1: Contextual Pain Trajectory



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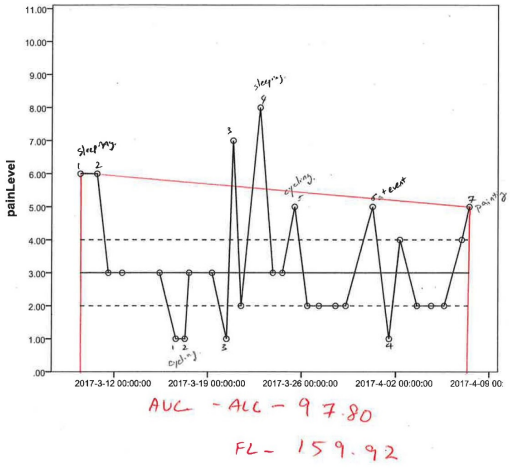

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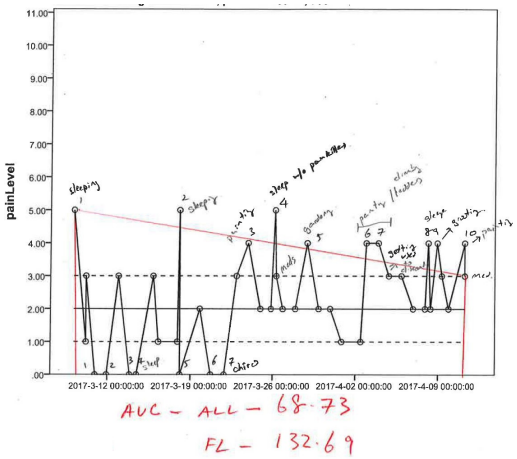


Figure G.4: Contextual Pain Trajectory

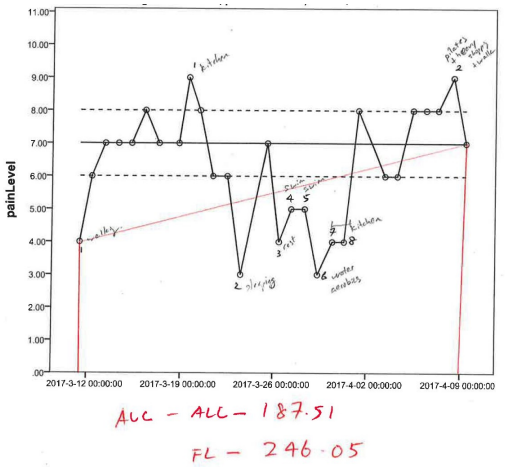
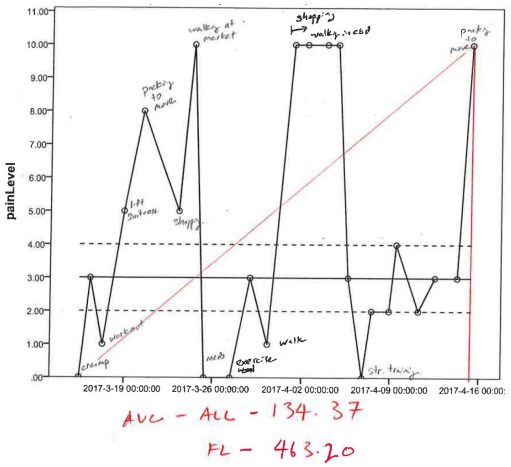


Figure G.5: Contextual Pain Trajectory



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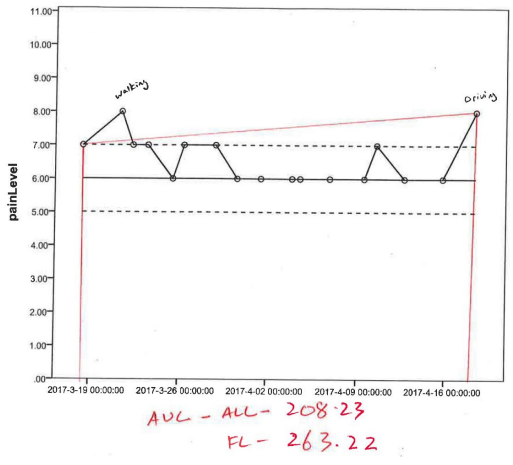

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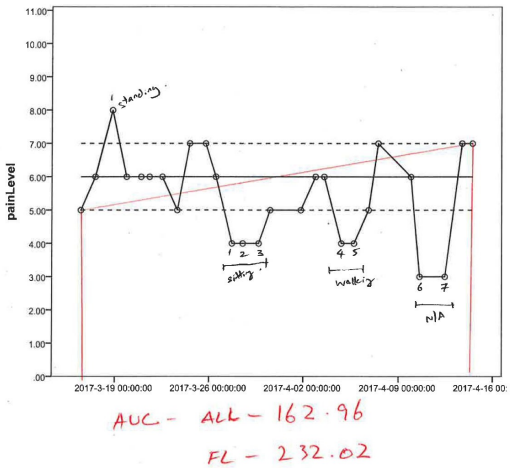

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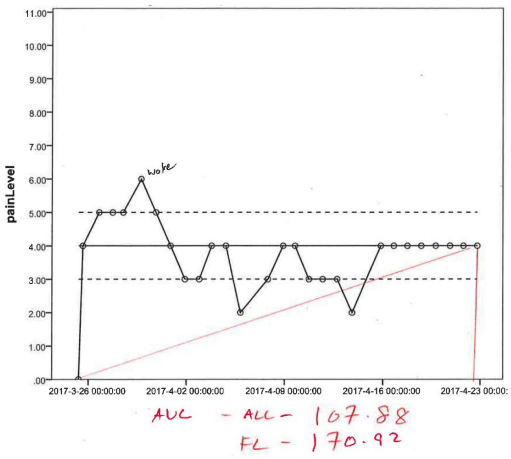

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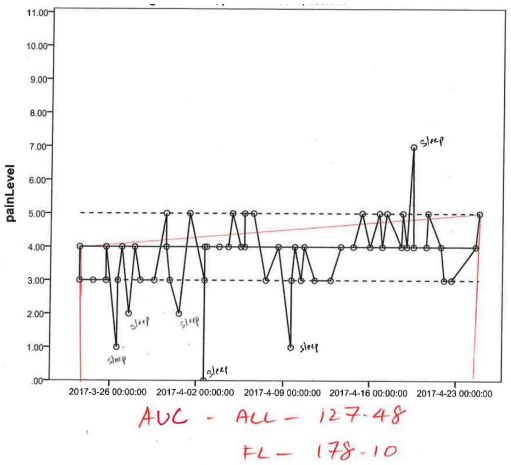
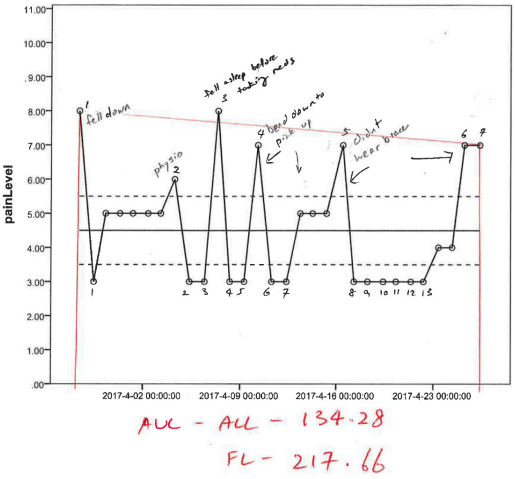


Figure G.10: Contextual Pain Trajectory



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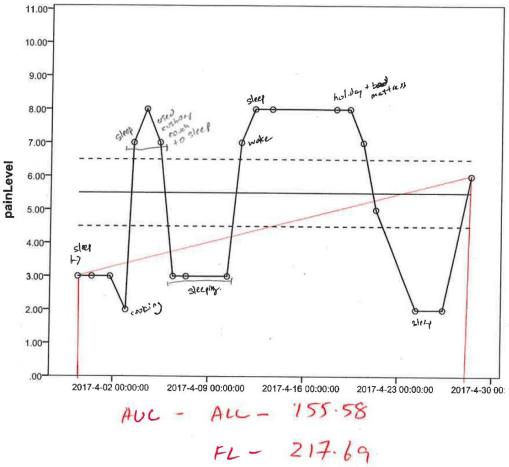

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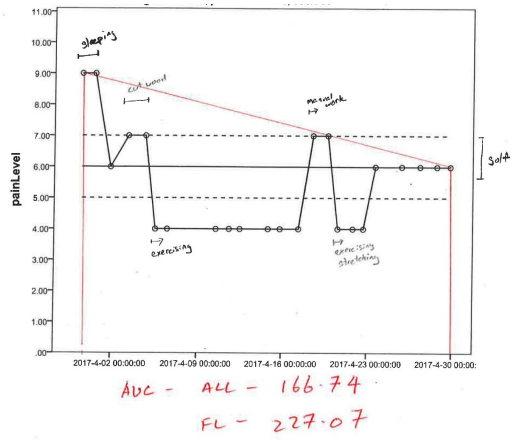

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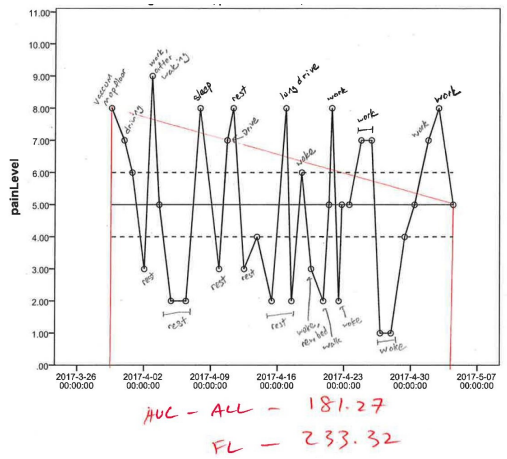

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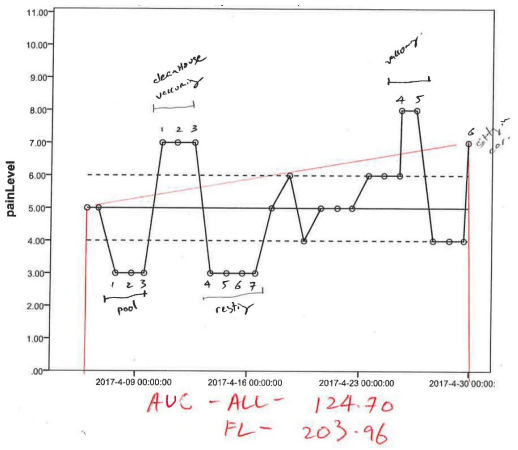

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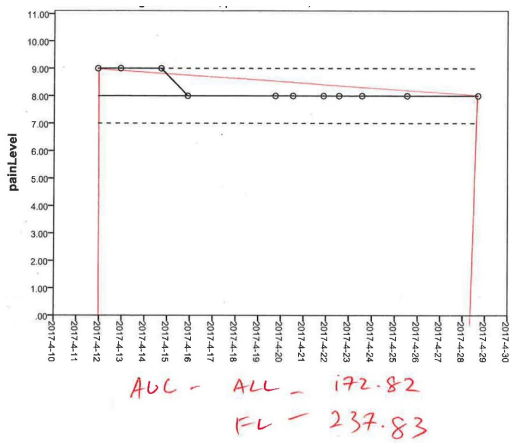

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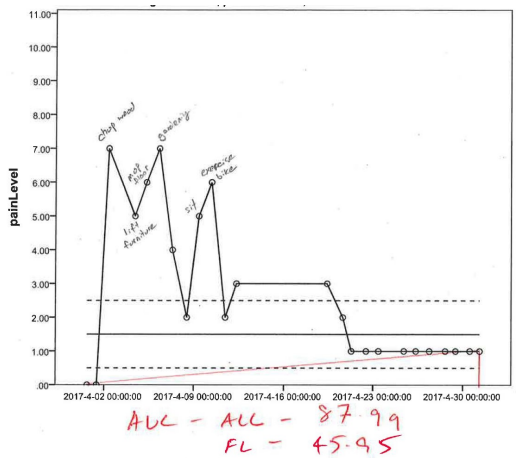

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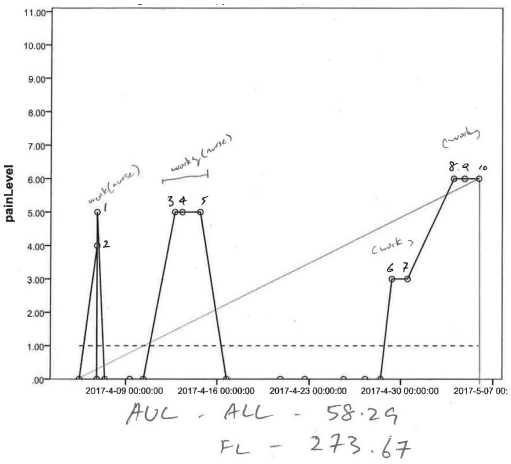

Figure G.18: Contextual Pain Trajectory

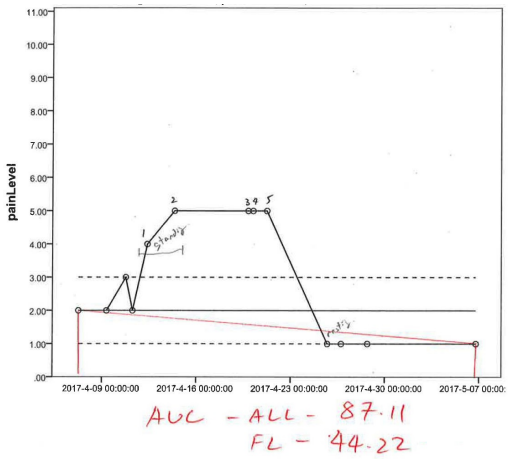

Figure G.19: Contextual Pain Trajectory

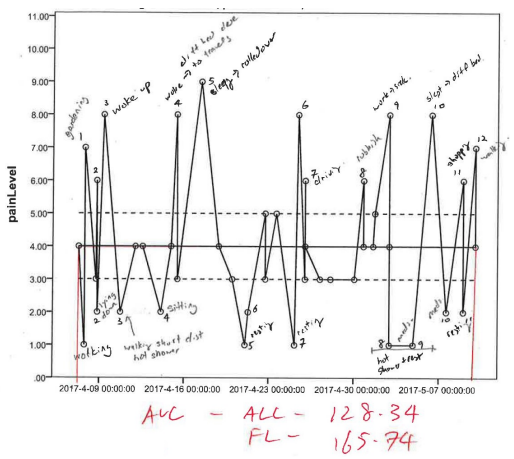

Figure G.20: Contextual Pain Trajectory

Appendix H

Published Papers

This appendix contains the publications arising from this thesis, sorted in ascending year order. The publications are documented in the author vita section.

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2015

A Context-Aware Pain Trajectory Framework for Low Back Pain Management

Tian Yu Goh
Monash University, tian.goh@monash.edu

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A CONTEXT-AWARE PAIN TRAJECTORY FRAMEWORK FOR LOW BACK PAIN MANAGEMENT

Tian Yu Goh, Faculty of Information Technology, Monash University, Caulfield, Australia, tian.goh@monash.edu

Abstract

Current advances in mobile and sensor technologies have provided new opportunities for many fields of research, especially in healthcare. Chronic pain is one such field, where low back pain is a common problem that affects 20% of the population, and is also a major contributor to disability. Unfortunately, not much is yet known about the contributing factors, nor the nature of low back pain itself. Existing research does not collect data frequently - with most studies only collecting pain data monthly, or half yearly. Experts agree that there is a need for the increase in frequency of data collection, and to study the context of the patient's pain experience in order to understand the nature of pain. Currently, there are not any research that attempts to include the context around the patient's pain experience, to collect and analyze data for correlations on an individual patient basis. This research will propose a context-aware pain trajectory approach capitalizing on the opportunities that arise from advances in mobile and sensor technologies, to increase the frequency of data collection, and enable the collection and integration of the patient's context into current low back pain models using day to day pain trajectories.

Keywords: Low Back Pain, Context Awareness, Context Model, Pain Trajectory

1 Research Topic

Low back pain is the leading chronic pain condition, and an important cause of disability worldwide (Driscoll et al., 2014). In Australia, an estimated 20% of the population suffer from persistent pain, which is estimated to cost $34 billion yearly, when taking into consideration lost workdays, health-care and other associated costs (Pain Management Research Institute, The University of Sydney, 2014). Chronic pain is defined as pain lasting more than 3 months (Merskey, 1986). There has been enormous growth in this field over the last decade, with 57% of existing research being published over this period of time (Elsevier, 2014). Studies have used a large variety of approaches in their attempt to study the nature, the causes and factors that contribute towards low back pain. These studies typically use a pain trajectory to represent pain intensity over time, and it has been shown to have some limitations. The current use of the pain trajectory does not allow for the understanding of the context around the changes in pain, and research shows that the study of the context, or factors of low back pain could increase the depth of analysis and understanding provided by the data. Unfortunately, current studies typically attempt to study entire populations without taking into consideration the context available (Cook, 2003; Dunn, Jordan, and Croft, 2006; Dunn et al., 2011; Stanford et al., 2008). Olson's work suggests that pain has an individualistic nature, and thus no two patients will have the same pain experience (Olson, 2014). Therefore, it is important to be able to understand the context around the patient's pain experience, and to be able to capture that contextual data. There currently are no existing approaches that provide the capability to do so in a unifying manner that utilizes recent advances in technology.

This research addresses some issues in data collection that are seen in low back pain studies, which includes the cost, accuracy and contextual usefulness towards understanding the nature of pain. It will do so by utilizing the benefits from advances in technology to increase the frequency of data collection, and provide the capability to collect data about the context of a patient's pain, and display it in a meaningful manner. This research is expected to contribute towards the understanding of the nature and context factors of low back pain for longitudinal studies in pain management.

Based on a review of existing literature, some gaps have been identified, which leads to two main research questions outlined in the following section.

2 Research Question and Aims

The two main research questions (RQ) are:

RQ1 - How can we provide an approach to enable higher frequency and richer sources of data collection for low back pain trajectories?

RQ2 - How to integrate the patient's context into current low back pain models?

As a sub-question to the second research question:

RQ2.1 - What is the impact of the context-aware pain trajectory approach on low back pain studies?

In answering these questions, this research aims to design and develop a framework that uses a Context-aware Pain Trajectory (CaPT) approach in incorporating richer sources of data, and support higher frequency of data collection for day-to-day low back pain trajectories. As part of answering the second RQ, this research will design and develop a context model to represent information from diverse sources such as sensors, APIs, social media, medical records and questionnaires about the patient's context in a unified, consistent manner for low back pain. Finally, a prototype of selected components of the framework will be implemented to validate the proposed context model and context-aware pain trajectory approach by conducting comprehensive evaluation, using simulations with secondary data in collaboration with domain experts, to assess the impact of the approach on low back pain studies.

In this research, low back pain provides the context to the project, but the design of the approach and model can be generalized to other chronic pain management fields and conditions.

The following section will provide an overview of the theoretical foundation from the existing research literature.

3 Theoretical Foundation

3.1 Longitudinal Studies of Low Back Pain

As outlined previously, chronic pain is an incredibly expensive and relatively widespread problem throughout the world. In Australia, an estimated 36.5 million work days each year is attributed towards chronic pain (Pain Management Research Institute, The University of Sydney, 2014), and in the United States, a 2012 review reported that it costs between $560 to $635 billion annually, and although these costs were conservatively estimated, it had already exceeded the economical costs of the 6 most costly major diagnoses, which includes cardiovascular diseases, injury and poisoning (Gaskin and Richard, 2012).
Low back pain is the second most commonly reported problem within the area of chronic pain at 29.4% (Henderson et al., 2013), and such studies typically are longitudinal studies due to their nature of monitoring a population of individuals over an extended period of time and collecting repeated measures of data. The cost associated with collecting data for such studies tends to be high due to the amount of data collection points required. Recent studies have begun adopting the use of technology in collecting data, both to increase the collection capabilities and reduce the overall cost of collecting useful data (Hendrick et al., 2009; Lall et al., 2012). It is seen that unlike other fields of similar studies, the rate of adoption of technology is relatively slow, and most studies typically collect data on an in-frequent basis.
The study of low back pain is a rapidly growing interdisciplinary field that is still being developed (Windt and Dunn, 2013), as much is not known about the specific nature of low back pain, and how it is affected by other characteristics such as clinical and demographics (Macedo et al., 2014). These approaches include investigation into causes and treatments for specific pain, and clinical trials on drugs that can block or ease pain. Furthermore, there are studies that focus on identifying factors that can affect pain, along with research towards understanding the nature of pain itself, which is made difficult by the fact that clinical pain is subjective in nature (Abu-Saad and Holzemer, 1981; McGuire, 1984), as it is a self-reported measure by the patient (Malhotra and Mackey, 2012), and is difficult to measure objectively and accurately (Loder and Burch, 2012).

3.1.1 Data Analysis

It has been observed that the data analysis techniques used in this field primarily consist of statistical analysis, with the literature suggesting that the most common analytical model being the latent class model. The latent class model is used to discover causal relationships between the factors and low back pain, it allows for pain profiles across multiple pain sites to be identified, and also provides the capability to categorize patients into generic classes based on their overall pain trajectory.
The pain trajectory is the visualization of the pattern or progress of pain intensity, and is represented as a two dimensional graph plotting pain intensity over time intervals (Chapman et al., 2011). It has been validated as being precise enough to classify patterns of reported pain in a reliable manner for patients (Chapman et al., 2011). Studies have used a variety of methods in trying to generically classify patients based on their overall pain trajectory, for example, clusters labeled as 'persistent mild', 'recovering', 'severe-chronic' and 'fluctuating' (Dunn, Jordan, and Croft, 2006).
Existing analysis approaches using statistics alone are not able to provide an understanding of low back pain. They are excellent for identifying characteristics as well as the significance of factors, which studies have used in characterizing populations of patients' pain trajectories. However this does not address the problem of pain having an individualistic nature (Olson, 2014). The statistical models are not able to analyze the context of the patient's pain experience. Therefore, it can be seen that there is a need to study the patient's pain experience in multiple factors. There currently does not exist research that attempts to

examine as many of these factors as possible. Existing research is focused on intervention studies for management of pain from a multidisciplinary perspective, or on models for a specific factor.

3.1.2 Data Collection

With regards to the data collection techniques, the most commonly used instruments are questionnaires. Recently, there has been a slow move towards the adoption of newer instruments for the collection of data, which includes diaries, and sensors (McGorry et al., 2000; Weering, Vollenbroek-Hutten, and Hermens, 2012). The collection modes for data are most commonly done in-person, via mail or over the telephone. There were few studies that utilized mobile SMS technology (Macedo et al., 2014), and lesser that utilized the Internet for collecting data from participants.

As mentioned previously, a problem with the frequency of the data collection intervals are that most studies collect data in-frequently, with monthly, half yearly, yearly being common intervals. The critical point here is the accuracy of patient recall on their pain experience over an extended period of time, where research shows that there is a small bias that can affect such data (Schneider et al., 2011; Turk and Melzack, 2011). Similarly, research shows that more accurate data is collected using diaries due to the real-time nature of such instruments, versus the reliance on the accuracy of patient memory recall (Turk and Melzack, 2011). There are a large variety of data collected that can be classified into various factors, which includes demographical data, psychological, medical history data, to name a few. There is evidence that shows that collection of data about the entire experience from multiple factors, or context should be carried out, in order to correctly understand the entire experience and nature of pain (O'Sullivan, 2012).

3.2 Context Awareness

The concept of context has been around since the 1990s, but only really evolved in the last decade. There are many definitions for context, but we adopt Dey's definition where "any information that can be used to characterize the situation of an entity, where an entity can be a person, place, or physical or computational object" (Dey, 2001, p. 304). Related to the concept of context is contextual awareness, which refers to the ability of a process, system, or program to consider the context by sensing states of its environment and itself, in order to react appropriately (Schilit, Adams, and Want, 1994).

Longitudinal studies in other fields already consider some form of context (Bowen et al., 2008; Cook et al., 2002). The study of context is predominant in fields such as psychology and behavioral sciences, as it provides important information on mechanisms of the phenomena through studying the context to understand the situation (Green et al., 2009; Mishler, 1979). Currently, there are no well developed taxonomies or models that exist to describe situational and contextual factors in relation to humans (Kelley, 2003), especially in the field of low back pain.

In applying lessons from other fields to low back pain, the context around the patient's pain experience can provide valuable information about the situation around the patient's low back pain, which could then lead to a better understanding of the fluctuation and changes in pain.

We define contextual data as data about the context of the phenomena. This research has identified two types of instruments, contextual and traditional. Traditional instruments are classified as such because they provide other data relevant to low back pain studies, but are not necessarily considered contextual information. Four such contextual instruments are sensors, third party data (API), social media and diaries. Similarly, two traditional instruments are pain scales to measure pain, and questionnaires.

The contextual data obtained is modeled using a context model. There are many classes of context models, but the model selected will have to support the contextual data instruments, have the capability for contextual reasoning, the ability to model change over time, and support mobile devices to utilize advances in technology. A comparison of a selection of common context models has produced the Fuzzy Situation Inference model (Haghighi et al., 2008), which this research will extend.

3.3 Summary

In summary, research shows that the intensity of pain varies across the course of a single day (Benedetti, 2002), therefore the existing frequency for collecting pain data is insufficient to produce an accurate understanding of the nature of pain. Pain has been said to be individualistic (Olson, 2014), thus the analysis should be done on an individual basis as the patients' pain experiences can vary with the context of their lifestyle and people around them (De Souza and Oliver Frank, 2011). While there currently are research studying contributing factors, there are no works that attempt to study the nature of pain from a wider perspective that includes contextual factors. Finally, there is a need to capitalize on the potential of using advances in technologies to enable higher frequency of data capture of patient pain context and changes in the patients' pain intensity.

The following section will highlight the research methodology and evaluation planned.

4 Proposed Research Methodology and Evaluation

The focus of this research is the design and development of the approach consisting of the framework which will provide the capabilities outlined in the research aims, as well as the context model. Therefore it will follow the Design Science methodology outlined by Hevner et al. (2004) and Peffers et al. (2007). Design science can be briefly described as a methodology that is concerned with producing an artifact that will achieve the goal.

The research development process will follow Peffers et al. (2007)'s DSRM Process Model, which outlines an iterative process shown in Figure 8 that starts by identifying the problem, defining objectives, design and development of an artifact, demonstration of suitable context to solve a problem, evaluating the artifact, iterating back to design and development and communicating the result.

This research will produce three deliverables, which are the context model to be included in the framework, the CaPT framework itself, and an implementation of part of the framework's components, which will be evaluated for efficiency and usability, as well as usefulness to domain experts.

There is a simulation planned, pending ethics approval which will consist of increasing the data collection frequency of an existing clinical trial, and adding real-time processing capabilities to the online data collection system that I built in 2013. There is a twofold importance here, first which is the ability to track participants in real-time, and to determine if the higher frequency of data collection will improve data analysis capabilities; The second being the demonstration that usage of such tools enables richer data collection without increased cost to researchers.

The final evaluation of this research will consist of simulations using real world secondary data resulting from a real world clinical trial that is in progress at Cabrini Health. There are a series of domain expert interviews planned to evaluate both the model and framework. This simulation will be conducted on the instantiation of some components of the framework as an Android Application.

5 Current Stage of Research

This research is currently in the design phase of the framework. The framework and models are being refined with collaboration from domain experts. As mentioned previously, this research proposes a context-aware approach to low back pain management using pain trajectories. This approach consists of two main parts, which are the Context-aware Pain Trajectory framework (CaPT), and the context model. The literature review on the existing research is almost complete, which will address part of RQ1 and RQ2. The following sections will provide a brief overview of these two parts, along with the expected contributions from this research.

5.1 Context-aware Pain Trajectory (CaPT) Framework

In addressing RQ1, we propose a framework that utilizes novel and rich sources of information around the patient's day to day pain experience, to produce a context-aware pain trajectory. The CaPT framework consists of two sets of components that belong to either the server or client side. The proposed CaPT framework is shown in Figure 1.

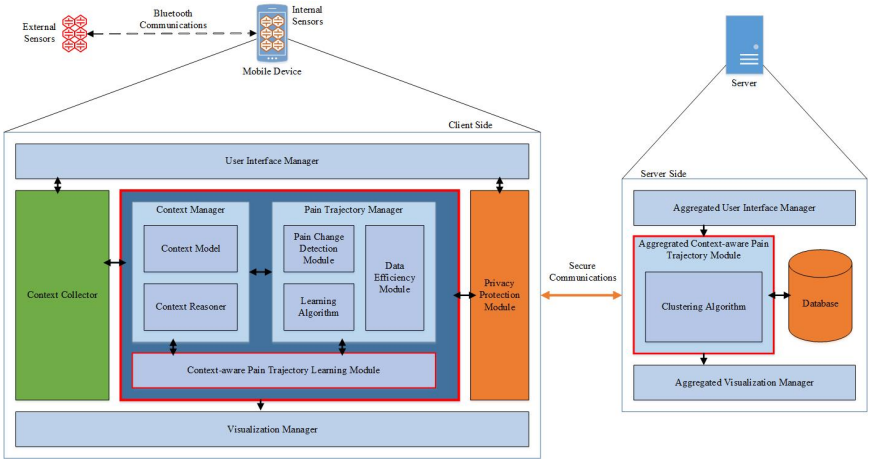

Figure 1. CaPT Framework

A brief overview of the components are provided as follows.

The client side contains seven main components. These are the Context Collector, Context Manager, Pain Trajectory Manager, Context-aware Pain Trajectory (CaPT) Learning Module, Visualization Manager, User Interface (UI) Manager, and the Privacy Protection Module. These modules are responsible for collecting input from the client side device, process and tag the data variables collected with their appropriate context factor using the context model, perform contextual reasoning, detect changes in reported pain intensity, and produce graphs which includes pain trajectories with context for the user. The context model will be discussed in the following section. The privacy protection module allows the user to set tags on all data variables collected with preset levels that determine what data is shared with the server.

Similarly, the server side contains four main modules, which are the the Database, the Aggregated CaPT (ACaPT) Module, the Aggregated Visualization Manager (AVM), and the Aggregated User Interface (AUI) Manager. Data is transmitted securely using private / public key encryption from the mobile devices to the server, and only public or shared data is sent. The data is tagged internally with a unique user ID for research and internal referencing purposes. The server modules have access to all data captured from all users who opt-in. The server side components contain the database to store all data generated and received in a secure manner, clustering and learning algorithms for analysis at multiple levels for researchers, as well as visualization routines for generating and displaying results and graphs of data and analysis collected at different custom levels.

5.2 Context Model

The context model addresses part of RQ2 by providing a context map of how each variable maps onto the context factors. This research has studied current context models for low back pain, and there have been multiple approaches to designing such models. Two of the main approaches are; i) modeling factors of pain leading to burden, and ii) modeling risk factors of pain. As this research is representing the context of a patient, it then makes sense to extend an approach that models contextual factors to some degree.
Through the literature review conducted, this research has identified ten contextual factors for the context model. These factors identified extend the factors identified in Buchbinder et al. (2011)'s work, and considers additional important context attributes based on the literature review in recent studies (Dunn et al., 2011; Lorenc and Marriott, 2014; McGorry et al., 2000; O'Sullivan, 2012; Paltoglou and Thelwall, 2012; Pang and Lee, 2008; Weering, Vollenbroek-Hutten, and Hermens, 2012). There are ten context factors, which includes Pain, Demographics, Employment, Physical, Disability, Social, Psychological, Medical History, Treatment and Environment. This context model will form part of the context model component within the CaPT framework, to allow the classification and tagging of contextual data collected with their relevant context factors.
The proposed context model is more comprehensive and supports new sources of data such as sensors, APIs and social media. It will help to address items to be supported by the framework, and to some extent, guide the capabilities of the framework previously described.

5.3 Expected Contributions

This research project will design and develop a new approach that utilizes novel and rich sources of information about patient's daily pain and pain experience using day to day pain trajectories that takes into consideration the patient's context for low back pain studies of pain management. This project has identified the limitations of the existing data analysis and collection methods, especially in assessing contributing factors of low back pain, as well as the issue of the accuracy brought about by the infrequent collection of pain data. This project has also identified opportunities that exist with utilizing advances in mobile and sensor technology to enhance data collection of contextual information towards an understanding of the patient's pain experience and context around the patient's pain events.
This research aims to contribute towards design and practice by the design of a new approach that enables higher data collection frequencies and the use of richer sources of data for low back pain trajectories. The framework used in the approach will provide the capability to capture contextual information from diverse sources about each pain event from the patient using richer sources of data in both passive and active ways. This research will extend and empirically validate current low back pain context models by considering the patient's context. The model will also be generalizable to other chronic pain management fields.
In contribution to knowledge, the framework and outcomes of this research will provide better insight into the treatment and management of low back pain for domain experts, and provide an opportunity for the patient to better self-manage and understand the nature of their pain, which can lead to lesser problems with over-diagnosis and over-management by doctors, and reduce the cost of unnecessary visits to doctors. This research is also expected to contribute to the body of knowledge in fields such as mobile health-care, fuzzy context reasoning, mobile and ubiquitous computing, and to the low back pain research community.

6 Plans for Completion

Currently, this research is focusing on the design and refinement of the proposed model and framework, and the familiarization with the Android development toolkit. The planning and design of the domain expert interview question and simulations are ongoing and expected to run through Nov 2015, with ethics submitted during the later part of this year. Part of this research is in collaboration with colleagues at Cabrini Health. There are publications planned for the IS and medical fields of conferences and journals,

some in collaboration with Cabrini Health. Figure 2 shows the planned research timeline. It is expected that this research will be completed by the first quarter of 2017.

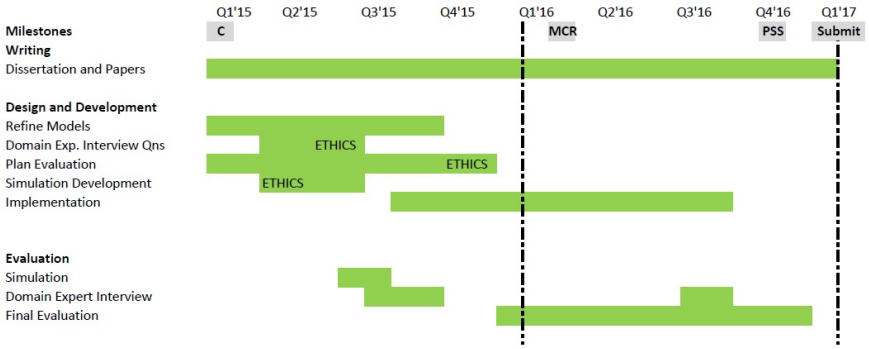

Figure 2. Research Timeline

In summary, in answering the research questions laid out previously, the following are planned:

- RQ1: Review of existing literature and models, selection, design and development of a framework that takes into consideration richer sources of data collection that enables higher frequency of data collection for low back pain trajectories. This is included in the literature review and the design of the framework. The framework will be validated using an instantiation over a simulated evaluation with real world secondary data with domain experts.
- RQ2: The review of existing contextual model literature for low back pain, and extension of a selected model using a contextual factor approach. The deliverable is the context model proposed, which will be refined over this year.
- RQ2.1: The impact of the new proposed approach will be evaluated as part of the simulation described previously, with the final evaluation that is planned in collaboration with Cabrini Health and domain experts. The outcome will be addressed in the thesis results and discussion chapter.

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Recommended Citation
Goh, Tian Yu; Haghighi, Pari Delir; Burstein, Frada; and Buchbinder, Rachelle, "Developing a Contextual Model towards Understanding Low Back Pain" (2015). *PACIS 2015 Proceedings*. 64.
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DEVELOPING A CONTEXTUAL MODEL TOWARDS UNDERSTANDING LOW BACK PAIN

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Abstract

Recent advances in mobile computing and sensor technology have provided new opportunities in data collection and analysis, especially in the medical fields of research. Low back pain is a key area within chronic pain management. It is a widespread problem and a major contributor towards disability worldwide. Researchers have concluded that pain can be an individualistic experience. Evidence from other fields of research show that studying the context of the phenomena can allow for a better understanding of its nature. Existing studies may not consider the full context of the patients' pain, and collect data infrequently (e.g. monthly or yearly). An explanation for this could be due to the cost and difficulty of collecting such data in the past. In this research, we propose a descriptive contextual model that extends a current low back pain model, with contextual attributes and factors. The goal of this research is to provide researchers with a descriptive contextual classification of variables into their respective factors, and to guide future studies in collecting such data, by utilizing advances in mobile and sensor technology.

Keywords: low back pain, contextual model, context factors, mHealth, eHealth

1 Introduction

In recent years, advances in mobile computing and sensor technology have provided researchers with new opportunities in data collection and analysis (Bonato 2005). This is particularly true in medical fields of research, where there has been a gradual shift towards the inclusion of such technology into medical care (Kulkarni and Öztürk 2007). There now exist new areas of research such as Mobile Health (mHealth), which was created to support the use of mobile technology in healthcare (Kumar et al. 2013). However, there still exist some fields of research in medicine that been observed as being slow to adopt such technology, of which one such field is chronic pain.

Chronic pain has been defined as pain experienced that lasts for more than 3 months (Merskey 1986), and is a widespread problem. Chronic low back pain (cLBP) is a leading chronic pain condition, and an important cause of disability worldwide (Hoy et al. 2014). In Australia, one in five of the population suffer from chronic pain, with a yearly cost of $34 billion to the economy. Low back pain studies typically are longitudinal studies as they monitor a population of individuals over a period of time, and collect repeated measures of data. Many approaches to studying cLBP exist, and the predominant approach involves studying the relationship between cLBP and its contributing factors. These studies focus on one factor and assess if there is a relationship between the factor and cLBP. These factors can be described as being contextual to cLBP, and studies commonly analyze the entire population at once, rather than individual episodes of cLBP in attempts to find correlations. Research suggests that pain is an individualistic experience, thus no two patients would experience the same pain (Olson 2014).

The study of context is not new to the field of research on the whole, and has been used to great effect in fields such as psychology and behavioural sciences (Green et al. 2009). There is evidence that suggests there is a need to obtain a shared perspective on the experience of the patient's pain in order to better understand the nature of cLBP and its factors (Howarth, Warne, and Haigh 2014). Existing research shows that there are factors that can be associated with cLBP, but not much is known about the extent and what specific factors these can contribute towards cLBP. In the majority of existing cLBP cases, it is unclear what caused the episode of pain, and therefore referred to as 'non-specific' cLBP. We suggest that the study of the context of the pain episode itself will provide a better understanding of the nature of a patient's pain. Unfortunately, no such framework or model currently exists to understand the context of a patient's cLBP experience. Existing models for cLBP are either focused on a single factor, with variables hypothesized to contribute towards it (Leboeuf–Yde 1999; Maul et al. 2003), or attempt to elicit risk factors of cLBP for a specific population (Bergström et al. 2007; Kovacs et al. 2003). Another study has categorized variables contributing to the burden of cLBP into factors (Buchbinder et al. 2011). None of these studies consider the context of the patient's pain during the data collection and analysis, nor do they attempt to study multiple factors at once.

This research will address the lack of consideration for the patient's context by extending a current cLBP model with contextual attributes and factors, with the goal of enabling a better understanding of cLBP. We will propose a contextual model which will guide and enable researchers in collecting data on cLBP. This research focuses on chronic low back pain and will refer to it as cLBP throughout the paper.

2 Methodology

This research is based on a literature review using the SCOPUS database and through Google Scholar. We searched for papers describing longitudinal studies in low back pain. The initial search from SCOPUS returned a total of 43,726 publications. The filtered results were about 4,000 publications, which were then read and analyzed to determine the current status of the field. Publications found mainly were from

the Spine, European Spine, BMC Musculoskeletal Disorders, Pain, Pain Physician, among other highly ranked journal outlets. The snowballing technique using the references in each paper, was used to discover other papers of interest.

3 Longitudinal Studies of Low Back Pain

Low back pain is a field that has experienced enormous growth, with almost 57% of existing research being published in the last ten years (Elsevier 2014). As mentioned previously, there are a large variety of approaches, which includes investigation into causes and treatments for specific pain, along with research towards understanding the nature of pain itself, which is made difficult by the fact that clinical pain is subjective in nature (Abu-Saad and Holzemer 1981; McGuire 1984).

There are a percentage of cLBP cases that can be attributed towards medical causes such as spine injury, genetic conditions and the like. This research focuses on non-specific cLBP, which refers to cLBP that cannot be pin-pointed to a specific cause or set of causes. Initial research in cLBP included targeting pain receptors to reduce or numb pain, but did not contribute to better care that lead to long term cure or effective treatment (Johnson 1974; Spiegel and Bloom 1983). Currently, the most common approaches in studying factors of cLBP fall into two main paths. The first being longitudinal studies in analyzing possible variables that are able to be related to a specific factor, such as the psychological factor, for a specific population; and the second being studies that conduct systematic reviews or theory building activities to elicit variables that relate to a factor of interest. Studies focusing on analyzing possible variables include research on weight lifting (Chaffin and PARK 1973), between occupations such as nurses (Maul et al. 2003), and populations such as children (Szpalski et al. 2002) or adolescents (Burton et al. 1996). Systematic reviews that attempt to establish if specific factors contribute towards cLBP have identified factors such as smoking (Leboeuf–Yde 1999), body weight (Leboeuf-Yde 2000), psychosocial factors (Hartvigsen et al. 2004; Hoogendoorn et al. 2000) and psychological factors (Pincus et al. 2002). There have been studies that describe these factors as risk factors towards cLBP, which include Smedley et al. (1995)'s work on specific manual nursing activities in relation to the risk of cLBP for nurses, and Kovacs et al. (2003)'s work on risk factors in a population based study of schoolchildren and their parents.

Current research focuses on the factors that contribute or have some relationship with cLBP itself. There are limited successes in identifying these factors within specific populations, but these do not consider the patient's context of pain. These studies typically collect data using traditional methods such as paper questionnaires and in-person interviews. The frequency of data collection seen in these longitudinal studies are also typically of an in-frequent nature, with monthly, 3-monthly and yearly collection being common. This is a problem as there is evidence that the accuracy of patient recall over an extended period of time has been shown to contain bias information, although this is not an issue with shorter periods of a week or less (Schneider et al. 2011; Turk and Melzack 2011). To some extent, part of the reason for this in-frequent data collection is due to the cost of obtaining such data, along with the logistical issue of conducting several hundred interviews or questionnaires every week for an extended period of time.

Experts in the field have identified the need to understand pain and its nature (McCracken, Vowles, and Eccleston 2004), or rather, the need to obtain a shared understanding of the patient's pain experience itself (De Souza and Oliver Frank 2011; Thastum and Herlin 2011). De Souza and Oliver Frank (2011)'s work analyzed patient experiences on the impact of chronic pain, and concluded that their findings were of limited generalizability as the patients' pain experiences changed as the pain varied with their lifestyles and context of the people around them. This suggests that the context of the patient's pain will contribute towards the understanding of the nature of pain itself.

Currently, a large amount of studies in cLBP use statistical analysis on entire populations. There are

currently no studies that conduct statistical analysis on an individual's pain to identify correlations before extending these correlations to the analysis of a population, that is to say, studies typically attempt to analyze the entire population without taking into consideration any, or all of the context available (Cook 2003; Dunn, Jordan, and Croft 2006; Dunn et al. 2011). It is important to then be able to understand the context around the patient's pain experience, and to be able to classify the contextual data in a unifying, coherent manner.

With advances in mobile and sensor technology over the last two decades, it has been possible to collect data in a more efficient manner at lower cost, by conducting questionnaires administered over the Internet, or through a mobile application. There are newer methods of collecting contextual data about the patient's thoughts, feelings and surroundings by using mobile diaries that a patient can enter information on. The same application is also able to collect data about the patient's pain (Gaertner et al. 2004). Apple Inc. (2015)'s ResearchKit platform allows researchers to obtain more data from participating patients in a patient-centered manner. It uses mobile devices which contains a suite of advanced sensors in both active and passive modes. These sensors, along with the mobile device enable the collection of real-time data at large volumes about the context around the patient, along with the pain experience that can be described by the patient in a diary format on the mobile device.

This research will discuss in the following section, contextual data, and propose a contextual model for studying cLBP.

4 Proposed Contextual Model for studying Low Back Pain

In the domain of cLBP, there is no standard methodology used to develop or design a contextual model. There are studies that have conducted systematic reviews to elicit variables related to a factor from existing research which was then used to develop a model. We have taken a different approach where we have examined existing literature as far back as the year 2000 and identified variables that could be grouped into factors, factors themselves that could be related to the context of the patient's pain, or provide important background data that have been used in statistical analysis of cLBP. Our review shows that there exists some models that are built up around specific factors (Leboeuf-Yde 2000; Pincus et al. 2002), and there are studies that consider single or multiple factors that can be contextual in nature (De Souza and Oliver Frank 2011; Karoly et al. 2014; Shaw et al. 2011, 2013). Through the literature review, a paper was identified that discusses development and validation of a model for the burden of cLBP (Buchbinder et al. 2011). The study identified six factors that contribute towards the burden of cLBP, presented as a hierarchical model. Their work also included validation of the naming of these factors. We will extend this model with contextual attributes which will be discussed below.

Context is not a new concept to research, but it is only in the last decade that it has really evolved. There exist many definitions of context, but we adopt Dey's definition as "any information that can be used to characterize the situation of an entity, where an entity can be a person, place, or physical or computational object" (Dey 2001, p. 304). The use of context in research is predominant in fields such as psychology and behavioural sciences, where the study of context is recommended in understanding a situation, in providing critical data about the mechanisms of the phenomena being studied (Green et al. 2009).

In this study, we consider the context of cLBP to be information about the environment surrounding the patient, information about the mental state of the patient, and information about the patient's current activity. Accompanying the context of cLBP is the information of cLBP itself, which primarily refers to the pain intensity, and type of pain; and the information that are the quantifiable statistics in classifying the patient into a population, which are demographical data including age, gender and country. As mentioned previously, existing research already consider some contextual factors. A sample of these studies are

shown in Table 1, along with the study's frequency of data collection. In Table 1, "Pain" refers to the factor of "Pain Characteristics".

Study	Factors	Frequency
Macedo et al. (2014)	Demographics, Physical, Psychological, Treatment, Pain, Medical History	Monthly
McGorry et al. (2000)	Pain, Disability, Medical History	Daily
Dunn, Jordan, and Croft (2006)	Demographics, Employment, Psychological, Pain, Disability	Monthly
Henschke et al. (2008)	Demographics, Employment, Physical, Psychological, Treatment, Pain, Disability, Medical History	Irregular Intervals (Week 6, Month 3, Month 12)
Dunn et al. (2011)	Demographics, Physical, Psychological, Pain, Medical History	3-Monthly
Dunn, Campbell, and Jordan (2013)	Demographics, Psychological, Pain, Disability	Monthly
Steffens et al. (2014)	Demographics, Pain, Psychological, Physical, Environment	Once
Edefonti et al. (2012)	Pain, Psychological, Environment	Daily

Table 1. Contextual factors in a sample of cLBP research

In the following subsection, we propose a set of identified factors from existing literature, of which a sample has been shown in Table 1, and include them in a contextual model.

4.1 Factors of Low Back Pain

Factors of cLBP can be considered as categories of variables which are contextual or non-contextual data. The data can be collected from a variety of sources, which includes sensors and direct input from the patient. Recent growth and advances in mobile technology present an unprecedented opportunity for collecting patient data using mobile and sensing devices. The use of such devices can also reduce the cost of data collection, especially since a large proportion of the urban population owns a smartphone. The sensors built into mobile devices are able to provide a rich source of contextual information about the user's current situation and surrounding environment.

As mentioned previously, studies of cLBP have considered single context factors, and to some extent multiple factors, but are limited in that they only consider specific dimensions to the data rather than the entire situation around the pain experience. An example of such a factor is demographics, which are most commonly collected and include variables such as age, gender, and country (Dunn, Campbell, and Jordan 2013; Dunn, Jordan, and Croft 2006; Dunn et al. 2011). Some other factors include disability (Henschke et al. 2008; Smeets et al. 2006), physical (Adamson et al. 2007; Dunn et al. 2011), and environment (Steffens et al. 2014). In this research, we have selected Buchbinder et al. (2011)'s work on the development of a model to understand the burden of cLBP, where they identified six factors that contribute towards the

burden of cLBP, and presented them as a hierarchical model. Their work also included validation of the naming of these factor names. We will extend this model with contextual attributes.

Through the review of existing literature, we have identified ten contextual factors that are described as follows, seperated into the three categories of contextual data that was mentioned previously. Buchbinder et al. (2011)'s six factors are Physical, Psychological, Social, Employment, Treatment and positive effects. We have adopted the first five factors, and merged the variables under positive effects into the Psychological factor. The model is extended with a further five factors, which are Environment, Medical History, Pain, Demographics and Disability. We describe the factors below in four categories, which are about the external influences, internal influences, current activity and other information relevant to the condition. We also describe some suggested methods of obtaining such data.

Factors about the external influences:

Employment - Employment is defined as occupation related details, and includes the type of work, which describes the nature of work being done, for example physical work or office work. Other points are the effects on the employment situation, and the effects on the workplace. Variables here can be collected using a questionnaire or survey implemented online or within a mobile application. Information such as the occupation details can be obtained once and updated as neccessary, but the information on the patient's perceived effects on their employment or workplace can be provided in the form of guided questions in a mobile diary.

Environment - Environment includes data about the context of weather, e.g. the temperature, and extends to wind chill, wind speed, wind direction, wind gust, air pressure, precipitation and relative humidity. We suggest that such information can be collected from available sensors on the device or via bluetooth, or from third party sources such as the local meteorological station using an API by obtaining the location data from the GPS sensor on the mobile device.

Factors about the internal influences:

Social - Social refers to the extent which the patient is interacting with other people around him or her. This includes psychosocial aspects at home, or negative reactions about the pain that are expressed towards others. Data in this category can be collected using questionnaires or diaries on the mobile devices or over the web.

Psychological - Psychological discusses aspects such as disempowerment, effort of living, negative mental effects, worries, life satisfaction, and depression. A majority of the aspects in this category are typically collected via questionnaires. These questionnaires can be conducted over the Internet in a browser or on the mobile device, and other information such as the feelings and thoughts of the patient can be derived from diary entries on the mobile diary.

Factors about the current activity:

Physical - Physical refers to the exercise and activities that are being carried out by the patient. It includes the exercise, or physical maintenance, or lack thereof, body functioning, participation in physical activities, and the current activity context. Some variables here can be collected via questionnaires or questions that the user answers, which includes information about their participation in physical activities. Other variables such as the current activity context can be obtained by using activity algorithms over accelerometer data collected from the sensors on the mobile device or wearable sensors such as fitness trackers.

Accompanying these are the factors containing other information relevant to the condition:

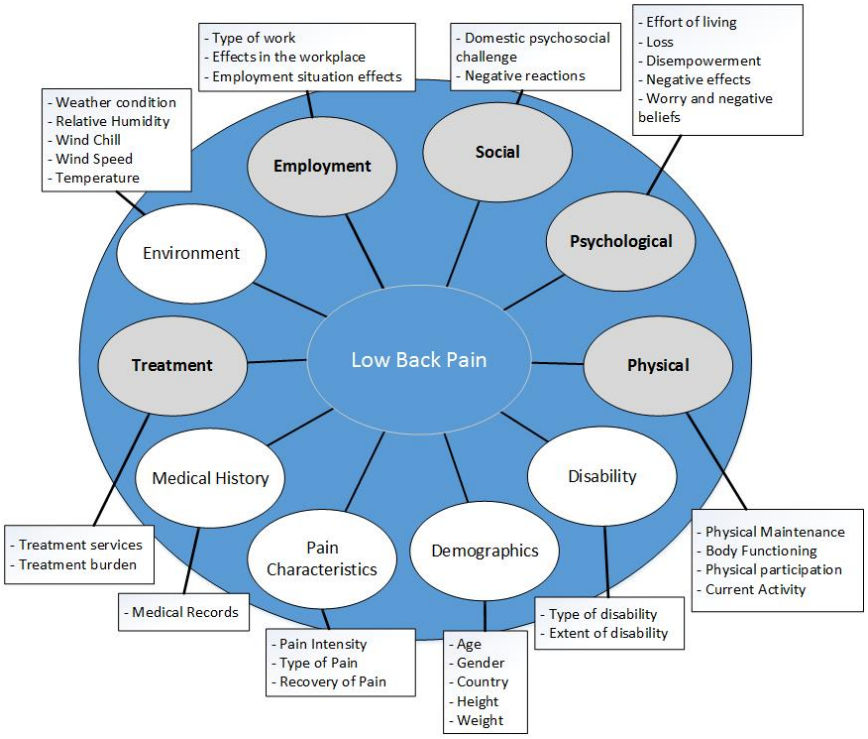
Pain Characteristics - Pain Characteristics refers to attributes that discuss the actual pain, or recovery of pain that the patient is experiencing. This can be collected using the mobile diary, or with simple questionnaires that can be also implemented on the mobile device or over the Internet in a web browser.

Demographics - Demographics are the quantifiable statistics of the patient to a population. Examples include age, gender, ethnicity, country and suburb. These data are typically collected once at the start of the study, and usually are obtained using questionnaires.

Disability - Disability is defined as information about the patient's disabilities. This information can be either collected from the patient's medical records or provided by the patient in a questionnaire.

Medical History - Medical history contains information about the patient's medical records and previous history. This is typically provided by a third party (secure) data store, or by the patient.

Treatment - This factor discusses the current treatment services received or the burden of such treatment, and can be collected from questionnaires or cross-referencing data from medical secure databases, for example the hospital that the patient is receiving treatment from.



4

Figure 1. Proposed Contextual Model for Low Back Pain

4.2 Contextual Model

As discussed previously, we have extended Buchbinder et al. (2011)'s work with contextual attributes. The model shown in Figure 1 links the ten factors as described in the previous section, to cLBP. These factors have a sample set of the common variables observed from the literature, attached in the boxes linked to each factor.

The model represents key contextual attributes and factors (illustrated in circles) that may be important to cLBP. The factors shown in shaded circles are from Buchbinder et al. (2011)'s study. Each factor is linked to a rectangle that provides a sample set of variables. These variables have been identified from studying the literature pertaining to cLBP. The proposed additional contextual factors need to be validated through future research and experiments.

5 Conclusion

While there are many studies that investigate the relationship of factors with cLBP, none specifically document and analyze the context of each pain episode. The collection of contextual data in an efficient, cost-effective manner is now available to researchers by using advances in mobile and sensor technology with platforms such as Apple's ResearchKit, or simply by using learning algorithms with the onboard mobile device sensors or wearable sensors. This paper has proposed a contextual model that extends a current cLBP burden model with contextual attributes. The use of this model in providing better depth into data analysis, will contribute towards a better understanding of cLBP by studying the context in which it occurs. An increased understanding of cLBP can then contribute towards better management and treatments for individual patients suffering from such pain.

There are some limitations to the proposed contextual model. First, the relationships between the factors and cLBP are largely untested. Secondly, this research does not form any conclusions on the strengths or extents of the factors and their variables in the contextual model in terms of their respective relationship with cLBP. The future use of the proposed contextual model will lead to a deeper, more complete understanding of chronic lower back pain, which could result in reinforcement, validation and identification of additional factors and relationships.

6 Future Research

This is a work in progress and needs verification and validation by domain experts and patients. There is an opportunity for the model to be used in building an application similar to Apple's ResearchKit where patients are able to opt-in and contribute data to research. The work could lead to better cLBP management targeted at reducing the events that could lead up to pain episodes in some patient populations, and also lead to a better understanding of the causes and contributors to cLBP.

Acknowledgements We would like to acknowledge Dr. Allison Macpherson from Cabrini Health for their assistance with the original cLBP burden model.

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Integrating contextual and online self-reported data for personalized healthcare: a tennis elbow case study

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Abstract

Advances in sensors and mobile technology have helped evolve the use of eHealth, especially in the field of chronic pain. Chronic pain is a widespread problem where self-management is important. Current studies tend to collect data at sparse intervals due to the cost involved in collecting data using traditional instruments. We demonstrate how technology enables richer data collection frequencies to analyse the influence of patients' context on their pain levels. In this paper, we present a case study as an add-on analysis to a clinical trial for lateral epicondylitis (tennis elbow). We explore the usefulness of on-line key data collected at higher frequencies in explaining or discovering changes in pain. This dataset allowed us to learn that there are no associations with temperature and humidity to this type of pain, that patients tend to have different pain experiences, and that pain at night tends to be higher than overall or activity-related pain.

Keywords eHealth, chronic pain, pain trajectory, context, tennis elbow

1 Introduction

In the last decade, eHealth has become an area that describes digital and technological solutions, that benefit and enhance the quality of healthcare. The adoption of sensors and mobile technology in eHealth has paved the way towards personalization of care, which is, care that is tailored or adjusted depending on the symptoms shown by the patient.

Chronic pain is defined as pain that persists beyond three months (Merskey 1986). As the definition suggests, patients typically do not get cured in a short period of time. In this area, one key component of their care is the self-management of pain. The majority of studies in this field are longitudinal studies, which collect repeated measures over an extended period of time. These studies tend to be expensive, and therefore limited in terms of data that can be collected, with the typical study using traditional data collection instruments such as paper questionnaires. These studies also tend to collect data at sparse intervals. With the use of sensors and mobile devices, we are able to evolve traditional data collection instruments and enable the collection of richer data from the patient, at higher frequencies.

In this study, our main purpose is to illustrate that the use of technology in data collection, at higher frequencies, can provide more informative results. We collected key data at increased frequencies to determine whether measurement of environmental factors such as the temperature and humidity influence symptoms. The analysis explored the usefulness of such data to explain changes in pain due to context, and whether increased data collection frequencies improve the depth of understanding on the trajectory of pain.

The study is an add-on data analysis component to an ongoing randomized controlled trial investigating the value of platelet rich plasma injection or glucocorticoid injection compared with placebo for lateral epicondylitis (LE) commonly known as (tennis elbow). Ethics approval for this study was granted by Monash University and Cabrini Health ethics committees.

The following section will provide some background to our research.

2 Background

2.1 eHealth

In the past, doctors have used sensors and handheld devices to collect data from patients, as is seen in studies such as Silva et al. (2015)'s work on creating a remote monitoring system using sensors and smartphones, Hayn et al. (2015)'s work on using accelerometer and pressure sensors for pressure ulcer risk assessment, or Fisher et al. (2015)'s work on wearable sensors for remote monitoring of symptoms in Parkinson's disease. More recently, technologies such as the Apple ResearchKit and CareKit (Apple Inc. 2016a; 2016b) have changed how doctors perceive the usefulness of technology in healthcare. Researchers are using these technologies as tools to provide better insight to patients about their condition, improving their own care management and health, and care providers about treatment and patient conditions (Apple Inc. 2016b). The move towards personalized care has introduced a need for more data on the patient's condition and context to be collected, in order to best provide accurate care for the patient. Traditionally, such data would have been collected during trips to the hospital or doctor, and in some cases, over the telephone check-ups on a patient's progress (Huang and Matricardi 2016; Raju et al. 2012). It was not too long ago when doctors scoffed at collecting this type of data on a frequent basis due to the problems faced with manpower and costs, but with the introduction of health monitoring devices that utilize sensors, mobile technology and the internet, this has become a reality.

The next section will briefly discuss existing issues in data collection for chronic pain.

2.2 Data Collection in Chronic Pain Studies

There are two main classes of chronic pain, the first being an identifiable class that can be attributed to a known cause; and the second being of a non-specific class, which is not attributed to a known cause (Krismer and van Tulder 2007). One of the main areas of non-specific chronic pain is low back pain, which is the leading cause of disability worldwide (Hoy et al. 2014).

Chronic pain studies typically focus on either identifying factors that contribute towards the pain, or on treatment methods and effectiveness. Regardless of their focus, these studies tend to be longitudinal in nature, that is - studies involving data collected with repeated measures over a period of time. Some of the more prominent studies in this area include Chaffin and Park (1973)'s longitudinal study of low back pain investigating associations with occupational weight lifting factors,

Dunn et al. (2006, 2013)'s work on a seven-year low back pain study on long term pain trajectories, Maul et al. (2003)'s eight-year study on low back pain among nurses, and Siddall et al. (2003)'s five-year study on pain following spinal cord injury.

In most of these studies involving identification of contributing factors, what is typically studied is the main measure of pain represented by a pain trajectory, which is the progress of pain over time. These studies typically attempt to generalize or categorize a population of participants into classes, or clusters (Axen et al. 2011; Dunn et al. 2006). Research shows that pain is typically a very individual experience (De Souza and Oliver Frank 2011; Olson 2014), meaning no two patients would experience the same pain, nor can one assume that pain ratings between patients are equal as patients have varying pain tolerance that cannot be objectively measured (Etherton et al. 2014; Reinhardt et al. 2013).

Similarly, such studies typically collect data from participants over a long period of time, which varies between months and a few years. The intervals of data collection observed also vary between weeks, months and years (Dunn et al. 2011; Henschke et al. 2008; Macedo et al. 2014; Bousema et al. 2007). This presents a problem, as any data collected that is of a sufficiently sparse interval will tend to miss the fluctuations and changes that take place between the intervals. To provide an example, this would be like taking a heart rate measure once every ten-minute interval for 15 seconds duration, which might sound reasonable, but be completely inaccurate for a patient requiring constant monitoring due to a heart condition. In context, this would mean that it would be ideal for a patient to be reporting changes to perceived pain, as soon as they experience it. Unfortunately, it is impossible to demonstrate this with existing data due to the intervals of data collection by current studies. Most studies would have either a sparse interval over an extended period of time, or closer intervals over a shorter period of time. The primary contributing reason to this decision is the cost of data collection – it is relatively expensive to conduct data collection using face to face, over the telephone, or mailed questionnaires, especially once the overhead cost in administering the study, manpower, time, postage costs, and printing costs of instruments required is factored in. This cost quickly scales up due to the population sample size required. As a result, an attempt to compromise by adjusting the intervals of data collection is made.

Traditionally, data collection in this field is done using survey instruments, either in person or via mail. With the emergence of eHealth, new methods of collecting data such as using a secure survey website, or a secure mobile application over the Internet is possible (Silva et al. 2015; Merolli et al. 2015; Stinson et al. 2013). Using such data collection methods can also reduce the manpower requirements in processing physical data collected. This also introduces a level of convenience to the participants, as they will be able to report or provide data while at home, or while mobile using the Internet. Platforms and tools such as ResearchKit or CareKit (Apple Inc. 2016a) bring value to the table by facilitating the environment necessary for researchers and doctors alike to develop applications that provide a two-way flow of information between science and patient care. Patients can provide data to researchers through the data collection application, and receive findings and information that is specific to their condition or context, which is a form of personalized care in itself. Applied in context to chronic pain, this would result in better understanding of pain and the conditions for both researchers and doctors, and a better ability to self-manage the patient's pain.

The following section will briefly describe the research context.

3 Research Context

LE is considered to be an overload injury. It is the overuse of specific muscles at the elbow, which leads to persistent elbow pain (Winston and Wolf 2015). Typically, two thirds of persistent elbow pain are attributed to LE. LE has a typical recovery period of 1-2 years for 80% to 90% of patients (Descatha et al. 2016).

The pain trajectory is used as the main measure of recovery for LE. The pain trajectory is a graph plotting the pain intensity over time. This pain trajectory is important in chronic pain as it is used as the primary measure of recovery and to monitor the patient's progress over time.

In personalized care, the intent is to improve and personalize healthcare for the individual patient. This requires an understanding of the unique context in which the patient is experiencing chronic pain, which can include the scenario or situation in which the experienced pain worsens, or is improved. We can do so by using sensors and online mobile-friendly questionnaires in collecting the relevant data. One issue that then rises is of the data required for the context to be understood. Currently, there are no context models in the specific space for our study on LE. We therefore build

upon the context model by Goh et al. (2015). Although the original model is formulated for low back pain, we believe that the model is generalizable to some extent for other chronic pain areas as they share similar context categories. In this study, we use the context categories provided by the model. One of these categories is the environment, which includes variables such as the weather. The weather has previously been identified to potentially have some influence on pain, which suggests that some symptoms of patients were individually affected by some weather conditions (Bossema et al. 2013).

We collected data online using a secure data collection site that was built for this purpose. We will consider these variables shown in Table 1, which includes the appropriate categories from the model. We have excluded some collected data from this study as they were not collected frequently enough, or the data returned was inaccurate. This is indicated in Table 1 under the 'Excluded' column.

Variable	Context Category	Excluded
Overall Pain	Pain Characteristics	
Pain at night	Pain Characteristics	
Activity pain	Pain Characteristics	
Min Temperature	Environment	
Max Temperature	Environment	
Humidity	Environment	
Independent Living	Disability	X
Exercise	Physical	X
Employment Effects	Employment	X

Table 1. Variables in Context Categories

4 Research Method

This study follows Peffers et al. (2007)'s Design Science Research Model (DSRM), that starts by identifying the problem, defining objectives, conducting design and development of an artifact, demonstration of suitable context to solve a problem, evaluating the artifact and communicating the result. The model is shown in Figure 1.

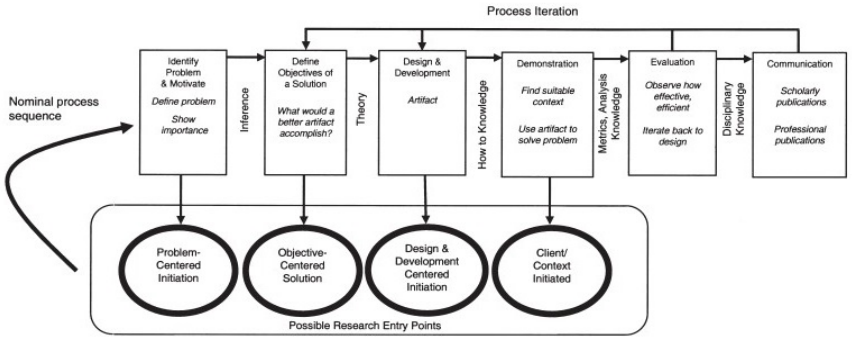

Figure 1. DSRM Process (Peffers et al. 2007, p.54)

Based on the DSRM Process, the problem identified was the issue of sparse intervals in longitudinal chronic pain studies. Our motivation was the emergence of eHealth technologies such as on-line surveys and various platforms such as ResearchKit. The objectives of our study was to then demonstrate how the use of technology can enable the collection of richer data at higher frequencies. This would enable increased explainability of data collected in longitudinal studies, and the ability to address the challenges faced by such studies using more traditional methods of data collection. As

mentioned previously, we designed and developed an on-line secure survey system with a mobile friendly interface for data collection, and then used it with a real world case study. In the section, we used the variables identified in Table 1 to demonstrate the difference with the increased frequency of data collection, when compared to sparser intervals.

4.1 Data Collection and Analysis

As this study is a three-arm randomized placebo-controlled trial, we made as few modifications as possible to the primary protocol of the study. Table 2 shows the adjustments in interval for data collection made to the trial, primarily in the increase of frequency of data collection of pain data to a weekly interval for the first twelve weeks, then three-weekly for the remaining weeks up to 52.

Variable	Original Interval	Adjusted Interval
Overall Pain	Weeks 0, 3, 6, 12, 24, 52	Weekly from 0 - 12, 4-weekly from 12 - 52
Pain at night	Weeks 0, 3, 6, 12, 24, 52	Weekly from 0 - 12, 4-weekly from 12 - 52
Activity pain	Weeks 0, 3, 6, 12, 24, 52	Weekly from 0 - 12, 4-weekly from 12 - 52

Table 2. Adjustments in interval for data collection

Data was collected using a secure website, with a mobile friendly interface to allow for entering of data via a smart-phone's browser. Participants were sent reminders to complete the surveys twice weekly via email.

Patients were recruited into the randomized trial via print and online advertisements, and from medical practitioners (physiotherapists, sports physicians, orthopaedic surgeons, rheumatologists and general practitioners). Patients were considered for eligibility based on five criteria and fifteen exclusion criteria. The eligibility criteria are as follows: 1) lateral elbow pain ≥ six weeks' duration; 2) reproducibility of pain by two or more of the following tests: palpation of the lateral epicondyle and/or the common extensor origin of the elbow, gripping, resisted wrist or second or third finger extension (dorsiflexion); 3) ultrasound-confirmed lesion; 4) age 18 to 65 years; and, 5) ability to read and write in English.

The exclusion criteria are as follows: 1) bilateral symptoms of lateral elbow pain, any other elbow pathology; 2) generalised inflammatory arthritis such as rheumatoid arthritis; 3) concurrent shoulder and/or neck pain and/or pain proximal to the elbow on the affected side; 4) any wound or skin lesion on the lateral side of the affected elbow; 5) neurological symptoms or signs in the affected arm; 6) severe infection; 7) known malignancy; 8) bleeding disorder; 9) previous surgery to the elbow; 10) receiving local glucocorticoid injection in the previous six months; 11) receiving oral glucocorticoids in the previous three months; 12) large tear ≥ 15mm in the common extensor origin; 13) torn lateral collateral ligament; 14) lack of informed consent; and, 15) any other reason thought likely to result in inability to complete the trial.

All participants in the trial were initially screened using the pain reproducibility screening form and had their clinical eligibility criteria confirmed. These participants were then administered a diagnostic ultrasound by an expert ultrasonographer. The ultrasound was used to determine final eligibility and to randomise participants. For this study, we included participants from all arms of the randomized trial.

We originally had a sample size of 36 participants, which was reduced to a final set of 11 due to specific exclusion criteria, which are outlined as follows: 1) incomplete or missing data; 2) entered data late (i.e. week 3 reported in week 4); and, 3) provided data via the researchers directly (phone or in person). We utilized data collected from the first 13 intervals, which is from Week 0 to Week 12.

Participants were asked to report their worst pain level experienced in the past 24 hours for 'overall pain experienced', 'activity-related pain', and 'pain experienced at night', using a vertical eleven-point Visual Analogue Scale (VAS) from 0 to 10, where 0 represents no pain, and 10, the worst imaginable pain.

Weather data was provided by an external third party data source, and aggregated from multiple government weather meteorological services for accuracy, sourced from forecast.io (2016). This data was matched to the previous 24 hours from time of reporting, using the participant's home suburb and postal code.

Data analysis was conducted in two stages. The first stage was a comparison of the pain trajectory, which is pain plotted over intervals of time, for the original sparse intervals vs the adjusted weekly intervals. We plotted graphs for each participant case, for the three pain variables. We used SPSS 24 (IBM Corporation 2016) software for analysis in stage one. The second stage was an analysis using a linear mixed model with fixed and random effects. We used pain as the dependent variable, with minimum temperature, maximum temperature, humidity and type of pain as fixed effects, and the interval clustered within individual participants for random effects. We coded the type of pain as a categorical factor variable with overall pain coded as the comparison group (1), activity-related pain and pain at night coded as (2) and (3) respectively. We used Stata 13 (StataCorp LP 2016) for analysis in stage two.

5 Results and Discussion

This section will first address the pain trajectories generated from the data collected, and will include descriptions for each figure. The participants have been randomly numbered for the figures. Following that, we will discuss the findings of the analysis conducted using the weather and pain data.

The results from the first stage are shown as a set of pain trajectories below, to illustrate the difference in trajectories obtained with a higher frequency of data collection. The pain trajectories cover 3 variables, with overall pain in purple, pain at night pain in blue, and activity-related pain in green. As described earlier, the data was collected at weekly intervals (solid lines), but to allow for a view of what the data would have been should we have proceeded with the original intervals as selected by our medical colleagues, we have included the original interval in short dashed lines of the color of the variable.

The trajectory of the participant in Figure 2 shows an overall recovering trajectory. The participant's reported overall pain is observed to steadily spike up to a peak in Week 2, and again at Week 4, before showing an overall improvement down to Week 12. In comparison, the pain experienced at night seems to be the highest reported as compared to activity or overall pain. The sparse intervals at weeks 0, 3, 6 and 12 tell a completely different story. It seems that the participant is recovering well, with an overall spike at week 3. The pain spikes at weeks 2 and 4 are missed with the sparse interval.

The participant in Figure 3 shows an overall slight recovery, for both night pain and overall pain. The reported pain is erratic and just based on the overall pain, there are spikes in pain observed, peaking at weeks 1, 3, 9 and 12. The sparse interval data (dashed line) does not track any of these fluctuations observed, with a general curve showing improvement up to week 6 before rebounding in week 12.

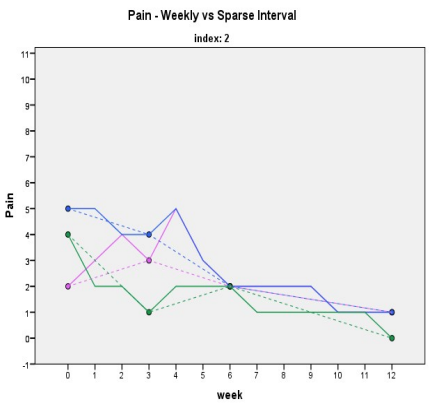

Figure 2. Pain Trajectory – 1

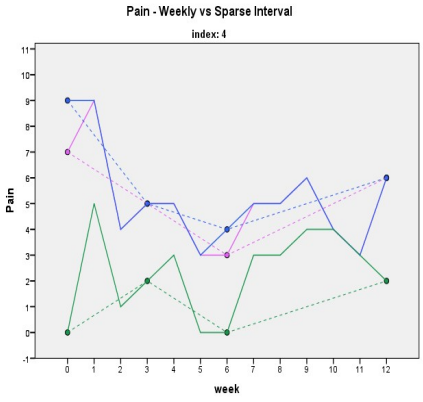

Figure 3. Pain Trajectory – 2

Figure 4 shows a participant with repeated rebounding pain events, where the pain level improves for a week before worsening again, as observed at weeks 2 and 7 at the negative drops in pain. The sparse intervals show an overall worsening trend, which is true of the full data collected for this participant. However, it is of interest to discover what caused the pain to rebound after minimum at weeks 2 and 7.

The participant in Figure 5 demonstrates an overall recovery trajectory, with one major rebound in pain at week 3. The sparse interval data at week 0, 3, 6 and 12 seems to capture the overall trajectory well, with the exception of the main rebound at week 3.

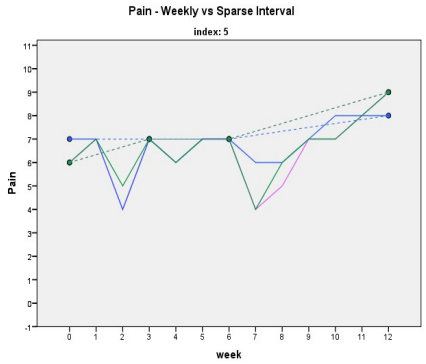

Figure 4. Pain Trajectory – 3

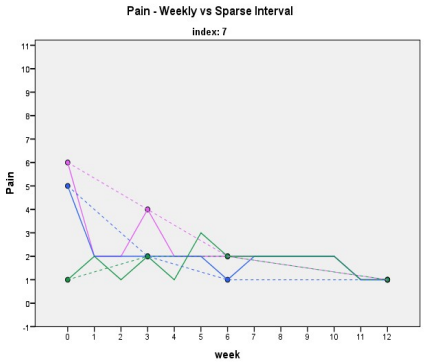

Figure 5. Pain Trajectory – 4

Figure 6 shows another relatively erratic pain trajectory. There are clear peaks in pain at weeks 2, 4, 8 and 12. The trajectory shows the patient improving in week 1 before an initial sharp rebound, although it did not reach the same level of pain as before. As before, the sparse interval fails to capture the bulk of the fluctuations detected, which is of interest.

The pain trajectory in Figure 7 illustrates an overall slight improvement in the condition, with pain peaking at week 3. There are periods of improvement with the rebound at week 3, over weeks 1 to 2. The second rebound in pain is at week 6, with recovery over 3 to 4, and finally a rebound at week 11 after recovery in week 9 to 10.

The sparse interval data fails to capture the three recovery phases in the participant's pain levels.

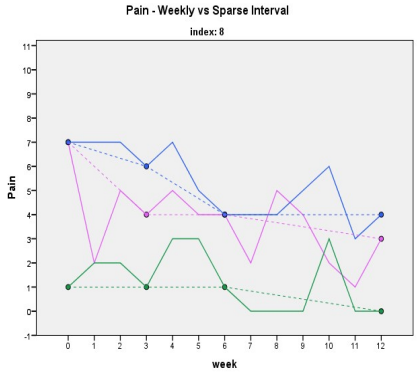

Figure 6. Pain Trajectory – 5

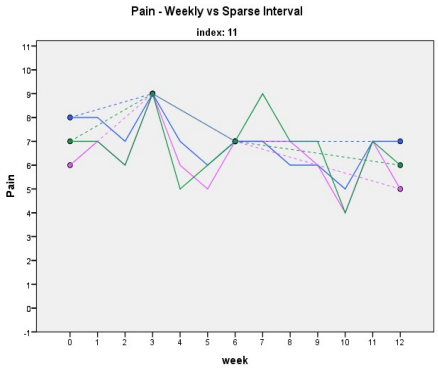

Figure 7. Pain Trajectory – 6

These pain trajectories demonstrate a clear difference in the pain experienced by each patient. It can be seen that the increased frequency of key data also enables the identification of fluctuations in pain that would have gone undetected at larger intervals. These fluctuations are of interest as it allows the identification and discovery of factors that affect or cause episodes of increased pain. Some other interesting points to note are also the differences between data reported for nightly pain vs overall pain. We believe that this introduces an opportunity to discover why such differences occur, which can lead to more effective treatment or interventions.

With regards to the second stage of analysis, we did not find any correlations between pain and temperature nor humidity. Table 3 illustrates the results of the model fitted.

Pain	Coefficient	Std. Err	z	P > |z|	Min 95% Conf.	Max 95% Conf.
minTemp	-0.0218	0.0257	-0.85	0.398	-0.0723	0.0287
maxTemp	0.0055	0.0148	0.37	0.710	-0.0235	0.0345
humidity	0.9893	0.5470	1.81	0.071	-0.0827	2.0615
Type - activity (2)	-0.9510	0.2981	-3.19	0.001	-1.5354	-0.3666
Type - night (3)	0.3706	0.1458	2.54	0.011	0.0847	0.6565
intercept	3.4534	0.7581	4.56	0.000	1.9674	4.9393

Table 3. Linear Mixed Model with fixed and random effects

Table 3 suggests that for the 11 included participants, pain level is not associated with minimum or maximum temperature or humidity. The average activity-related pain is 0.95 units lower than overall pain, and the average pain at night is 0.37 higher than overall pain.

We extended the model in Table 3 by including the interval as a fixed effect, and these results are shown in Table 4.

Pain	Coefficient	Std. Err	z	P > |z|	Min 95% Conf.	Max 95% Conf.
minTemp	-0.0498	0.0324	-1.54	0.124	-0.1134	0.0136
maxTemp	0.0086	0.0154	0.56	0.573	-0.0215	0.0388
humidity	1.0198	0.7770	1.31	0.189	-0.5031	2.5428
interval	-0.1403	0.0338	-4.15	0.000	-0.2066	-0.0739
Type - activity (2)	-0.9510	0.2981	-3.19	0.001	-1.5354	-0.3666
Type - night (3)	0.3706	0.1458	2.54	0.011	0.0847	0.6565
intercept	3.8145	0.8838	4.32	0.000	2.0822	5.5469

Table 4. Linear Mixed Model with fixed and random effects including interval as fixed effect

Similar to Table 3, none of the weather variables in the results shown in Table 4 are associated with pain. Pain is shown to decrease across the intervals as expected. Compared with overall pain, activity pain is lower, and pain at night is higher.

Based on the results of the model run for Table 3 and Table 4, there is no association with temperature or humidity with pain. As expected, the participants show a general recovery across intervals (time). Pain at night is shown to be higher than overall pain, and activity-related pain is lower than overall pain.

6 Conclusion

The introduction of sensors and mobile technologies in eHealth, and the advent of platforms such as ResearchKit and CareKit (Apple Inc. 2016a) has led to an increasing amount of chronic pain studies that utilize such technologies. However, we have yet to see other studies that address the critical problem of sparse data intervals, especially in chronic pain. We have illustrated in this study that increasing the data collection intervals will allow the detection of previously unknown fluctuations in the data, thereby possibly increasing the usefulness of the results and data. The increased frequency of data collection has identified interesting fluctuations in pain that are unexplained. This has been made possible with the use of eHealth technologies to overcome limitations of traditional data collection methods such as paper surveys. Such technologies can allow for participants to provide more accurate data in a convenient manner, enabling a path towards personalized healthcare.

There are some limitations to the data, the analysis, as well as our findings in this study.

First, the weather data collected was based on the previous 24 hours minimum and maximum temperature of the participant's home suburb. However, this may not have been the exact location of participants when they completed data collection. We did not differentiate between indoors or outdoors temperature as the participants were asked to provide a rating of the worst pain experienced in the past 24 hours, which probably includes time spent both indoors and outdoors. Similarly, the limitations to the study as a whole were our inability to collect and study other contextual factors such as physical activity, use of analgesia and emotional factors.

Secondly, the question provided to the participants was not about their current pain, but the worst pain experienced in the past 24 hours. Although unlikely there may have been recall bias. This is a two-pronged problem where both the data collected, and the questions asked have to be devised in a way that provides an accurate way to combine data from multiple sources. We believe that for the analysis to be accurate, the method of data collection has to be altered somewhat. We recommend that participants be asked to provide current ratings of pain rather than for a past period of time. The participants should also be asked to report any perceived changes as they occur. This will allow for the reported pain to be as accurate as possible.

Thirdly, there were incidents where the participant forgot to enter the data, and provided the information late (memory recall) to the system, or directly to the researchers. In these cases, we removed the participant from analysis as a result of an inability to map the data to the correct time period for the environmental context.

Fourthly, our sample number was small. While these data provided a useful insight into the fluctuation in pain seen over weekly intervals in people participating on a LE trial, whether or not more frequent data collection would alter the trial findings remains to be determined. On the other hand, further research trying to explain these fluctuations may provide useful insights into why these fluctuations occur and how these might best be managed.

Finally, in using Goh et al. (2015)'s context model categorizations in this study, we have utilized a minimal set of context factors. It is possible to include other contextual factors listed on the model, but we have not done so due to constraints of the clinical trial.

This paper has reported on findings from a case study conducted in conjunction with a clinical trial. We believe that this research has multiple implications in the information systems and medical domains of knowledge. First, although we have a small sample size, it is clear that the participants had different pain trajectories or experiences in pain. This supports the theory that pain is an individual experience (Olson 2014). Second, this study has been only made possible through eHealth - using technology for healthcare purposes. However, issues were met with participants not entering data in a timely manner. This remains an important issue, especially for longitudinal studies where data is typically collected over an extended period of time. Third, this study shows that collecting data at higher frequencies provides more informative results, and is possible with the use of technology. This allows traditional data collection instruments to evolve and surpass its limitations in the path towards personalized healthcare. Finally, as participants in this study are enrolled in an ongoing trial in which neither the participants nor outcome assessors know which treatment has been received we were unable to assess the pain data according to treatment group. We intend to follow up on this at the conclusion of trial to determine whether analysis by treatment group reveals any additional insights into the pain fluctuations that were observed.

7 Future Research

We will be extending this study into a larger scale data collection research. There is an opportunity to conduct a larger scale study with a larger set of context mapped variables with chronic pain patients. The work can potentially lead to better personalized healthcare, and to a deeper understanding of chronic pain conditions. There is also an opportunity to explore if the increase in the burden of response, or reporting requirements has had an impact on the motivation and willingness for participants to complete the study on time. We are looking to investigate this in a future study.

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Acknowledgements

We would like to acknowledge Professor Leonid Churilov for his assistance with the statistical model selection.

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Empirical study of user experience on mobile data collection for chronic low back pain

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Abstract

Design of mobile, personalised healthcare information systems facilitate a paradigm shift in management of chronic conditions. They provide an infrastructure for creating personalised treatment plans that are evidence based. This is especially important in chronic pain, which is a long-term condition and requires self-management by the patient. In this paper, we use a mobile accessible, web based system to collect daily reports on chronic low back pain. Based on this data a pain trajectory is generated to provide a report for patients to track their pain. We present an empirical study exploring the experiences of the participants, the usability, and issues that encompass frequent data collection using such systems in chronic low back pain.

Keywords Chronic Pain, Pain Trajectory, Empirical Study, Personalised Healthcare, Low Back Pain

1 Introduction

Personalised healthcare and medicine began from tailoring treatments and medication based on the biological profile of an individual using their DNA, and has driven a change in paradigm away from a 'one size fits all' healthcare approach, towards personalised treatments. One recent development of interest is the Quantified Self (QS), which describes "any individual engaged in the self-tracking of any kind of biological, physical, behavioural, or environmental information" (Swan 2013). The concept of QS is especially relevant in the field of Chronic Pain, where the self-management of pain is critical to the long-term treatment of most chronic pain conditions (Goh et al. 2016). Thus, the collection of such information in QS can be considered as the contextual data available around pain experiences. QS isn't sufficient by itself to trace or track every factor possible, but is required in order to track specific factors that affect the individual patient.

QS is considered to be a specialised area of data collection. Doctors have specialist instruments that assist in viewing or studying specific incidents of pain, such as questionnaires or equipment that can scan or monitor various pointers that may trigger pain. The critical problem here is that - for self-management of pain, patients do not have such instruments available, as these specialised instruments are not and have not been translated into self-recordable instruments to study the burden of cLBP.

Personalised healthcare and QS combined have also enabled a second change in paradigm, away from episodic treatment of chronic pain, towards continuous healthcare. Continuous healthcare refers to the provision of healthcare that is ongoing and adjusted according to the symptoms of the patient, and is independent of the patients' visits to their doctors (Fernandaz and Ong 2015). Instead, by collecting real-time information and data on the patient's experience of pain, it is possible to provide real time advice and enable the understanding of how behaviours and actions affect the patient's outcome and tailor therapy accordingly. Therefore, it becomes possible to have personalised, close to real-time monitoring, with feedback to the patient which has the potential to better target therapies including medication so that rather than a set prescription medications and other therapies can be better targeted to peak pain. This has the potential to significantly reduce the use of medications such as narcotics, whose use is currently at epidemic proportions with significant community wide harm.

Real-time information on the patient's experience of pain is critical as recall of pain has been shown to be a potential affect with longer durations (Schneider et al. 2011; Turk and Melzack 2011). Ideally, pain should be measured as close to when the patient experiences it as possible. In research on Tennis Elbow, Goh et al. (2016) showed that it would be promising to collect data using a web based, mobile accessible data collection site with contextual factors. The use of mobile devices such as smartphones to collect data makes sense as many people carry around such a device on a regular basis, and has been done in other research studies (Boulos et al. 2011; Medhanyie et al. 2015; Torous et al. 2014).

This study focuses on exploring the mobile data collection method for chronic low back pain, and to study the strengths, limitations and impact that such methods would have on the participant. In answering this research question, we have conducted an empirical study that used mobile devices to collect data on daily changes in cLBP levels. The theoretical foundation supporting this study was based on a contextual model for low back pain that was discussed previously (Goh et al. 2015). In this paper, we report the study results on the usability of the web-based system empirically as a reflection from the process of setting it up, as well as the data collected. The results are discussed in the context of what participants found to like or dislike, which can be considered factors that drive the use or disuse of the system. This study builds on the generalised usability guidelines recommended by Nielsen (1995), which were widely referred by more recent studies of mobile technologies, including those applied for healthcare applications (Arnhold et al. 2014; Villarreal et al. 2015). The study received ethics approval from the university ethics committee, and was conducted in collaboration with colleagues from Victorian hospitals.

The following sections will briefly discuss chronic pain within personalised healthcare, data collection in terms of the use of some mobile technologies, outline our research methods and then present our findings and discussion of the results.

2 Chronic Pain in Personalised Healthcare

Chronic pain is pain that persists beyond three months (Merskey 1986). This means that the patients suffering from chronic pain typically do not recover after an extended period, and in many cases, not at all. Chronic Low Back Pain (cLBP) is a chronic, ongoing condition that can be classified into two classes: i) Specific, and ii) Non-Specific. Specific refers to cLBP that has an attributable cause or condition, whereas Non-specific refers to cLBP that can't be resolved to a specific cause of the pain (Savigny et al.

2009). Pain intensity is represented visually as a Pain Trajectory (PT), which presents an overview of the pain experienced over time using an eleven-point scale of 0 to 10. The pain trajectory is important as it visually shows the experience of pain over time. Non-specific cLBP typically doesn't have an estimated recovery period and is expected to take years for improvement, therefore the emphasis in treatment is the self-management of pain over an extended period of time.

Pain is a very individual experience, with no two patients having the same pain experience (Kongsted et al. 2016; Olson 2014). This can be due to any combination of lifestyle patterns, occupation, living conditions, and not least of all - the type of chronic pain that the patient is suffering from. Currently, chronic Low Back Pain (cLBP) is the leading contributor to disability (Hoy et al. 2014). In studying such pain, existing studies typically collect data specific to one domain of interest, such as the patterns of cLBP in nurses (Maul et al. 2003), the effect of weather on cLBP (Steffens et al. 2014), or even depression symptoms as a factor in cLBP (Pinheiro et al. 2016).

Pain is a self-reported variable, and is typically collected using validated measures such as the Visual Analogy Scale (VAS) (Bijur et al. 2001), Numerical Pain Rating Scale (NPRS)(Farrar et al. 2001), or Categorical Rating Scale (CRS)(Hartrick et al. 2003). This data is commonly collected at intervals of monthly, and 3-monthly in the case of clinical randomized trials.

Research in chronic pain discussing personalised healthcare, or means towards more individualised measures and treatment have started to identify the need for more granular data (Kongsted et al. 2017), especially in the case of cLBP where the majority of the cases are non-specific. A recent review of non-specific low back pain by Maher et al. (2016) identified a major research priority in the field, which was to understand what causes low back pain. The same review also described the need to identify phenotypes with a pathoanatomical or clinical basis in order to find new approaches to self-management of cLBP.

The move towards personalised healthcare is also present in the use of medication. Schork (2015) put forward a case towards 'one person trials' for medication, by utilising mobile devices (i.e. apple watch, monitors) that can collect health data such as glucose or heart rate information. Zheng et al. (2008) proposed a self-management system for chronic pain that would enable monitoring of changes in chronic conditions that can be provided to the individual patient as feedback, in order to self-adjust their lifestyle and activity patterns to reduce pain.

The following sub-section will outline some studies that utilising dairy style or web based questionnaires in Chronic Pain.

2.1 Mobile Technologies in Data Collection for Chronic Pain

We reviewed recent studies utilising mobile accessible data collection methods over a period of time to collect data on Chronic Pain.

Stinson et al. (2006) evaluated the usability of an electronic chronic pain diary for adolescents suffering from arthritis. The diary collected pain ratings three times daily using the VAS measure, along with a picture of the body that allowed the patient to indicate where they were hurting, along with questions on how much it hurt, among other questions from the Brief Pain Inventory-Short Form. The researchers also reported that the use of such diaries require more consideration on the user interface design.

Macedo et al. (2014) used short messaging service (SMS) to poll participants of the study for their pain ratings every month for a year. They reported that there were participants that did not reply to the messages, and there were participants that did not own mobile phones, or know how to use SMS. Kristjansdottir et al. (2013) evaluated the efficacy of a smartphone based intervention for self-management of chronic pain. The device used 3-daily diary style entries over a period of four weeks. They report that such mobile interventions are beneficial, especially when personalised feedback is provided. Similarly, a systematic review by Cuijpers et al. (2008) shows that internet based interventions are comparable to face-to-face versions, and will be a major method in delivering such interventions in the future.

Although there were studies through history that utilised such data collection methods, we found none that focused on the use of mobile devices (i.e. smartphones) that enable the patient to self-monitor their pain using a pain trajectory. The following section will describe the research design of this study.

3 Research Design

This study used a participatory research approach, as the research project was collaborative in nature (Linger 2006). This was necessary for us to make use of the expertise that the medical researchers had,

in enabling the collaborative design of new questionnaires that collected contextual data about the pain experienced. The instruments used had to be adjusted in collaboration with the clinicians as the normal usability questions did not apply. The questionnaires formulated this way used both validated questions and instruments, as well as new questions to collect information about the context of pain from the participant.

There were four inclusion criteria for this study: i) Participant must be currently have chronic low back pain; ii) Participant must reside in Australia; iii) Participant must have access to the Internet regularly; iv) Participant must have an email address that they check regularly.

We contacted 899 people in total via email, with 94 (10.5%) people signing up to the study. Of these 94, 5 participants dropped out during the study, giving a participation rate of (95%) of those who were recruited and a completion rate of 95%. The response rate for the exit questionnaire was 42.6% of the cohort.

Data was collected using an online, mobile-accessible secure data collection system that was custom built for this purpose. The system provided a view of the last seven days of pain reports as a pain trajectory that was featured on the user's dashboard upon logging into the system. The system sent daily reminders at a self-selected time of either 6am, 12pm or 6pm via email to the participant.

The study had four questionnaires, two of which collected daily and weekly pain data, over a period of 32 days. The other two questionnaires were administered at the completion of the study, and contained questions on usability, as well as the usefulness of the system and the pain trajectory display. These exit questionnaires were anonymized and was sent on the 34th day after beginning the study. The questionnaires used in this study were developed in collaboration with clinicians from Victorian hospitals.

The pain questionnaires collected data on pain intensity using the NPRS, as well as contextual variables that were identified by a contextual model of chronic pain (Buchbinder et al. 2011; Goh et al. 2015), as seen in Figure 1. The system provided the pain trajectory of the previous seven days' worth of pain reports to the participant, as seen in Figure 1b.

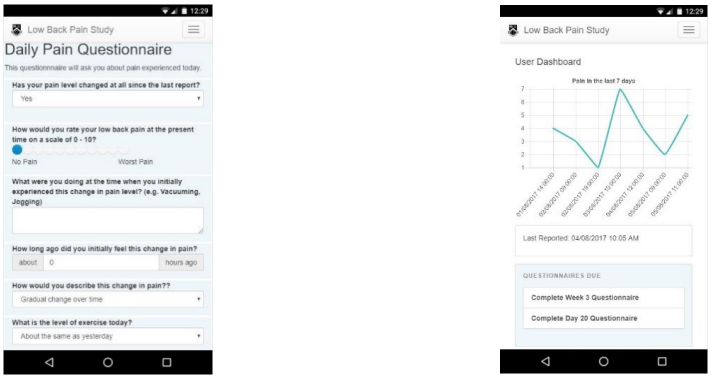

Figure 1. User Interface of (a) System Daily Questionnaire and (b) System Dashboard with Pain Trajectory

The exit questionnaire was administered depending on the status of the participant. There was one for participants choosing to opt-out, or drop out of the study, as well as one for participants that completed the study. The exit questionnaires are described in Appendix 1.

From the viewpoint of setting up such a study, there are various considerations such as the security of the data, which typically is classified as 'critical' by data protection and privacy Acts. This means that the data stored must be encrypted and secured to some extent such that only the authorised researchers would be able to access it. Similarly, traffic to and from the data collection system must be secure and encrypted to prevent data leaks.

4 Data Analysis

The analysis will be primarily based around the exit questionnaire, as well as email and phone contact notes between the researchers and the participants over the course of the study.

We used NVivo to perform qualitative thematic analysis (Fereday and Muir-Cochrane 2006) to identify themes and code the data collected from the questionnaire, as well as the notes taken from the phone and email contacts between the participants and the researchers. The thematic analysis was aimed at understanding the impact that using such a system has on the participant. We intentionally made the questions open-ended in order to capture the user experience.

To better understand and represent the themes found throughout the data, we classified these into common themes. We found that there were four main themes that pertained to: i) self-management of pain; ii) user experience; iii) questionnaire design; and iv) compliance. Further sub-themes emerged from each main theme, as shown in Table 1.

Main Theme	Sub-Themes
Self-Management of Pain	Monitoring of Pain over Time
	Awareness of cLBP
	Self-Reflecting Behaviour
User Experience	Usability and Accessibility
Questionnaire Design	Question Response Granularity
	Daily Diary Response Format
Compliance	Issues with responding to questionnaires
	Missing Data

Table 1. Themes from Thematic Analysis

The following section will discuss our findings from the study.

5 Results and Discussion

We discuss the findings using the four main themes identified from the thematic analysis of the questionnaire data and notes taken during the study in this section.

5.1 Self-Management of Pain

The theme for self-management of pain relates to the ability of participants to self-manage or understand their own pain. This includes enabling the monitoring of their own pain, increased awareness and enabling self-reflecting behaviour with guided contextual questions.

Most participants described the ability to monitor their own pain levels useful, and one such participant mentioned liking the ability to "note(-ing) the status of my back pain systematically". The pain trajectory graph shown on the dashboard allowed the monitoring of their own pain over time, and they could correlate and better remember what their pain was like at a previous reporting point. Another participant described it as "seeing the change over time" helped with their understanding on how their pain fluctuated and changed over time depending on what they did. It was also described as being "interesting to take note of my pain over the period and the changes …" that the participant experienced. The ability to monitor their pain has also increased the participants' awareness of their own cLBP, as described in the next section.

The diary style where the participants "describe daily where the pain initiated from", combined with the 7-day pain trajectory graph allowed them to be more aware of the days that they did not experience much pain, and "enabled me to appreciate the good days more than I would ordinarily", or that it "helped … realise my back pain isn't as bad as some days". There was also an increase in awareness of potential triggers of pain as participants identified some activities that they did that would cause an increase of pain, which was described as being "more aware of what activities aggravated or helped my back pain" and "… of what affects my pain". As the participants become more aware of their own cLBP, we observed some self-reflecting behaviour, as described in the following section.

Some participants experienced self-reflecting behaviour, with reports that it "made me take more care in what I did", and at the same time, "made me think about what I was doing to manage my back pain". Some participants also reported that being able to "describe daily where the pain initiated from" was something they liked about the system. Some participants also communicated via email or phone that they liked how they could "... confirm the pain I had was as I thought". Participants also commented that it was great as the system "drew my attention to the different levels of pain and gave me opportunities to do something proactive about them", and that "I could see what my back pain was and relate it to what I had been doing". On the other hand, there were participants with severe pain who commented that such systems were not so good as it made them "think about something I try very hard to ignore". Some participants that mostly experienced constant pain reported that it was not as useful, and made them to think about the pain all the same.

5.2 User Experience

In discussing the user experience, we asked the participants to rate their experience on an 11-point scale from 0 to 10, with 0 representing 'Worst' and 10 representing 'Best'. The average experience rating was 7.2, with a median score of 8, with 60% of respondents rating above the average score. We identified two themes within this area, the usability and accessibility of the system, which are discussed as follows.

We found that participants tended to describe the 'usability' of the system as a separate attribute or feature to the 'accessibility' of the system. Accessibility is not an attribute that has been used in usability studies, and is not discussed as a part of the ten usability heuristics in Nielsen (1995)'s work, nor the models described in Harrison et al. (2013) and Baharuddin et al. (2013). Participants described the system as being "easy to use", "easy to complete" and "simple", with some participants commenting that it was great as "the prompts where a good reminder". The system was available over the Internet, and accessible using a modern web browser such as Google Chrome. It also had mobile views that allowed easy access on the go using smartphones or tablets, which was participants liked as it enabled "being able to log in anytime". The data suggests that the accessibility of a system plays a part in the usability, or intention to use a system. The researchers also received email and phone calls after the study to thank them for the opportunity to "let me know more about my actual pain", and in one case that "it didn't always hurt as much as I thought".

5.3 Questionnaire Design

The questionnaires used in the system were designed using a participatory research approach in collaboration with clinicians. One of the objectives was to reduce the response load or burden of the participant when responding to these questionnaires. Therefore, we designed them to be short and guided diary styled using short questions that had specific selections, or short questions that would have open fields for answering.

During the first week of the study period, we had contact from participants regarding answering these questionnaires. There is a question that asks about 'how long ago did you experience this pain', and the answer field was for 'about x hours'. The researchers discussed this and decided to use a whole number result (i.e. 1 hour) instead of decimals as we felt that no one would want to provide extremely accurate numbers (i.e. 0.33 hours). There were many participants that experienced errors as the system would not allow them to provide such accuracy, in the words of one participant that reported "couldn't submit and there was an error on the hour question that i put 1.56 hours on". We amended the question to read 'in whole numbers' instead to avoid confusion.

Participants also reported that the question responses did not offer enough granularity, such as "sometimes I couldn't exactly explain my pain", or "there was no way to describe the nature of the pain e.g. aching, stabbing, cramping, throbbing, ... using yes or no as alternatives is frustrating too because I don't know if I missed any", and "the information I could provide to explain the variances in pain to be too limiting". There needs to be further revision to the questionnaires used in expanding the way that we ask the participant on pain.

Some participants also reported that the questions were not very relevant or useful to their specific condition as there were "not enough expansive causes of back pain and associated pain", and for some participants that did not exercise on a regular basis or at all, "the exercise question was not relevant".

When asked about the use of the daily response format, participants were mostly positive and some reported "liking(d) that you had to do it every day", with participants being more aware and "... take more care in what I did", in terms of activities during the day. Concerns that we had on the burden of response regarding the time it would take to complete the questionnaire led us to designing the questionnaire in a way that would allow the participants to complete it in a short amount of time be

completed in a short manner, which seems like it was well appreciated by participants, who also reported that "it was very easy", but would be better for the duration of the study to be shorter. The average daily response took about 48.18 seconds, or just under a minute.

5.4 Compliance

Compliance issues are broken down into two sub themes: i) issues to do with responding to the questionnaires; and ii) missing data from participants.

The most common issue we had were technical issues to do with the participant's Internet connection, with 15% of participants reporting this problem. Some participants reported that they had "initial log on difficulties" in the first week of the study, which stemmed from them not remembering their password that was provided during the registration process. The system was amended to also include their password in their welcome email for the participants' convenience. The other most common report from participants was that they could not remember if they did report on time or if they forgot to complete it as the system did not give them an overview of the reports that were missing, as summed up by a participant: "I'm not sure if I did, I just can't be sure that I didn't".

In terms of missing data, we identified five main reasons that participants reported as the reason to them not completing surveys, which were that "I forgot to complete the survey although I received a reminder", "was away on holiday", "too busy at work", "didn't do it on the weekends" and "there was no change in pain".

Participants that reported no change in pain found this style of daily reporting very tedious and of no benefit to them as they said that their pain does not fluctuate and that they are "not as sensitive to pain" after living with it for an extended period.

6 Conclusion and Future Research

We presented an empirical study that utilised a mobile-accessible, web based data collection system for chronic low back pain. It is expected that personalised healthcare will grow over the years in adoption and research that combine newer technologies that include sensors and mobile phones. This study has discussed some findings in terms of using daily questionnaires for the collection of data, as well as the use of a 7-day pain trajectory in helping memory recall and self-management of cLBP. This study also used Goh et al. (2016)'s recommendation that in collecting self-reports for pain intensity, that the question asks for current pain instead of pain for the past period of time. We have not seen many studies that address the integration of sources of contextual data into the routine data collection of cLBP in order to understand the patient's pain experience.

There are some limitations to the findings in this study. The sample size in this study is not indicative of the population, but a small representation of the views from users of such a system. The system was built to be a web-based instead of native android or apple device application in order to have a single unified site that will also accommodate participants that want to make reports from desktop based devices.

We believe that the findings of this research have multiple implications in both the medical domain of knowledge, as well as the domain of information systems, especially for researchers that want to build onto the existing work.

The development of such data collection instruments such as the daily questionnaire has to be using validated outcomes, and where none exist for the measure to be collected, it is imperative that the work is done in a participatory, collaborative way that includes the medical experts such that the data collected can be analysed in a meaningful manner.

It may be useful to have a system that is capable of 'learning', that is; it allows participants to add options to questions as we found that participants actually wanted to be more descriptive in their answers where we were prescriptive in the options available.

Some participants that already have been living with chronic pain do not want to think of the pain, and try to distance themselves from the pain. This is true especially if the study protocol requires daily reporting as ours did. There needs to be a clear separation between self-reflection and simply making the patient think about how bad the pain was. One participant that contacted us via phone near the conclusion of the study described how the pain was so bad that they usually avoid thinking about the pain and immerse themselves in work or other activities.

The use of the pain trajectory as a representation of the experienced pain in the last seven days helped with patient recall of their previous reports, and in turn made the data reporting more accurate. It also

played a part in allowing participants to better understand their historical pain, with some participants reporting that they now realise that their pain was not as bad as they originally thought. This has implications for the data collection frequency as such a display simply is not useful at larger intervals. The usefulness here stems from having daily reports, as well as ad-hoc reports that are provided when the patient experiences changes in pain.

This work reinforces the finding made by Goh et al. (2016) that participants do not always enter pain reports in a timely manner. As discussed previously, there was missing data as participants forgot to provide the pain report due to various factors, despite reminders being sent daily. There needs to be further work into studying how this can be best alleviated.

The participation rate of 94 sign ups from the cohort contacted doesn't reflect the likely utility of such a device as it was expected to get a modest participation rate from recruitment. Having 95% of the signed up cohort complete the study means that once the study started, people seemed to like it, which is important. The participants that were signed up to the study did not miss many reports, with more than half of the participants having 29 days of reports on average. The completion rate of the exit questionnaire indicates that the results are not unbiased, in that either people that liked or disliked the system have responded. There needs to be further work to look into this further in a systematic manner.

When designing such systems that are primarily used via mobile devices, the usability of the system on a mobile device must be considered separately to its counterpart on a desktop device. Our study used the following design rules: i) simple and consistent layout and design; ii) larger nodes and elements for ease of pressing; iii) distinct and clear use of colours to differentiate components; and iv) the interaction required of the interface is clear and visible through using visual affordances that requires no explanation (Norman 2013). These compliment the standard user design guidelines provided by Nielsen (1995), as well as these current studies (Joyce et al. 2016; Nayebi et al. 2012).

In considering usability testing attributes or variables, there have been studies that reviewed or elicited such measures. We find that most studies revolve around the standard Nielsen (1995) guidelines, and tend to use a similar set of usability attributes or variables in their model. The PACMAD model proposed by Harrison et al. (2013) describes an extension of Nielsen (1995)'s work, and identifies seven usability attributes for mobile applications, and considers the use factors of the user, task and context that impact the final design of an interface. Baharuddin et al. (2013) identified ten usability 'dimensions' that are based on the contextual factors of the user, environment, technology and task. This study took the approach of considering usability and other factors that impact the user's experience by eliciting likes and dislikes of the system from participants by coding themes from the responses by the participants. Our results agree with the usability models discussed, but align closer to Baharuddin et al. (2013)'s work where the user experience or 'usability' was affected by the context in which the system was used for a specific task, or set of tasks. We found that the user experience was impacted by the environment, and the technology (e.g. iPad, android device, desktop computer, laptop) where the system was being used.

In future work, we intend to develop the questionnaires designed through participatory research further to encompass more contextual factors, including the use of sensors to detect and learn the patients' regular movement and activity patterns. There are opportunities to extend this study to improve the use of such a system by participants, to understand what times are best for reminders to be sent and to explore the patient's mood in relation to their experienced pain. We are also interested in the potential to link this to other data collection methods in order to make it a more integrated system. There will also be further work on how such systems could impact the participant's daily routine and potentially their self-management or understanding of their own chronic pain. We also intend to build upon the themes coded in the analysis of this work to identify factors that affect the user's intention to use such a system. Another potential area to explore is on how technology can best help alleviate the non-compliance of participants in terms of reporting their pain. This work would potentially lead to a deeper understanding of non-specific cLBP and a formal methodology of contextual data collection for cLBP.

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Appendix 1

The following are the two exit questionnaires used in the study.

Exit Questionnaire A: For participants opting out mid study (dropping out)

1. Why are you opting out of this study?
    a. Not Interested
    b. Time constraints
    c. Technical Difficulties
    d. Other (please describe)

Exit Questionnaire B: For participants that have completed the study

1. What did you like about the study?
    1.1. Did you find the graph on the user dashboard page showing you the last seven days of pain reported useful?

    Yes / No

    1.2. Why?
2. What didn't you like about the study?
3. Is there anything that we can do to improve the study?
4. Did you miss any daily reports?

    Yes / No

    4.1. (If yes) Why?
        a) There was no change in pain
        b) I forgot
        c) There were technical issues
        d) Other (please describe)
5. Please rate your experience using this system from 0 – 10

    [Sliding scale from 0-10, where 0 represents worst and 10 represents best]

Acknowledgements

We would like to acknowledge Professor Rachelle Buchbinder for her input into this research. This research was supported by an Australian Government Research Training Program Scholarship and a grant from the Monash Institute of Medical Engineering.

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Vita

Publications arising from this thesis (attached in Appendix H) include:

Goh, T. Y., Burstein, F., Haghighi, P. D., Cicuttini, F., & Urquhart, D. M. (2017),
Empirical study of user experience on mobile data collection for chronic low back pain. In *Proceedings of the 28th Australasian Conference On Information Systems* Hobart, Australia. https://doi.org/10.4225/03/5ab842064e3ce

Goh, T. Y., Burstein, F., Haghighi, P. D., Macpherson, A., Staples, M., & Buchbinder, R. (2016),
Integrating contextual and online self-reported data for personalized healthcare: a tennis elbow case study. In *Proceedings of the 27th Australasian Conference On Information Systems* Wollongong, Australia. https://doi.org/10.4225/03/5ab841766ee13

Goh, T. Y., Haghighi, P. D., Burstein, F., & Buchbinder, R. (2015),
Developing a Contextual Model towards Understanding Low Back Pain. In *PACIS 2015 Proceedings* Singapore. https://doi.org/10.4225/03/5ab840c8c0d41

Goh, T. Y. (2015),
A Context-Aware Pain Trajectory Framework for Low Back Pain Management. In *PACIS 2015 Proceedings* Singapore. https://doi.org/10.4225/03/5ab8401840fa0

Presentations arising from this thesis include:

Goh, T. Y. (2017),
It Hurts! Why, What, Where and When? Using Mobile Technology to Monitor and Manage Low Back Pain. Presented at *Faculty of Information Technology Innovation Showcase* Melbourne, Australia.

Goh, T. Y. (2017),

Chronic Low Back Pain - Towards Personalised Care. Presented at *Faculty of Information Technology Innovation Showcase* Melbourne, Australia.

Goh, T. Y. (2017),

It Hurts! Why, What, Where and When? Using Mobile Technology to Monitor and Manage Low Back Pain. Presented at *Monash University Open Day* Melbourne, Australia.

Goh, T. Y. (2016),

It Hurts! Why, What, Where and When? Examining the Patient's Context for Chronic Pain Management. Presented at *Monash Institute of Medical Engineering MedTech Industry Innovators Day* Melbourne, Australia.

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Goh, T. Y., Haghighi, P. D., Burstein, F., & Buchbinder, R. (2015),

Developing a Contextual Model Towards Understanding Low Back Pain. Presented at *19th Pacific Asia Conference on Information Systems* Singapore.

Goh, T. Y. (2015),

A Context-Aware Pain Trajectory Framework for Low Back Pain Management. Presented at *19th Pacific Asia Conference on Information Systems Doctoral Consortium* Singapore.

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This thesis was typeset with LaTeX 2$_\varepsilon$[1] by the author.

[1] LaTeX 2$_\varepsilon$ is an extension of LaTeX. LaTeX is a collection of macros for TeX. TeX is a trademark of the American Mathematical Society. The macros used in formatting this thesis were written by Glenn Maughan and modified by Dean Thompson, David Squire and Tian Yu Goh of Monash University.

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