

**Mixed-methods evaluation of a nurse-pharmacist managed
pain clinic**

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The candidate confirms that the work submitted is his own, except where work which has formed part of jointly-authored publications has been included. The contribution of the candidate and the other authors to this work has been explicitly indicated below. The candidate confirms that appropriate credit has been given within the thesis where reference has been made to the work of others. To date, the following papers have been published.

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Conference abstracts

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Other publications

- HADI, M.A., ALLDRED, D.P., BRIGGS, M., CLOSS, S.J. 2012. A model for a pain management clinic led by the combined efforts of a pharmacist and a nurse. *The Translator*, 6, 3.
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The author of this thesis was the first and corresponding author for all the publications. He drafted the papers, revised as per supervisors' feedback, formatted according to the journal style, submitted to the respective journals, and answered the queries raised by the editorial office, reviewers and the production office.

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Abstract

Background: Under-treatment of chronic pain within the community is a global problem. There is a growing interest to evaluate the role of nurses and pharmacists in chronic pain management with an aim to improve access to and quality of pain services.

Aim: The research presented in this thesis had two aims: first, to evaluate the effectiveness of pharmacist-led medication review in chronic pain management; second, to evaluate the impact of a community based nurse-pharmacist managed pain clinic.

Methods: A systematic review and meta-analysis was conducted to evaluate the effectiveness of pharmacist-led medication review in chronic pain management. For the second aim, a mixed-methods study consisting of a quasi-experimental design and a qualitative descriptive design was undertaken. Pain intensity was the primary outcome. The secondary outcomes included: physical functioning; emotional functioning; quality of life; chronic pain grade and patient satisfaction. Patient satisfaction was evaluated using face-to-face, semi-structured qualitative interviews.

Results: Of the 578 papers screened, five RCTs were included in the systematic review and three in the meta-analysis. Compared to the control, the meta-analysis found that patients in the intervention group had: a statistically significant reduction in pain intensity of 0.8 point (95% CI -1.28 to -0.36) and 0.7 point (95% CI -1.19 to -0.20) at 3-months and 6-months respectively; and 4.84 point (95% CI, -7.38 to -2.29) at 3-months and -3.82 point (95% CI, -6.49 to -1.14) at 6-months improvement in physical functioning.

Seventy nine patients with a mean age of 46.5 years (SD \pm 14.4) took part in the quasi-experimental study. Thirty-six and 9 patients completed discharge and 3-month follow-up assessments respectively. Compared to baseline, statistically significant reductions were noted for two of the four outcome measures: pain intensity ($P=0.02$), and interference of pain with physical functioning ($P=0.02$) on discharge from the service. The majority of the patients were, in general, satisfied with the service. Four contributing factors to patient satisfaction were

identified: ample consultation time; in-depth specialised knowledge; listening and understanding to patients' needs; and a holistic approach.

Conclusion: Community-based pain clinics managed by a nurse and pharmacist have the potential to improve chronic pain management in the community by providing timely access to a specialised pain service, ensuring safe and effective use of analgesics (medication reviews) and promoting self-management (patient education). Both pharmacist-led medication review and nurse-pharmacist managed pain clinics can reduce pain intensity and improve physical functioning. The long term impact of the pain clinic could not be fully elucidated from this research as the planned follow-up data collection could not be completed due to decommissioning of the service.

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List of Abbreviations

BPI	Brief pain inventory
BP	Bodily pain
BPS	The British Pain Society
CBT	Cognitive behavioural therapy
CMO	Chief Medical Officer
DRP	Drug related problem
GP	General practitioner
GH	General health
HADS	Hospital anxiety and depression scale
HCP	Healthcare professional
HRQoL	Health related quality of life
IASP	International Association for the Study of Pain
IRAS	Integrated research application system
IMPACT	Initiative on methods, measurement, and pain assessment in clinical trials
MH	Mental health
MRC	Medical research council
NRES	National research ethics service
NRS	Numerical rating scale
NHS	National health services
NPMP	Nurse-pharmacist managed pain clinic
OGSR	Office of grants and scholarly research
PCT	Primary care trust
PF	Physical functioning
RP	Physical role

QoL	Quality of life
QM	Quality Metric Incorporated
R&D	Research and development
RP	Role-Physical
RCT	Randomised controlled trial
SF-36	Short- form 36
TTM	Transtheoretical model
VT	Vitality

CHAPTER 1

INTRODUCTION

CHAPTER 1

INTRODUCTION

This thesis presents research work carried out for the author's PhD degree undertaken at the School of Healthcare, University of Leeds, Leeds, UK. The School of Healthcare's Pain research group and, partly by, the Medicines Management research group, supported the author for his PhD degree to specifically build on the former group's earlier work on an innovative community-based, nurse-pharmacist managed pain service. Therefore, the focus of the studentship and subsequent research study was to develop further evidence on the effectiveness of the nurse-pharmacist managed pain clinic.

This introductory chapter provides a brief overview of the prevalence and socioeconomic burden of chronic pain, the challenges in relation to its management, and the role of pharmacists and nurses in chronic pain management. Following this is a description of the research paradigm/world view which guided this research. A brief account of the author's journey through his PhD is then described and finally, a summary of the contents of each chapter is provided.

1.0 Background

Being a subjective and personal experience, pain is a difficult phenomenon to define and measure. The International Association for Study of Pain (IASP) has defined pain as “*an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage*” (IASP subcommittee on Taxonomy, 1979). Chronic pain has been defined as continuous, long-term pain of more than 12 weeks (3-months) or after the time that healing would have been thought to have occurred in pain after trauma or surgery (The British Pain Society, 2006). The 3-month cut off to differentiate chronic pain from acute is not universal and a 6-month cut-off has also been used (Merskey and Bogduk, 1994, Breivik et al., 2006). Furthermore, defining chronic pain solely by duration has also been challenged, as ‘duration’ solely neither reflects the multi-dimensional nature of chronic pain nor indicates whether or not long-term pain is clinically significant (Turk and Rudy, 1988, Turk and Melzack, 2001). Nonetheless, to date, duration-based definitions, although questionable, are frequently used to describe chronic pain in both research and clinical practice settings. Chronic pain is broadly categorised into two types: nociceptive pain and neuropathic pain. Nociceptive pain is caused by damage to body tissue and usually described as a sharp, aching, or throbbing pain. Neuropathic pain results when there is actual nerve disease or damage and is often described as spontaneous burning pain (IASP subcommittee on Taxonomy, 1986, Merskey and Bogduk, 1994).

The growing prevalence of chronic pain presents a significant threat to public health globally. Worldwide, the point prevalence estimates derived from population-based studies vary considerably, ranging from 2% to over 55%

(Verhaak et al., 1998, Elliott et al., 1999, Blyth et al., 2001, Catala' et al., 2002, Moulin et al., 2002, Eriksen et al., 2003, Breivik et al., 2006, Neville et al., 2008). This wide variation in the prevalence of chronic pain is principally attributed to the differences in the definitions of chronic pain used, types of populations studied, and the survey methodology used (Johannes et al., 2010). In the USA, a recent internet-based survey estimated weighted point prevalence of chronic pain to be 30.7% (95% CI, 29.8–31.7) with a higher prevalence among females (34.3%) than males (27.4%) (Johannes et al., 2010). In Europe, a survey reported that chronic pain affected 19% of adults (Breivik et al., 2006). In the UK, it has been estimated that five million people develop chronic pain each year (Chief Medical Officer for England, 2008). Estimation of chronic pain burden in the community is essential so that necessary healthcare and social services can be developed to effectively manage the problem.

Chronic pain often interferes with daily activities and is associated with loss of productivity, work absenteeism, carer burden and high utilisation of healthcare resources (Steenstra et al., 2005, Breivik et al., 2006). It was estimated that lost productive work due to arthritis cost the US economy US\$ 7.1 billion (£4.3 billion) during 2003-04 (Ricci et al., 2005). In the UK, the indirect cost of back pain alone was estimated to be more than £10 billion (Mainiadakis and Gray, 2000). Furthermore, chronic pain is the second most common reason for claiming incapacity benefit in the UK (Chief Medical Officer for England, 2008). In terms of burden on healthcare systems, chronic pain accounted for 4.6 million appointments per year within primary care in the UK at a cost of around £69 million on appointments alone. In 2007, the National Health Services (NHS) in England spent £584 million on 67 million prescriptions for analgesic and anti-inflammatory drugs (Chief Medical Officer for England, 2008).

Given these negative consequences of chronic pain both on individuals and society, timely and effective management of chronic pain is crucial. Chronic pain is primarily managed within primary care. However, suboptimal and inadequate management of chronic pain within primary care has been reported in the literature (Breivik et al., 2006, McDermott et al., 2006). Barriers to effective pain relief are multifactorial and include: clinician related-barriers; patient related-barriers and healthcare system-related barriers (Glajchen, 2001). Clinician-related barriers include: inadequate knowledge and assessment skills, negative attitudes toward prescribing of opioid analgesics, and fear of regulatory scrutiny for prescribing controlled substances (Von Roenn et al., 1993, Cleeland, 1993, Glajchen, 2001). Patient related-barriers include: communication problems, psychological issues such as anxiety, depression and anger, and other issues such as non-compliance with the prescribed medication and fear of addiction, tolerance and side effects (Ward et al., 1993, Glajchen, 2001). Healthcare system related-barriers include: inaccessibility and unaffordability of multidisciplinary pain clinics, lack of neighbourhood pharmacies, non-availability of high doses of opioids at the pharmacy (not relevant in the UK), and long waiting times for appointments in secondary care (Glajchen, 2001). These multifactorial problems make chronic pain management challenging.

In terms of chronic pain management in the UK, the CMO's annual report of 2008 was the first government document that highlighted the issues of inadequate pain management in primary care and the lack of clear clinical standards for chronic pain management, and called for immediate action to address these issues (Chief Medical Officer for England, 2008). The report also directed the relevant agencies to improve the quality of local pain services.

Subsequent to the CMO's report, the National Pain Audit was conducted to assess the nature and quality of, and access to chronic pain services in the UK. The audit also found a *"clear variation in provision of service and no agreed standards of care"* (Price et al., 2012, P. 5). Additionally, the audit also found that a number of services were not even meeting the minimum requirement for an effective pain service set by the International Association for the Study of Pain (IASP) and the Faculty of Pain Medicine of the Royal College of Anaesthetics (Price et al., 2012), indicating a considerable room for improvement in the delivery of chronic pain services.

Within the NHS, there has been a desire to shift the focus of care from hospitals to the community to reduce the burden on secondary care and to improve timely access to care. To accomplish this and to meet patients' growing expectations, given the economic constraints, the roles of nurses and pharmacists within the healthcare system has evolved and become more patient centred, leading to the development of a number of nurse-led and pharmacist-led services. These reforms began in 2000 when the Department of Health (DoH) published health services plan for the NHS incorporating a proposal to extend nurses' role within the NHS (Department of Health, 2000).

In the context of chronic pain management, there is a growing interest among researchers to evaluate these nurse and/or pharmacist managed services as chronic pain is often inadequately managed in primary care. The research work conducted and presented in this thesis is a small step towards improving chronic pain management in community. Firstly, a systematic review evaluating the effectiveness of pharmacist-led medication review in chronic pain management is presented (Chapter 3). Secondly, the effectiveness of a community based nurse-pharmacist managed pain clinic, one of the initiatives of

the local primary care trust (PCT) to improve access to quality pain service, reduce burden on secondary care and waiting times, is evaluated. The specific aims and objectives are outlined in section 2.9. A brief historical overview of the development of the clinic and its working is outlined in the next chapter (section 2.8.1).

1.1 About the author and his PhD journey

Like most of the children born in Pakistan, I was raised to become a medical doctor. To fulfil my father's dream, who is a physician himself, I worked hard but was unable to secure admission in a medical college. Subsequently, I joined a pharmacy school at a local university in 2002. On the first day of my university, I made a promise to my father that I would complete a PhD to fulfil his dream. At that time, I had no idea what a PhD was except that it would enable me to write "Dr" before my name. That is how I initially acquired the idea and motivation of doing a PhD.

My first experience with 'research' was during my Master's degree (Clinical Pharmacy) in Malaysia. It was short but an exciting experience which gave me a glimpse of future PhD research. Subsequently, I developed an interest in research and my motivation for doing a PhD also grew beyond merely adding the "Dr" title before my name. After completing master's degree, I started looking for a PhD scholarship whilst working as a lecturer in Clinical Pharmacy at a public university in Malaysia. Subsequently, I was awarded a PhD scholarship by the School of Healthcare, University of Leeds. I chose this project, a mixed-methods evaluation of a nurse-pharmacist managed pain clinic, for two main reasons: 1) In the past, I was predominantly a quantitative researcher with very limited experience of qualitative research, therefore, I saw

this project as a training opportunity to develop in-depth understanding of qualitative, quantitative and mixed-methods methodologies and gain some hands on experience in using different methodologies; 2) The project had elements of both pharmacy practice research and health services research, my areas of interest.

Over all, I enjoyed and learnt a lot during my PhD. But there were some hard and long days as well. From applying for the scholarship to developing the protocol, to submitting the applications for ethics and research governance approval, to recruiting patients, to undertaking the qualitative and the quantitative analysis, and to finally writing up thesis, it was a series of challenges one after another. However, I received excellent support from family and supervisors, which helped me to overcome these challenges. Publication of my work in peer-reviewed journals gave me motivation and pushed me forward. Ultimately, during the third year of PhD I was successful in applying for a lecturer in pharmacy practice position in a reputable university. However, moving countries with my family and starting a new job in the middle of thesis write up was very challenging. Again support from family and supervisors enabled me to overcome these challenges and complete my write-up.

1.1.1 Author's research paradigm: Pragmatism

Being a practice researcher rather than a philosopher, this was the most difficult and challenging part of the thesis perhaps due to author's limited knowledge of the subject area. The aim of this section was not to start a philosophical debate to prove the superiority of one paradigm over another, rather the purpose of including this section in the introduction chapter is to make the author's stance (philosophical assumptions) clear from the outset, enabling the reader to meaningfully understand the research work detailed in the later chapters.

“A paradigm is a basic set of beliefs that guide action” (Guba, 1990, P. 17).

It is also known as philosophical assumptions, epistemologies and ontologies (Crotty, 1998), broadly conceived research methodologies and alternative knowledge claims (Creswell, 2003). There are various research paradigms, descriptions of which are beyond the scope of this thesis. Among the most commonly used paradigms are (Creswell, 2007): Positivism - claims of knowledge are based on cause and effect thinking and reductionism, often associated with quantitative approaches (Phillips and Burbules, 2000); Constructivism - individuals seek understanding of the world in which they live and work; Advocacy/participatory – which states that the research should have an action agenda to help people involved in the research study (study participants) (Kemmis and Wilkinson, 1998); and Pragmatism - focuses on the outcomes of the research and chooses methods on the principle of “what-works”. The key features of pragmatism are as follows (Creswell, 2007):

- Pragmatism is not associated with any specific system of philosophy and reality.
- Researchers using pragmatism as their research paradigm are free to choose the methods and procedures that are most suitable in answering the research question.
- Pragmatic researchers can use multiple methods of data collection and analysis within a research study, if deemed necessary.
- Pragmatist researcher believes that the research is not free from social, political and historical contexts.

In this thesis, the author has taken the stance of a pragmatist researcher – where the research question dictates the choice of methods used. Methods

belonging to different research paradigms were chosen because of their suitability to answer the research questions. For example, a meta-analysis was undertaken, typically associated with positivist paradigm, to evaluate the effectiveness of pharmacist-led medication review in chronic pain management (See chapter 3). Whereas, a qualitative approach was adopted to explore patients' views about their experiences of the nurse-pharmacist managed pain clinic, typically associated with the constructivist paradigm (See chapters 4 and 7).

1.2 Structure of the thesis and writing style

This thesis consists of eight chapters. At the beginning of each chapter, a brief summary about the contents of the chapter is provided to facilitate reading. A third person objective style has been adopted throughout the thesis. The author has identified himself in this thesis as "the author" and/or MAH, except for this chapter where first person style has been used occasionally as well.

Chapter 1: Introduction

This chapter provides contextual background of the study. A brief account of the author's journey through his PhD is presented. Following that, the world view/paradigm governing the whole thesis is explained. Finally, a brief description of the contents of each chapter of this thesis is outlined.

Chapter 2: Literature review

In this chapter, the objectives of conducting the literature review and the search strategy used for searching electronic databases are presented. To give the reader a broader picture of the roles of nurses and pharmacists in chronic pain management, studies describing and/or evaluating their roles are summarised

in this chapter. Then the historical background and working of the nurse-pharmacist managed pain clinic under investigation is explained. Finally, the aims and objectives of the present study in relation to the limitations of the current evidence supporting the clinic's effectiveness are outlined.

Chapter 3: Effectiveness of pharmacist-led medication review in chronic pain management: a systematic review and meta-analysis

This chapter presents the rationale, aim and objectives, methods, and results of a systematic review undertaken to evaluate the effectiveness of pharmacist-led medication review in chronic pain management. Implications of findings on clinical practice are discussed and recommendations for future research are also suggested.

Chapter 4: Methodology

In this chapter, a brief overview of various research methodologies available to healthcare researchers is presented. The selection of a particular research methodology, mixed-methods, underpinning this study is justified in relation to the aim and objectives of the study. Finally, the rationale for selecting an embedded design for this study is described together with the selection of specific quantitative (quasi-experimental) and qualitative (descriptive qualitative) designs is justified.

Chapter 5: Methods

In this chapter, the choice of particular methods used in this study, from sample size calculation to data analysis is debated and justified. Although in the same chapter, the methods used within quantitative and qualitative phases are

presented separately to improve clarity. The steps taken to ensure ethical conduct of the study are also outlined.

Chapter 6: Results - Quantitative

As the name suggests, this chapter presents results of the quasi-experimental study (quantitative phase). Tables and figures are used, where necessary, to illustrate and summarise findings. In order to facilitate reading, the chapter is divided into small sections in line with the research questions.

Chapter 7: Findings - Qualitative

In this chapter, the findings of the qualitative descriptive study are presented. Anonymised quotations from patients' interviews are also given to support findings of the study.

Chapter 8: Discussion

In this chapter, findings of both quantitative and qualitative phases are discussed. Limitations to this study are highlighted and recommendations for future research are described. Plans for dissemination of research findings are also outlined.

CHAPTER 2

LITERATURE REVIEW

CHAPTER 2

LITERATURE REVIEW

2.1 Introduction

The literature review is an important component in designing and conducting a research study as it allows the researcher to place his work in context of what is already known, preventing duplication and allowing meaningful comparisons with other studies in the similar area of research.

This chapter presents a critical summary of existing literature on various aspects of chronic pain including its epidemiology and management with the aim of highlighting the growing socioeconomic burden of chronic pain and challenges in its management. There were four objectives for conducting the literature review:

- I. To obtain an overview of chronic pain prevalence and challenges in its management
- II. To gather evidence on the role of pharmacists and nurses in chronic pain management.
- III. To inform the development of the methodology for the current study.
- IV. To identify key outcome measures commonly used to evaluate the effectiveness of chronic pain management interventions.

The first two objectives are comprehensively dealt with in this chapter. The remaining two objectives are related to the methodology and methods of the present study and are discussed in detail in the methodology (Chapter 4) and methods (Chapter 5) chapters, where an overview of various research

methodologies in healthcare research is provided and selection of a particular methodology and methods is debated and justified.

This chapter begins with a detailed account of the search strategy employed to identify relevant articles. In order to facilitate easy comprehension for readers the chapter is divided into two sections: Chronic pain burden and its challenges; and the role of nurses and pharmacists in chronic pain management. In the first section, the prevalence of chronic pain, health resource utilisation due to chronic pain and its impact on physical and emotional functioning (quality of life) are discussed to establish the scope of the problem. Current challenges in chronic pain management within primary care are also discussed. The second section critically assesses current research evidence to support the role of nurses and pharmacists in chronic pain management. Following this, the working of the nurse-pharmacist managed pain clinic under investigation, is explained. The limitations of the research evidence supporting the pain clinic are then highlighted, leading to the aim(s) and objectives for this study.

2.2 Literature search

In order to ensure a robust and in-depth search of the literature, in line with the search objectives, the search strategy was divided into three groups. In the first group, literature related to the prevalence and socioeconomic burden of chronic pain was searched and reviewed. The rationale for presenting epidemiological aspects of chronic pain and existing challenges in its management is to highlight the necessity for development of innovative services to reduce disease burden and ensure optimum care. In the second group, papers evaluating the roles of general practitioners (GPs), multidisciplinary pain clinics, nurses and pharmacists in chronic pain management were searched. In the third and final group, literature related to the methodological innovations in health services research in general and chronic pain in particular were searched with an aim to inform methodology, methods, outcome measures and scales for the present study. Electronic databases including Medline (via Ovid), EMBASE (via Ovid), Cochrane Library, Cumulative Index to Nursing and Allied Health Literature (CINAHL) (via EMBSCO), Google Scholar and PsycINFO were searched from the date of their inception. Each of these databases was searched from the date of their inception to January 2011. However, the literature search and review was regularly updated throughout the study period in order to keep abreast with the latest research in the field. The key terms used were: chronic pain; non-malignant pain; quality of life; physical functioning; emotional functioning; anxiety; depression; pain management; non-pharmacological management; pharmacological management; multidisciplinary pain clinic; interdisciplinary pain clinic; nurse-led; nursing interventions; pharmacist-led; pharmaceutical care; medicines management; pharmacist; community; pain scales; outcome measures. These search terms were combined with Boolean operators such as

AND, OR and NOT to refine search results wherever necessary. In addition to the search of electronic databases, websites of the British Pain Society, the American Pain Society and the International Association for Study of Pain (IASP) were also searched. Reference lists of relevant articles were also searched to identify any additional articles. The retrieved articles were critically appraised.

2.3 Prevalence of chronic pain

Keeping in view the growing prevalence, multidimensional nature as well as complexity of its management, chronic pain has become a challenging issue not only for the patients but also for the healthcare professionals and systems, and society. A considerable increase in the prevalence of chronic pain has been reported over the past two decades. A study conducted in the US reported an increase in the prevalence of chronic low back pain alone from 3.9% in 1992 to 10.2% in 2006 (Freburger et al., 2009). Likewise, a two to fourfold increase in the prevalence of chronic pain has also been reported in the UK (Harkness et al., 2005). As mentioned earlier in chapter 1 (section 1.0), owing to differences in definitions of chronic pain, variation in study populations and the research methodology used for surveys, the estimated prevalence of chronic pain varies substantially, ranging from 2% to 55% (Verhaak et al., 1998, Elliott et al., 1999, Blyth et al., 2001, Catala' et al., 2002, Moulin et al., 2002, Eriksen et al., 2003, Breivik et al., 2006, Neville et al., 2008). Recent studies from the US (Johannes et al., 2010) and the Europe (Breivik et al., 2006) have estimated the prevalence of chronic pain to be approximately one in three and one in five respectively. In Europe, the prevalence of chronic pain was highest in Norway (30%) and least in Spain (12%) (Breivik et al., 2006). These studies also reported a higher prevalence of chronic pain among females compared to males. In addition to

female gender, other significant predictors of chronic pain include: old age, poor housing and type of employment (Price et al., 2012). In Europe, back pain was noted to be the most common type of chronic pain followed by knee pain (Breivik et al., 2006).

In the UK, it has been estimated that chronic pain of moderate to severe intensity affects 7.8 million people (Chief Medical Officer for England, 2008). In 2011, the National Health Survey in England reported that chronic pain affects more than 14 million adults (Bridges, 2012). The National Health Survey further reported that 31% men and 37% women suffer from chronic pain, with older people more likely to report chronic pain than younger people (Bridges, 2012). The National Pain audit reported the average annual incidence estimated at 8.3% with the average annual recovery rate of 5.4% (Price et al., 2012). The growing prevalence would require additional human and financial resources to cater for patients' needs, putting an additional burden on the healthcare system.

2.4 Economic and societal burden of chronic pain

Loss of productivity, carer burden and high utilisation of healthcare resources are often associated with chronic pain (Steenstra et al., 2005). Additionally, chronic pain patients have been reported to have poorer health related quality of life compared to the patients with other chronic diseases (Laas et al., 2009). In terms of loss of productivity, 9.9 million work days are lost annually in Australia (van Leeuwen et al., 2006) and one million in Denmark due to chronic pain (Eriksen et al., 2003). Breivik et al. (2006) reported that the mean number of work days lost, among 15 European countries and Israel, in the past 6 months was highest in Finland (19.8 days) and lowest in France (5 days). Furthermore, one in four participants reported that pain had an impact on their employment status. Similarly, in the UK, it has been estimated that 25% of chronic pain

patients will lose their jobs because of pain (Chief Medical Officer for England, 2008).

A number of studies have estimated the economic burden due to work absenteeism and loss of productivity associated with chronic pain (Maniadakis and Gray, 2000, Walker et al., 2003, Phillips, 2009, Gaskin and Richard, 2012). In the UK, the indirect cost of back pain alone was estimated to be £10.7 billion (Maniadakis and Gray, 2000). In the US, a recent study reported that the value of lost productivity due to pain ranged from \$299 to \$335 billion (£182.4 billion to £216.5 billion) (Gaskin and Richard, 2012). Although significantly less than the indirect costs, the direct costs associated with chronic pain are quite substantial. In 2007, The National Health Service (NHS) in England spent £584 million on 67 million prescriptions for analgesics (Chief Medical Officer for England, 2008). In Australia, the direct cost of lower back pain alone in 2001 was estimated to be AU\$ 1.02 billion (£56.4 million) with an overall cost of AU\$9.17 billion (£5.06 billion) (Walker et al., 2003). In the US, the overall annual cost associated with chronic has been estimated to range from \$560 to \$635 billion (£ 341 billion to £387 billion), more than the annual costs of heart disease (\$309 billion; £188 billion), cancer (\$243 billion; £148 billion), and diabetes (\$188 billion; 114 £billion) (Gaskin and Richard, 2012).

The utilisation of healthcare resources by chronic pain patients is significantly more than other chronic diseases with women utilizing more healthcare resources than men (Blyth et al., 2004, Eriksen et al., 2004, Breivik et al., 2006, Kaur et al., 2007, Price et al., 2012). In Denmark, patients with chronic pain had on average 12.8 contacts per year with a primary healthcare provider compared with 7.3 for the control group (Eriksen et al., 2004). Australian data showed that compared to non-chronic pain patients, chronic

pain patients were five times more likely to visit the Accident and Emergency department (Blyth et al., 2004). Data from Europe (n=4780) demonstrated that more than half (54%) of the respondents had seen two to six different doctors for their pain and 60% visited their doctors two to nine times in the past 6 months due to pain (Breivik et al., 2006) .

Given this high economic and societal burden of chronic pain, early and effective management of chronic pain is crucial not only for improving patient outcomes but also for avoiding unnecessary humanistic and financial burden on the healthcare system and society.

2.5 Management of chronic pain

Chronic pain is commonly managed within primary care. However, given the complex nature of chronic pain, care provided within the primary care is often suboptimal and inadequate (Breivik et al., 2006, McDermott et al., 2006). This is primarily because treatment approaches in primary care are usually unidisciplinary and are often based on the biomedical model, which assumes that the presentation of chronic pain is due to a specific physical pathology. The treatment is then targeted to rectify that physical pathology either pharmacologically or surgically (Gatchel and Okifuji, 2006). However, this approach is not applicable to all cases of chronic pain, because it is not always possible to identify a specific physical cause (Gatchel and Okifuji, 2006). The alternative, biopsychosocial pain model assumes that the clinical presentation of chronic pain is a result of complex interactions among physiological, psychological and social factors. An effective treatment modality should therefore focus on all three areas (Turk and Gatchel, 2002, Gatchel, 2005).

In theory, multidisciplinary pain clinics based on the biopsychosocial model can effectively manage chronic pain. Various systematic reviews have documented the effectiveness of multidisciplinary pain management programmes/clinics in various settings and chronic pain conditions (Flor et al., 1992, van Tulder et al., 1997, Guzmán et al., 2001, Thomsen et al., 2001, Scascighini et al., 2008). Multidisciplinary pain clinics have been reported to reduce pain intensity ranging from 14% (Moore et al., 1984) to 60% (Tollison et al., 1985), with an average reduction of 20% to 30% (Flor et al., 1992). Flor et al. (1992) reported, in a meta-analysis, a 65% increase in physical activity in patients receiving multidisciplinary pain treatments compared to a 35% increase in patients receiving conventional medical care. Similarly, return to work rate was reported to be higher in patients in multidisciplinary programmes compared to conventional medical treatments (mean 66% vs. 27% respectively).

More recently, Scascighini et al. (2008) conducted a comprehensive systematic review of RCTs to evaluate the effectiveness of multidisciplinary pain programmes in chronic pain management. The review included 35 studies but the authors were unable to undertake meta-analysis due to heterogeneity in study design, patient population and nature of the intervention. The authors drew conclusions on the effectiveness of the multidisciplinary interventions based on a four level rating system (strong evidence, moderate evidence, limited evidence and no evidence) developed by Cochrane Back Review Group (van Tulder et al., 2003). They reported: strong evidence (multiple high quality RCTs with consistent results) supporting superiority of multidisciplinary treatment compared with waiting list control (WLC) and treatment as usual (TAU); moderate evidence (one high quality RCT and one or more low quality RCTs with consistent results) in favour of multidisciplinary pain clinics compared

with non-multidisciplinary treatments (e.g. physiotherapy with discussion group, patient education). In terms of aetiology of chronic pain, patients with fibromyalgia and/or chronic back pain were likely to gain more benefit from multidisciplinary treatment modalities compared with patients with other chronic pain diagnoses (moderate evidence). For mixed chronic pain patient population, limited evidence (one high quality RCT, or multiple low quality RCTs with consistent findings, or contradictory outcomes of studies with high and low quality) supporting effectiveness of multidisciplinary treatment compared with WLC or TAU was reported. Furthermore, comprehensive inpatient programmes were found to be more effective than the outpatient programmes (moderate evidence). However, neither the duration of programme nor the programme components influenced the effectiveness of the programme. The authors highlighted the need for internationally recognised standards of multidisciplinary programmes to ensure better outcomes for chronic pain patients. Notably, trials were not excluded based on their quality therefore many of the RCTs included in the systematic review may have lacked quality in design or execution/reporting.

Finally, in addition to clinical effectiveness, multidisciplinary pain clinics have been found to be cost effective (Gatchel and Okifuji, 2006). However, timely acceptable access and affordability of such multidisciplinary pain clinics remains an issue.

2.5.1 Barriers to effective chronic pain management

As mentioned earlier (Chapter 1, section 1.1), there are a number of barriers related to the healthcare-systems, clinicians and patients which interfere with achieving optimal pain relief (Glajchen, 2001). Clinicians' inadequate knowledge and limited assessment skills are frequently seen as barriers to effective

management of chronic pain. In a survey in the UK, GPs described helplessness and dissatisfaction with their ability to manage chronic pain patients (Stannard and Johnson, 2003). In another study in the USA, 88% of the physicians reported that their training in pain management as poor in medical school, and 73% felt that residency training was fair or poor (Von Roenn et al., 1993, Von Gunten and Von Roenn, 1994). Other clinician-related barriers include: negative attitudes toward prescribing of opioid analgesics (due to fear of abuse and addiction), and fear of regulatory scrutiny for prescribing controlled substances (Von Roenn et al., 1993, Cleeland, 1993, Glajchen, 2001).

Patient-related barriers include: communication problems, psychological issues such as anxiety, depression and anger; and other issues such as non-adherence with the prescribed medication and fear of addiction, tolerance and side effects (Ward et al., 1993, Glajchen, 2001). Anxiety and depression are frequently occurring co-morbidities and are associated with chronic pain (Sagheer et al., 2013, Wong et al., 2011). In the UK, 49% of chronic pain patients experience depression (Chief Medical Officer for England, 2008). Adherence with the prescribed medicines is essential for effective pain relief. However, non-adherence with the prescribed medicines and abuse of opioid analgesics by the chronic pain patients have frequently been reported in the literature (Berndt et al., 1993, Broekmans et al., 2009, Couto et al., 2009). A retrospective analysis of 938,586 patients' urine test samples to estimate compliance with prescribed opioid analgesics, found that 3 out of 4 patients were not taking their medicines as prescribed by their clinicians and 38% of patients had no detectable level of prescribed medicine (Couto et al., 2009). More importantly, 29% had a non-prescribed medication present and 27% had a drug level higher than expected in their urine samples. However, the study did

not explore the reasons for non-adherence and abuse of opioid analgesics. Fear of addiction and intolerance towards the side effects might be responsible, at least in part, for the above mentioned findings.

Healthcare system-related barriers include: inaccessibility and unaffordability of multidisciplinary pain clinics, lack of a neighbourhood pharmacy, non-availability of high doses of opioids at the pharmacy, and long waiting times for appointments in secondary care (Glajchen, 2001). The waiting time for six months or more from the time of referral to treatment is associated with a worsening of health-related quality of life and psychological wellbeing. (Lynch et al., 2008). In Canada, the median waiting time for a first appointment in public multidisciplinary pain treatment facilities was six months, 12 times more than similar private facilities (Peng et al., 2007). Unfortunately, no established benchmarks or guidelines for acceptable wait times specific to the treatment of chronic pain exist (Lynch et al., 2007). However, generic standards are followed in the UK (Price et al., 2012), usually 18 weeks. (Price et al., 2012). These multifactorial problems make chronic pain management challenging.

2.5.2 Chronic pain management: The UK perspective

The access to and quality of pain services in the UK is a matter of deep concern. In 2008, there was one pain specialist for 32,000 people in pain (Chief Medical Officer for England, 2008). The National Pain Audit found a lack of clear standards of care and variation in access to multidisciplinary care. Of the 204 pain services evaluated, the audit reported that only 40% of clinics in England met the minimum criteria for multidisciplinary clinics by having a psychologist, a physiotherapist and a physician (Price et al., 2012). Furthermore, 80% of clinics in England and 50% in Wales met the 18 week generic standard waiting time.

The report also found that many of the chronic pain services were not even meeting the minimum criteria for an effective pain service as outlined by the IASP and the Faculty of Pain Medicine of the Royal College of Anaesthetists. The report made a number of recommendations aiming to improve access to and quality of pain services in the UK. The key recommendations included: information about local pain services should be made readily available to patients; the Royal College of Anaesthetists should adopt IASP guidance on minimum waiting times for pain services; service commissioners should integrate physiotherapy and psychology services into local care pathways for pain; and every specialist pain service should be supported by a medical consultant to provide expert advice.

Given the limited capacity of GPs, the lack of pain specialists and issues surrounding accessibility and affordability of multidisciplinary pain clinics, the role of pharmacists and nurses has grown significantly in the past decade. In the following sections, the evidence to support the roles of nurses and pharmacists in chronic pain management, both independently or as part of multidisciplinary teams, is explored.

2.6 The role of pharmacists in chronic pain management

Until recently, and still in some developing countries, the role of pharmacists within healthcare systems globally was limited to the dispensing of medications. Although dispensing of medications still remains an important responsibility of pharmacists, with the introduction of the concept of pharmaceutical care, the focus of pharmaceutical services has shifted from products to patients. Consequently, a number of patient-oriented pharmacist-led services have been developed in both hospital and community settings. Pharmaceutical care is defined as *“the responsible provision of drug therapy for the purpose of*

achieving definite outcomes that improve a patient's quality of life” ” (Hepler and Strand, 1990, P. 539). These outcomes include: curing and/or preventing disease; slowing down its progress; and an elimination or reduction of a patient's symptomatology (Hepler and Strand, 1990). The basic essence of pharmaceutical care is that the pharmacist develops, implements and monitors a therapeutic plan in consultation with the patient, with the patient playing an active role in decision making. The aim of pharmaceutical care is to identify, prevent and resolve actual or potential drug related problems (Hepler and Strand, 1990). More recently, terms such as “medicines management” and “medicines optimisation” have frequently been used in literature to describe pharmacist’s activities to promote safe and effective use of medicines (Barber, 2001).

In the context of chronic pain, the role of pharmacists in its management has expanded significantly in the past two decades. Research evidence to support the role of pharmacists in chronic pain management is also growing. During the literature search, both observational studies and randomised controlled trials evaluating the effectiveness of the role of the pharmacists in chronic pain management were found. Based on the literature review, pharmacist-led interventions for chronic pain management can be broadly categorised into two categories: medication review and prescribing; and educational interventions. However, in most instances medication review and patient education were delivered concurrently as part of pharmacist-led interventions. These interventions have been delivered either independently or as part of multidisciplinary teams in different settings. In the following paragraphs, research studies evaluating the role of pharmacists in chronic pain management are critically reviewed. A description of the nature of the

intervention(s) and settings has also been provided to highlight the variations in the nature, mode and delivery of pharmacist-led interventions in chronic pain management. A systematic review evaluating the effectiveness of pharmacist-led medication review is presented in the next chapter (Chapter 3).

For clarity, studies evaluating the role of pharmacists in chronic pain management have been divided into two sections: Descriptive observational studies and randomised controlled trials.

2.6.1 Descriptive observational studies

The literature review found a few observational studies, described below, which only described the nature of pharmacist-led intervention in chronic pain management without providing any significant data to support their effectiveness.

Weitzel et al. (2004) described the development and working of a pharmacist-managed headache clinic in an interdisciplinary community health centre affiliated with the University of Florida, USA. The clinic was established in 2000 on the request of the clinical nurse practitioner and followed a stratified care approach for the management of migraine. In the stratified care approach, patients were stratified and treated based on the severity of their migraine (Lipton et al., 2000). In terms of the working of the clinic, patients were referred to the pharmacist by the patients' primary care physician (PCP), and during the initial one hour long consultation, the pharmacist conducted a medication review and obtained a headache history. The pharmacist, in consultation with the patient, developed a therapeutic plan based on the available guidelines. During follow up appointments, the pharmacist reviewed the pharmacotherapeutic plan and adjusted it according to the patients' needs. From 2000 to 2003 the clinic

enrolled 37 patients. Pharmacist's recommendations included: requested non-pharmacologic treatment for 1 patient, addition of immediate-relief drug therapy for 20; addition of prophylactic drugs for 14; modification of treatment regimen for 7; and referral to consultant for 3 patients. Twenty-six patients (70%) reported a decrease in headache frequency and severity, while the rest reported no change. The main focus of the paper was to describe the nature of service rather than to evaluate its effectiveness.

Similarly, three more studies (Rapoport and Akbik, 2004, Dole et al., 2007, Fan and Elgourt, 2008) described the working of a pharmacist managed pain clinic with little or no data to support their effectiveness. Rapoport and Akbik (2004) described a pharmacist-managed pain clinic within a multidisciplinary pain service, consisting of a neurologist, a psychiatrist, an anaesthesiologist, an anaesthesiology fellow and two pharmacists, at a Veterans Affairs medical centre in Boston, USA. Fan and Elgourt (2008) described a pain management pharmacy service in a community hospital in the USA and Dole et al. (2007) described a pain service with a pharmacist with prescribing authority in Mexico. In all three studies, the role of the pharmacist was to develop a therapeutic plan, monitor outcomes, adjust medicines as per the requirement, prevent the abuse of opioid analgesics, improving adherence to prescribed medication, refill prescriptions, prevent drug related problems and side effects, and make referrals to other healthcare professionals if necessary. The overall aim of these services was to ensure effective, efficient and adequate analgesia to all patients referred to these services. Dole et al. (2007) also reported a significant reduction in pain intensity scores (Mean difference 1.1; SD \pm 2.5), measured on a 1 to 10 visual analogue scale (VAS) ($P < 0.001$), and the pain service generated an overall profit equivalent to a 9% return on

investment (annual revenue \$107,550 (£65,755); annual salary \$98,851 (£60,437)).

In the UK, McDermott et al. (2006) described a method of identifying chronic pain patients in primary care and the feasibility and acceptability of a pharmacist-led medication review in one general practice in Aberdeenshire, Scotland, UK. Chronic pain patients were identified using a Microsoft Access based Audit Tool (NIMROD). In total, the case notes of 132 patients were reviewed and the pharmacist made 192 recommendations about the safe and appropriate use of medications. Of these 192 recommendations, 108 (56%) were directly related to the use of analgesics. However, outcomes such as pain intensity and physical functioning were not measured. This was the first study in the UK to report a method for the identification of chronic pain patients in the general practice and was therefore instrumental in the development of an RCT, which evaluated the effectiveness of pharmacist-led medication reviews in the primary care setting (described below; section 2.6.2).

In addition to descriptive studies, one quasi-experimental study using a single group pre-test post-test design and multiple outcome measures was also found (Chelminski et al., 2005). Typical single group pre-post study designs lack control group and randomization, which threatens the validity and reliability of the findings (Fisher et al., 2002). Nevertheless, such studies are important in providing important information about the nature of the intervention and patient population, the suitability of the intervention in the desired population, and, most importantly, informing the design of future RCTs (Shadish et al., 2002). Chelminski et al. (2005), in the USA, evaluated a primary care based multi-disciplinary disease management programme for chronic pain patients with a high burden of psychiatric comorbidity. The multi-disciplinary team consisted of

patient's primary care physician (PCP), a clinical pharmacist, a psychiatrist with a sub-specialisation in pain management and a programme assistant with training in health behaviour. The aims of the programme were to: prevent substance (opioids) abuse; titrate patients' pain medications to ensure optimal analgesia; and identify and manage patients with depression. Once enrolled, participants were asked to complete the Brief Pain inventory (BPI) (Cleeland and Ryan, 1994), the Centre for Epidemiological Studies-Depression Scale (CESD) (Radloff, 1977) and the Pain disability Index (PDI) (Tait et al., 1987) at baseline and 3-month follow up. Substance abuse was monitored through clinical history and urine toxicological screening (UTS). Eighty five patients enrolled in the study with an average baseline pain score of 6.5. Fifteen patients withdrew from the study after identification of substance abuse. At 3-month follow-up, the authors reported a statistically significant ($p=0.003$) 1 point reduction in pain score, from 6.5 to 5.5 on an 11 point NRS. Importantly, the reduction in the pain score was statistically significant but not clinically significant. However, there were significant improvements in mean PDI score ($p<0.001$) and CESD score ($p<0.001$). Remarkably, the proportion of depressed patients fell from 79% to 54% ($p=0.003$). However, substance abuse was reported in 32% of the patients.

2.6.2 Randomised controlled trials (RCTs)

In healthcare research, RCTs are considered the gold standard to evaluate the effectiveness of an intervention. In addition to a number of descriptive and observational studies described above, a few randomised controlled clinical trials evaluating the effectiveness of pharmacist-led interventions in chronic pain management were also found (Gammaitoni et al., 2000, Hay et al., 2006, Hoffmann et al., 2008, Petkova, 2009, Marra et al., 2012, Bruhn et al., 2013).

These RCTs vary in terms of the nature of the intervention, settings, patient population, duration of follow-up, and outcome measures and scales used. A detailed description of all of these trials, except for a trial by Petkova (2009) is provided in the next chapter as they are part of the systematic review undertaken as part of this thesis. The trial by Petkova (2009) did not fulfil the inclusion criteria for the systematic review (described in the next chapter). Although, the trial by Bruhn et al. (2013) was included in the systematic review, the detailed results were published after its completion, therefore it was not included in the data analysis and is briefly presented here.

In Bulgaria, Petkova (2009) conducted a randomised controlled trial to evaluate the effectiveness of a community pharmacy-based pharmacist-led education programme for arthritis patients. The educational leaflets were prepared in the form of a self-study program based on the National Health Insurance Fund for treatment of arthritis diseases (clinical paths for physical treatment and rehabilitation of arthritis diseases and musculoskeletal system) and by the Arthritis Foundation. However, the nature of education programme was not described extensively. In total 90 patients were enrolled, 45 each in the intervention and control groups. Neither the method of power calculation nor the method for allocation concealment was reported. Furthermore, instead of making comparisons between the intervention and control groups for all the outcomes, comparisons within groups (pretest-posttest) were only reported. Nevertheless, significant reduction in the frequency of 'severe pain' was reported in the intervention group compared to the control, the only comparison reported in paper. Therefore, in the presence of a high risk of selection and reporting bias, the trial provided limited useful information about the effectiveness of the intervention.

In the UK, Bruhn et al. (2013) conducted an exploratory trial to evaluate the effectiveness of pharmacist-led medication review, with or without pharmacist prescribing in primary care among patients with chronic pain. Patients were randomised to one of the three arms: pharmacist medication review and prescribing (prescribing arm); pharmacist medication review and recommendations to the GP (review arm); and treatment as usual (TAU) arm. At 6 months follow-up, compared to the TAU, there was a significant reduction in pain intensity in both the intervention groups ($p=0.02$). However, there was no difference in the disability, measured by the chronic pain grade questionnaire CPG ($p=0.05$). Similarly, there was no significant improvement in the SF-12 physical composite score (PCS) between the trial arms ($p=0.75$) and a slight deterioration in SF-12 mental composite score (MCS) in the intervention arms, and a statistically significant deterioration in the TAU arm ($p= 0.002$). Since it was an exploratory trial the authors did not perform any power calculations, leading to a higher risk of type II error.

2.6.3 Systematic reviews

During the literature search, two systematic reviews (Bennett et al., 2011, Elias et al., 2011) were also found. Elias et al (2011) conducted a systematic review to evaluate the impact of pharmacist-led interventions in the management of osteoporosis. Since the focus of this thesis is on chronic pain, therefore further details of the systematic review are not included here.

Bennett et al. (2011) conducted a systematic review to evaluate the effectiveness of pharmacist-led educational interventions in chronic pain management. They included RCTs in which educational interventions were delivered by pharmacists independently or as part of a multicomponent intervention to chronic pain patients (pain lasting ≥ 3 months). Four RCTs,

including one involving cancer patients, randomizing 400 patients in total were identified. The authors undertook a meta-analysis and reported: on average, a 0.5 point reduction in pain intensity on a 0 to 10 numerical rating scale in the intervention group compared to the control; more than 50% reduction in adverse effects; and an approximately 1 point improvement in patient satisfaction with treatment on a 0 to 10 rating scale. However, the interventions had no effect on reducing pain interference with daily activities and improving self-efficacy. Although the effect on pain intensity was statistically significant, the authors were unable to demonstrate clinical significance of the interventions. Furthermore, the effect of the intervention on “worst pain” and “current pain” were not statistically significant - 0.11 and - 0.003 points, respectively. There were two limitations in terms of the conduct of meta-analysis: Firstly, a RCT involving cancer pain patients was included together with RCTs involving chronic pain patients, leading to clinical heterogeneity. Secondly, the time points at which follow-up measures were obtained varied between 1 to 16 weeks; combining short-term trials with long-term trials is not recommended as it produces a larger treatment effect than combining longer term trials alone (Moore et al., 2010a).

From the above discussion, despite the highlighted limitations, it can be concluded that there is a potential role of pharmacists in chronic pain management. However, more evidence is required before a wider clinical role of pharmacists in chronic pain management can be advocated.

2.7 Role of nurses in chronic pain management

Since the 1980s nurses have been actively involved in managing chronic pain patients. However, over the past four decades, with changes in healthcare systems globally, the role of nurses in chronic pain management has evolved

substantially and has become more independent (e.g. nurse prescribing), although nurses still remain an integral part of most of the multidisciplinary pain programmes (Middleton, 2004). Various nurse-led interventions have been developed and evaluated in chronic pain management including the teaching of coping strategies such as breathing exercises and relaxation, cognitive behavioural therapy (CBT), sensorial stimulations, psycho-education, magnetic therapy, guided imagery and music therapy, motivational interviewing, hypnosis training and prescribing (Lefort et al., 1998, Schofield et al., 1998, Mannix et al., 1999, Becker et al., 2000, Kim, 2001, Simmons et al., 2002, Wells-Federman et al., 2002, McCaffrey and Freeman, 2003, Siedliecki and Good, 2006). Nurse-prescribing in chronic pain is perhaps the most recent nursing intervention in chronic pain management. Specialist pain nurses with prescribing authority can improve access to appropriate pain medicines, a barrier to effective pain management (Stenner and Courtenay, 2008). In the UK, the two main forms of nurse prescribing are: nurse independent prescribing (NIP), and nurse supplementary prescribing (NSP) (Department of Health, 2006). NIP enables nurses to prescribe any licensed medicine within their area of competence, including thirteen controlled drugs (Department of Health, 2006). For NSP, any medicine can be prescribed in line with the clinical management plan (CMP) agreed between the physician, who makes the initial diagnosis, the nurse prescriber and the patient.

Given that the nature of nurse-led interventions is quite diverse in chronic pain management, a number of studies, both observational and RCTs have been conducted to evaluate their effectiveness. The detailed presentation of all these studies is beyond the scope of this thesis, therefore only key RCTs and systematic reviews are briefly described below.

2.7.1 Randomised controlled trials

As mentioned above, a number of randomised controlled trials have been conducted to evaluate the effectiveness of various nurse-led interventions in chronic pain management. To avoid duplication, RCTs included in the systematic reviews have been briefly discussed in the systematic review section (section 2.6.2). The other key clinical trials are described below.

Jones et al. (2002) conducted an RCT and cost analysis to evaluate the effectiveness of a nurse-led education programme in reducing the chronic use of non-steroidal anti-inflammatory drugs (NSAIDs) by chronic pain patients in general practice in Nottinghamshire, UK. Of the 237 patients randomised 222 completed the 6-month follow-up. Patients in the control group received simple advice regarding the use of NSAIDs while the patients in the intervention group received advice, from a nurse practitioner trained in musculoskeletal assessment, on weight reduction, aerobic exercises, use of local heat and cold, back and neck care, massage and relaxation techniques. In addition, a therapeutic plan was drawn up in consultation with individual patients, tailored to their needs, in the intervention group to stop or reduce the use of NSAID. The intervention session lasted for 30-60 minutes. Change in NSAID use in 6-months post intervention was the primary outcome measure. The secondary outcome measures included changes in health status (measured by SF-36), quality of life (measured with EQ-5D) and the cost of drug and health services. Compared with control, an additional 28% of patients in the intervention group either stopped taking NSAIDs or reduced their dosage more than 50% at 6 months post intervention without having a negative impact on health status and quality of life. Furthermore, the authors reported a significant reduction in NSAID prescription costs in the intervention group compared with the control

(median reduction in NSAID costs per patient of £-2.61 in the intervention group was vs control over the 6-months). However, although non-significant, an increase in the overall drug prescription costs was noticed in both groups.

Another RCT conducted in the UK by Ryan et al. (2006) evaluated the effectiveness of a rheumatology expert nurse-led drug monitoring programme and reported statistically significant improvement in the Arthritis Impact Scale in the intervention group compared to the usual care group ($p=0.03$). In addition, a mean improvement of 1.8 in the Rheumatology Attitude Index (RAI) score was also reported in the intervention group compared to a mean deterioration of 0.3 in the usual care group. However, the change in the Disease Activity Scores (DAS) was not statistically significant, in the intervention group compared with the control, at 3 and 7 months follow-up but was significant at 12 months. Furthermore, there were no differences in terms of the use of NSAIDs (61% in the intervention group vs 53% in the control group) and steroids (39% in the intervention group vs 38% in the control group) in both the groups. The trial randomised 71 new RA patients who were about to start new disease modifying anti-rheumatic therapy at a district general hospital. The intervention was based on the Pendleton's framework (seven consultation tasks), explained elsewhere (Pendleton et al., 1984), to assess patients' needs in addition to the monitoring of drug safety delivered by a trained rheumatology expert nurse. Patients in the control group received care from an outpatient staff nurse for drug safety monitoring. Data were collected at the baseline, 3, 7 and 12 months. Interestingly, despite the fact that one of the aims of the intervention was to monitor drug safety, no data were reported on safety /adverse events. Mazzuca et al. (2004) in the USA, similar to the findings of Ryan et al. (2006), also documented a statistically significant reduction in the use of NSAIDs among

osteoarthritis patients in the intervention group (received nurse-led education on non-pharmacological modalities including quadriceps strengthening exercises, counselling on the principles of joint protection, and the use of thermal modalities) compared to the control (26% in the intervention vs 5% in the control ; $p=0.02$).

The above mentioned trials reported positive outcomes in the nurse-led intervention group. However, a few studies (4 studies) found during the literature search failed to demonstrate the effectiveness of nurse-led interventions.

Victor et al. (2005), in the UK, conducted a cluster randomised trial to compare the effectiveness of a nurse-led primary care based education programme, consisting of a home visit and four 1-hour teaching sessions, for patients with osteoarthritis of the knee with a waiting list control group. In total, 193 patients (73 controls; 120 interventions) were recruited and followed up at 1,3, 6 and 12 months. Only 125 patients (53 controls; 72 interventions) completed the 12 months follow up, dropout rate 35.2%. There were no statistically significant differences between the intervention and control groups in any of the outcome measures including the arthritis helpfulness index (AHI), quality of life (measured by the SF-36), pain, disability and stiffness (measured by WOMAC), and osteoarthritis knowledge at either 1-month or 12-month follow-up. The authors linked the lack of benefit to the short duration of the intervention and the heterogeneous nature of the population studied.

Tijhuis et al. (2002) compared the effectiveness of care provided by a clinical nurse specialist with an inpatient team care and day patient team care in patients with RA. In total, 210 (nurse specialist 71; inpatients 71; day patients 68) patients were recruited from the outpatient clinics of the rheumatology

departments of 6 hospitals in Leiden, The Netherlands. The clinical nurse specialist provided information about RA, prescribed, in consultation with the rheumatologist, and provided joint splints, adaptive equipment and other house adaptations if necessary. On an average, the duration of care provided by the nurse specialist was 12 weeks with a mean of 3 appointments per patient. Both day care and inpatient care teams consisted of nurses, a rheumatologist, an occupational therapist, a physical therapist, and a social worker. Both inpatients and day patients were prescribed a treatment programme of equal intensity tailored to the individual patient needs. Inpatients stayed overnight in the clinic for 12 consecutive days. On the other hand, day care patients stayed for 3 days a week (10am to 4pm) for 3 weeks with a fixed bed rest for 1.5 hours. After the intervention, the patients in all three groups received routine treatment from their rheumatologist. Outcomes were assessed at the baseline, 6, 12, 26 and 52 weeks. There were significant improvements in functional status (measured with the Health Assessment Questionnaire (HAQ)), quality of life (measured with the RAND 36-item Health Survey 1.0 and the Rheumatoid Arthritis Quality of Life (RAQoL) questionnaire), health utility (measured with the Health Utility Index scale) and disease activity (measured with the Disease Activity Score (DAS)) from the baseline (all $p < 0.05$). However, there were no significant differences between the three groups for any outcome measure except for patient satisfaction; where patients in the clinical nurse specialist care were significantly less satisfied than the patients in the inpatient care and day care ($P < 0.001$). The reasons for dissatisfaction, however, were not explored. This was probably due to the fact that the patients in the other two groups were provided with more intense care compared to the patients in the clinical nurse specialist care. But the clinical benefit of all the interventions was similar. Since there were no significant differences in any of the clinical outcomes between the three groups,

the authors would have been able to make a strong case for nurse-led care for patients with RA by performing the cost-minimization analysis.

In a German primary care setting, Leonhardt et al. (2008) conducted a cluster randomised controlled trial to evaluate the effectiveness of a Transtheoretical Model (TTM) based motivational counselling approach by trained practice nurses to improve physical activity among patients with low back pain (LBP). TTM is a theory based counselling technique designed to promote physical activity (Prochaska and DiClemente, 1983), and is often used in combination with motivational interviewing (Miller and Rollnick, 1991). This 3-arm cluster RCT compared motivational counselling by trained nurses (Group A) to general counselling by the GPs (Group B) and usual care (Group C). The GPs in group A and B were trained in using German LBP guidelines. However, in Group B, the nurses received additional training in TTM-based motivational counselling. Patients had up to three counselling sessions with the nurses, 15 to 20 minutes each. In the usual care group, the GPs received LBP guidelines in mail with no training with regards to its implementation. Outcome measures included a total physical activity score measured with the Freiburger Questionnaire on Physical Activity (FQPA) (primary outcome) and a mean self-efficacy score (secondary outcome) measured on a 1 to 5 numerical rating scale (NRS), assessed at baseline, 6 and 12 months. The trial recruited 1378 LBP patients both with acute and chronic symptoms. One hundred and sixty seven (12.1%) patients dropped out by 12 months. There were significant improvements in patients' physical activity in all study arms both at 6 and 12 months compared to the baseline. However, there was no significant improvement in physical functioning when compared with the control (usual care) group, indicating the lack of intervention effect. The lack of benefit could

be partly explained by the inadequate performance of the practice nurses, implementation barriers within German healthcare system and the heterogeneous sample.

Sørensen and Frich (2008) performed a cost consequence analysis, based on an RCT, of a nurse-follow up intervention for chronic pain patients discharged from a multidisciplinary pain centre in Copenhagen, Denmark. In total, 102 chronic pain patients attending a multidisciplinary pain centre at a university hospital were randomised into a control and intervention group, and followed up for two years. Over two years, the nurses visited patients 7 times in total (every fourth month). The purposes of these visits were to: monitor pharmacotherapy and side effects, and refer to the GP if required; reinforce patients' knowledge about chronic pain and coping strategies; and detect symptoms depression associated with pain. There were no statistically significant differences in the health status, measured by SF-36, between the two groups. The cost of the nurse intervention was €35,000 (£29,066) over the two years, with an average cost of €648 (£538) per patient. Although not statistically significant, patients in the control group used more health resources worth €7046 (£5851) compared with €4004 (£3325) (difference €3460 (£2873), 46%). However, the overall cost of the intervention was much more than the savings on the usage of other health resources. Therefore the intervention was not deemed to be cost-effective.

2.7.2 Systematic reviews

The literature search found three systematic reviews (Sindhu, 1996, Castillo-Bueno et al., 2010, Ndosu et al., 2011). One of the systematic (Sindhu, 1996) reviews evaluated the effectiveness of non-pharmacological nursing interventions among patients with acute pain, therefore it is not presented here.

Castillo-Bueno et al. (2010) conducted a systematic review to evaluate the effectiveness of nursing interventions, specifically non-pharmacological, in the management of chronic pain. There are two important aspects in terms of the design of the systematic review: Firstly, the authors used a six-month cut off, instead of a more frequently used 3-month cut off, to define chronic pain in the systematic review. Secondly, the inclusion criteria also included quasi-experimental studies in addition to the RCTs. Of the 1666 articles retrieved, eight randomised controlled trials were included in the review. The authors were unable to undertake meta-analysis due to heterogeneity among the included studies in terms of study population, nature of intervention and duration of follow-up. Of the eight trials included, two trials evaluated the effectiveness of music as a nursing intervention for the management of chronic pain (McCaffrey and Freeman, 2003, Siedliecki and Good, 2006); one trial each evaluated cognitive behavioural therapy (Becker et al., 2000), psycho-education programme (Lefort et al., 1998), physical exercise programme (Simmons et al., 2002), magnetic field therapy (Kim, 2001), guided imagery (Mannix et al., 1999), and sensorial simulation (Schofield et al., 1998). The review found that the cognitive behavioural and the sensorial stimulation programmes were effective in reducing perceived pain, and psycho-education and music therapy programmes reduced osteoarticular pain. Guided imagery and magnetic field therapy benefited patients with chronic headache while physical exercise programme improved mobility among elderly but did not relieve pain. However, the clinical significance of these findings were not demonstrated in the review. Furthermore, it should be noted here that, since the meta-analysis was not undertaken, the findings of this systematic review were based on the findings of small 1 to 2 individual trials for each nursing intervention. Therefore, no conclusive evidence can be drawn to support the effectiveness of these

interventions in chronic pain management from this systematic review. Furthermore, the cost-effectiveness of these findings were not demonstrated in the review. Despite these limitations, the review authors concluded that these interventions were effective, except the physical exercise programme, and should be considered in addition to the standard pharmacological treatment for the management of chronic pain. On the contrary, this author believes that the use of these interventions in routine clinical practice should not be recommended until more high quality evidence is available to support their effectiveness.

Ndosi et al. (2011) conducted a systematic review of randomised controlled trials to compare the effectiveness of nurse-led interventions with usual care among rheumatoid arthritis patients. The review included 4 RCTs involving 431 patients in total. The included trials had an overall low risk of bias and followed up patients for 1 to 2 months. Three trials were reported from the UK and one from the Netherlands. There were no statistically significant differences between the groups (usual care vs nurse-led care) for the two disease activity scores (DAS) primary outcomes; DAS 28 (ratio of means (RoM) = 0.96, 95%CI [0.90–1.02], P= 0.16); and plasma viscosity (RoM = 1 95%CI [0.8–1.26], p= 0.99). However, significant improvement was noticed in the Ritchie Articular Index (RoM = 0.89, 95%CI [0.84–0.95], P<0.001) in the nurse-led care group compared with the usual care group. Furthermore, statistically significant improvements were found in the nurse-led care group compared to the usual care group for quality of life (RAQoL RoM = 0.83, 95%CI [0.75–0.92], P<0.001), patient knowledge (PKQ RoM = 4.39, 95%CI [3.35–5.72], P<0.001) and fatigue (median difference = - 330, P= 0.02). However, statistically non-significant differences were reported for other secondary outcomes including

functional status, stiffness and coping with arthritis. Interestingly, the results of two of the secondary outcomes (satisfaction and pain) varied in their statistical significance when assessed using different tools. In summary, the systematic review and meta-analysis could not generate conclusive evidence to support the nurse-led interventions in the management of RA, necessitating more good quality RCTs to strengthen the evidence.

To summarise, the RCTs evaluating the effectiveness of the nurse-led interventions have documented mixed results. The RCTs varied in terms of the nature of intervention, patient population, duration of follow up, settings and outcomes measures. Due to this heterogeneity, systematic review authors were unable to undertake meta-analysis. Subsequently, no conclusive evidence can be drawn from the existing literature. However, it would not be incorrect to conclude here that there is a potential role for nurses in the management of chronic pain, but more high quality research work is required to identify the type of patients who could benefit more from such services.

2.8 Combined nurse-pharmacist managed pain clinics

Despite a number of studies supporting the role of nurses and pharmacists in chronic pain management, examples of combined nurse-pharmacists managed clinics are almost non-existent in the literature. This is perhaps due to the fact that the role of pharmacists in chronic pain management is relatively new unlike nurses who have traditionally been part of multidisciplinary pain management teams. The author could only retrieve two studies evaluating the impact of combined nurse-pharmacist managed pain clinics on patient reported outcomes. One study was conducted by Weidemer et al. (2007) in the USA and the other by Briggs et al. (2008) in the UK. The nature of the services, and type of patients referred to the clinics were completely different in the two studies,

however there were some similarities in the roles of nurses and pharmacists within both of the services. This study was conceived in order to address the limitations of the Briggs et al. (2008) study and to further evaluate the effectiveness of a nurse-pharmacist managed chronic pain service. Since this study was based on the Briggs et al. (2008) study, the working of the clinic, limitations to the current evidence are presented in more detail to give contextual background and rationale for this study (described below; section 2.8.1).

In the USA, Weidemer et al. (2007) conducted a naturalistic prospective study to evaluate the impact of a combined nurse practitioner (NP) and clinical pharmacist run pain management clinic in a large primary care medical centre, the Opioid Renewal Clinic (ORC) For the ORC, the NP and clinical pharmacist developed and implemented a structured approach to prescribing and monitoring of opioids to ensure their safe and effective use. The overall aim was to reduce abuse of opioids among patients. The NP and clinical pharmacist were supported by a multidisciplinary team of consultants (psychiatrist, rheumatologist, orthopaedist and neurologist) Limitations of single group pre-post study designs have already been discussed earlier in this chapter (section 2.6.1). Patients were referred to the programme by their primary care practitioners (PCP).. A multidisciplinary pain management team arranged bi-weekly meetings with a nurse practitioner and clinical pharmacist and advised them on treatment plans. The authors reported that 'aberrant' behaviours were resolved in 77 (45%) of the 171 patients with documented 'aberrant' behaviour. Furthermore, significant pharmacy cost savings were also reported. Twenty-two patients were further referred for addiction treatment. No data on pain relief and physical functioning were reported.

2.8.1 The nurse-pharmacist managed pain clinic (NPMPC)

The foundation of the clinic was laid with the establishment of the Community Pain Forum in 2001 (Closs et al., 2011). The forum then undertook focus group interviews involving 72 healthcare professionals to assess local needs for the provision of chronic pain service (Briggs et al., 2004). In 2004, upon completion of the pain service needs assessment project, a multidisciplinary Chronic Pain Steering Group was set up consisting of representatives of the primary care trust (PCT) and the Leeds Teaching Hospitals NHS Trust (LTHT) (Closs et al., 2011). The group developed guidelines for the management of chronic pain and proposed the establishment of a community-based pain clinic, jointly managed by a nurse and a pharmacist. Subsequently the clinic was established and started receiving chronic pain patients in 2005.

In order to provide the best possible professional service, a district nurse (KM) underwent a specialized pain management training programme at an associated hospital pain clinic. The services of a community pharmacist were secured through a working arrangement between Boots Pharmacy and the PCT. The community pharmacist worked for one day per week at the pain clinic. To ensure a smooth work flow, comprehensive referral pathways and clinical guidelines were also developed. The patients with chronic pain were referred by general practitioners (GPs) either to the pharmacist-nurse managed pain clinic or to secondary care based on local guidelines. For example, patients with malignant pain, or psychiatric disorder were directly referred to secondary care. However, if deemed necessary, the nurse and/or the pharmacist could further refer any patient to secondary care. Together with the referral note, the GPs also sent the details of patients' and current and past medical and medication history to the clinic.

Prior to the first consultation, while waiting to be seen by the nurse and the pharmacist, the clinical nurse specialist (CNS) administered the Brief Pain Inventory (BPI) (Cleeland and Ryan, 1994) to assess pain intensity, severity and interference with daily activities; and the Hospital Anxiety and Depression Scale (HADS) (Zigmond and Snaith, 1983) to assess anxiety and depression (emotional functioning) to all patients. During consultation, the pharmacist obtained all relevant medication and medical history. The pharmacist then discussed any adverse effects and the degree of pain relief with the current prescribed medication with the patient. Issues such as adherence to the prescribed medicines and use of any over the counter (OTC) medicine or complementary and alternative therapy were also explored during the consultations. The pharmacist then reviewed patients' medicines, provided medication counselling and checked for drug interactions with the aim of ensuring optimal use of analgesics through a concordant approach. The nurse educated the patient about pain, clarified any misconceptions, and supported the development of skills needed to self-manage. Finally, the pharmacist and nurse discussed the future treatment plan with the patient and, where needed, made recommendations to the GP. Safety and suitability of analgesic use was assessed based on medical and medication history before making any recommendation. The common medication related recommendations included: dose adjustment, stopping a particular analgesic and addition or substitution of analgesics (opioid to non-opioid or NSAID and vice versa). The GP then reviewed the treatment and changed it as appropriate. During the follow-up visits, the patients were seen only by the clinical nurse specialist unless considered necessary by the clinical nurse specialist. BPI and HADS were also administered on follow-up visits to monitor progress with the treatment. During the follow up visits the clinical nurse specialist reinforced self-management

skills, provided further patient education, resolved any issues with medication use and monitored patients for any adverse events. On average, the first session lasted for one hour and the follow-up sessions lasted for 30–40 minutes and the patient was usually discharged after three to four sessions. The clinic received more than 150 to 200 new patients every year.

In 2012, the local PCT decommissioned the service, despite the fact that the pilot study showed favourable outcomes and a mixed-methods study, this one, was going on at that time. The services of the nurse pain specialist were transferred to the musculoskeletal services. However, pharmacist services were discontinued, a decision not based on existing evidence which supports the role of pharmacist in chronic pain management. How the termination of the service affected this study is highlighted later in the thesis (Chapter 5).

2.8.2 Research evidence

A pilot study was conducted by Briggs et al. (2008) to evaluate the impact of the nurse-pharmacist managed pain clinic on pain intensity, using a retrospective single group pre-test-post-test design. A research nurse (JB) who was not involved in delivering the service collected data by reviewing patients' clinical notes available at the pain clinic. Sixty five patients were included in the study with a mean age of 57 (SD 15) years. The discharge pain score was only available for 37 patients. The pain intensity was assessed using an 11-point (0 to 10) Numerical Rating Scale (NRS). The authors reported a significant reduction in pain score from a mean of 8 upon referral to 6.3 at discharge ($P < 0.0001$). Furthermore, referrals to secondary care were also reduced. Of the 120 patients attending the clinic, only 13 were further referred to secondary care. However, the pilot study provided limited information about the nature of the intervention, sociodemographic and clinical characteristics of patients

referred to the clinic, and the clinical significance of the effect size. Additionally, the retrospective study design, small sample size, and the use of pain scores alone as an outcome measure, further limits the usefulness of the findings. The present study was designed to address these issues and develop robust evidence to establish the effectiveness (or otherwise) of the nurse-pharmacist managed pain clinic described above.

2.9 Aims and objectives

After carefully reviewing the existing literature, two main research gaps were identified. Firstly, there was a lack of clear evidence to support the effectiveness of pharmacist-led medication review in chronic pain management as RCTs have reported inconsistent results. Secondly, further research evidence was required to support the effectiveness of the nurse-pharmacist managed pain clinic and to overcome the limitations of Briggs et al. (2008). As mentioned earlier, this clinic provided an excellent example of public-private sector partnership in healthcare settings. This was another important reason to further evaluate the effectiveness of the clinic, so that, if effective, more such services could be established widely. This thesis was set to fulfil these research gaps. Therefore, the first aim was to conduct a systematic review to evaluate the effectiveness of pharmacist-led medication review in chronic pain management. The objectives were:

1. Does pharmacist-led medication review decrease pain intensity?
2. Does it reduce medication-related adverse effects?
3. Does it improve patients' physical functioning and quality of life?
4. Are patients satisfied with the service provided by pharmacists?

The second aim was to evaluate the impact of a nurse-pharmacist managed pain clinic (NPMPC) on patient reported outcomes.

The objectives were to:

1. study the socioeconomic and clinical characteristics of patients attending the NPMPC.
2. assess the impact of NPMPC on pain intensity.
3. evaluate the impact of NPMPC on physical functioning, emotional functioning and health related quality of life (HRQoL).
4. explore issues around patients' satisfaction with the pain management service provided by NPMPC.

CHAPTER 3

**EFFECTIVENESS OF PHARMACIST- LED MEDICATION
REVIEW IN CHRONIC PAIN MANAGEMENT: SYSTEMATIC
REVIEW AND META-ANALYSIS**

CHAPTER 3

EFFECTIVENESS OF PHARMACIST- LED MEDICATION REVIEW IN CHRONIC PAIN MANAGEMENT: SYSTEMATIC REVIEW AND META-ANALYSIS

3.1 Introduction

As described in the earlier chapter, mixed results have been reported by the randomised controlled trials (RCTs) evaluating the effectiveness of pharmacist led medication review in chronic pain management. With the aim of generating substantial evidence, a systematic review of RCTs evaluating the effectiveness of pharmacist-led medication review in chronic pain management is reported in this chapter.

The chapter begins with a brief general overview of systematic reviews and the importance of the development of a systematic review protocol and its registration. That is followed by the discussion on the rationale of undertaking the present systematic review, and then its aim and objectives are presented. Then methods and results are described in detail. Finally, the results are discussed and implications for future research and practice are suggested.

3.2 Systematic review: An overview

Chalmers and Altman (1995) described systematic review as a review that has been assembled using a systematic approach, thoroughly described in the methods section, to minimize bias and random errors. It aims to identify and summarise relevant research evidence against pre-determined inclusion criteria

with the intention of answering a particular review/research question (Higgins and Green, 2011). Since systematic reviews use pre-set inclusion criteria and systematic methods to minimize biases, the results obtained are more reliable thus facilitating the decision making process. The systematic review differs from traditional literature reviews and commentaries as being reproducible, transparent and less biased. Systematic reviews not only collate research evidence but also identify research gaps.

Until recently, systematic reviews were only used in medical research to synthesize evidence on the effectiveness of healthcare interventions by combining data extracted from controlled trials. However, with the growing use of qualitative and mixed-methods research designs in healthcare to inform policy and practice, systematic review methods for qualitative and mixed-methods research have also been developed in the last decade (Gough et al., 2012). The detailed description of each method is beyond the scope of this thesis. The choice of which data (quantitative, qualitative or both) to be used is primarily determined by the scope of the review and the review questions. A number of methods are available for the synthesis of qualitative research including Meta-ethnography (Noblit and Hare, 1988), Meta-study (Paterson et al., 2001), Meta-narrative (Greenhalgh et al., 2005), Critical Interpretive Synthesis (Dixon-Woods et al., 2006), Frame work synthesis (Brunton et al., 2006) and Textual Narrative synthesis (Lucas et al., 2007). Broadly, there are two approaches to integrate qualitative and quantitative data in mixed-methods systematic reviews: Multilevel synthesis (Thomas et al., 2004) and parallel synthesis (Noyes and Popay, 2007). Quantitative systematic reviews synthesise data obtained from primary studies either narratively or statistically. The quantitative data for systematic review can be extracted from both randomised

controlled trials (RCTs) and non-randomised studies (epidemiological studies). However, being considered as the 'gold standard' for measuring effectiveness of an intervention, RCTs are the most frequently used research methodology in systematic reviews especially for '*what works*' systematic reviews.

The statistical combination of data from two or more primary studies is referred to as meta-analysis (Higgins and Green, 2011). Meta-analysis generally produces a single estimate of treatment effect (Huque, 1988) thereby increasing the power and precision of the results of primary studies (Higgins and Green, 2011). Other advantages of meta-analysis include resolving disagreements between results of different primary studies, if any, and answering unaddressed questions of primary studies. Therefore it is not always feasible or reasonable to conduct a meta-analysis due to variations in research design, differences in study population and quality of reported data within primary studies. Meta-analysis of studies at high risk of bias and in the presence of publication bias may also not be appropriate and may be criticised for combining 'apples with oranges' (Higgins and Green, 2011). Meta-analysis can be misleading if the above mentioned issues are not carefully considered. If statistical combination is not possible in a review, data are combined narratively. The process involved in conducting a systematic review is similar irrespective of the type of data to be combined. The basic steps involved in conducting a systematic review are shown in Figure 3.1.

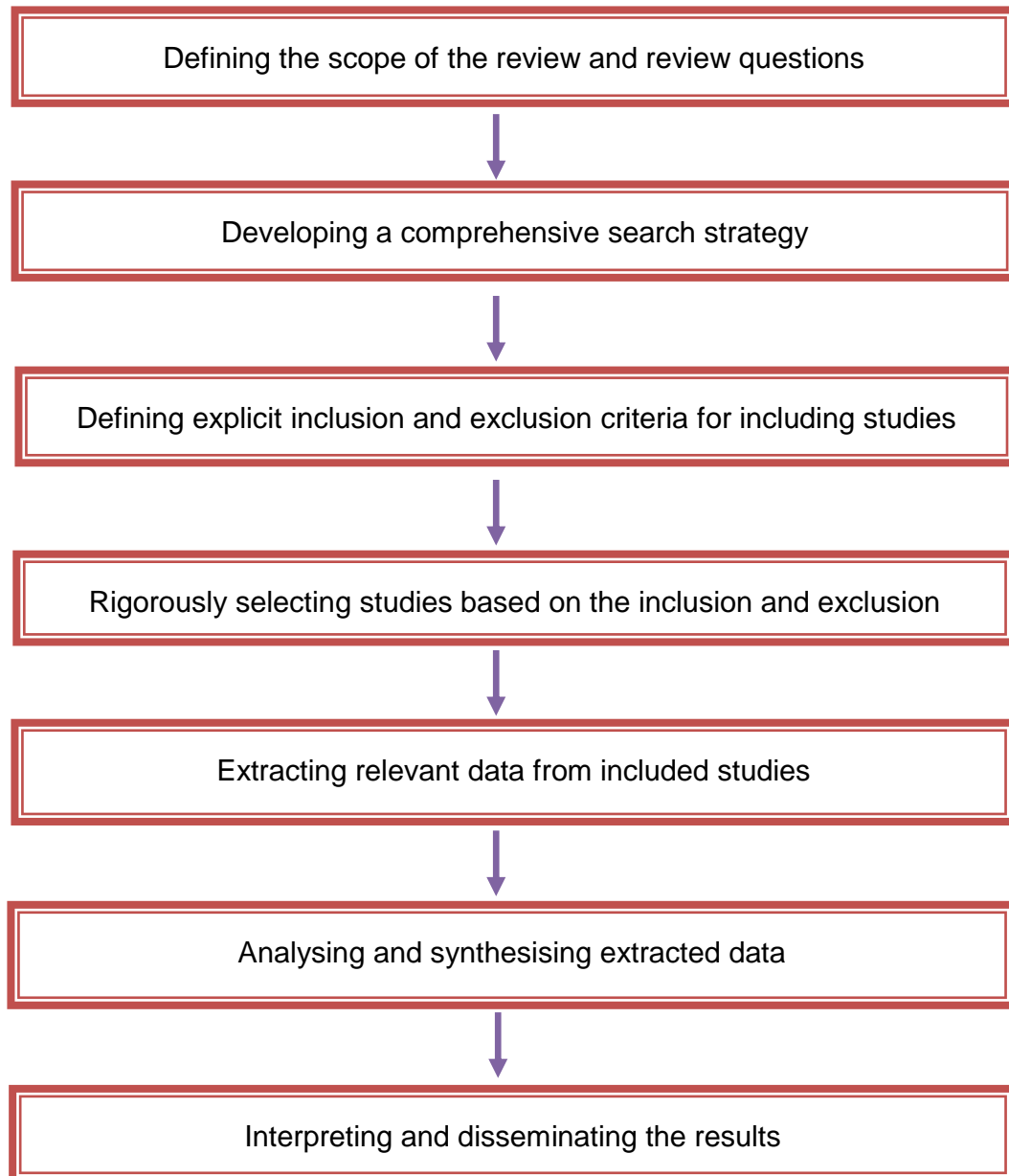


Figure 3.1. Basic steps in conducting a systematic review

3.2.1 Systematic reviews in evidence-based medicine

“Evidence-based medicine (EBM) is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research” (Sackett et al., 1996, P. 71). Over the past two decades, there has been an enormous increase in the volume of health related published research and consequently it has become increasingly difficult for researchers and practitioners to keep abreast of the latest findings. It is impossible for healthcare professionals and policy makers to have the time, expertise and resources to locate, read, critically appraise and interpret all relevant research findings to make an informed decision about patient care based on current evidence (Higgins and Green, 2011). Systematic reviews can potentially resolve this problem by identifying, critically appraising, and synthesising the research evidence. Depending on the research question, well designed and conducted systematic reviews may provide the best research evidence (Merlin et al., 2009); therefore they have an important position in evidence-based medicine in guiding healthcare policies and informing clinical decision-making.

3.1.3 The review protocol: Rationale and importance

A systematic review protocol details the research questions, search strategy, inclusion/exclusion criteria and planned data analysis (Higgins and Green, 2011). The protocol should always be written in advance to ensure transparency and reproducibility. The PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines (Moher *et al.*, 2009) also recommend the development of and adherence to systematic review protocols

to avoid the introduction of bias. Changes in protocol may be necessary but should always be reported together with the reason in the review (Moher et al., 2009). Changes such as adding or removing outcomes, or performing unplanned subgroup analyses have the potential to introduce bias and the prospective registration/publication of protocols can help safeguard against these biases as it allows the reader to compare what was planned (protocol) with what has been reported in the finished systematic review (Stewart et al., 2012). Furthermore, registration helps researchers in complying with PRISMA guidelines and increasing awareness of their review (Stewart et al., 2012).

In order to ensure transparency and avoid duplication, the systematic review protocol was registered with PROSPERO, an international register for prospective registration of systematic reviews developed and maintained by the National Institute of Health Research's (NIHR) Centre for Reviews and Dissemination (CRD) at the University of York, UK. (Registration number: CRD42012001957) and published in the Canadian Pharmacists Journal (Hadi et al., 2012). PROSPERO is the only international online resource to register systematic reviews in healthcare (Centre for Reviews and Dissemination, 2012).

3.2 Rationale for the review

The management of chronic pain is complex as chronic pain does not only interfere with physical functioning but also causes deterioration in emotional functioning and quality of life. Accessibility and affordability of multidisciplinary pain clinics further complicates its management. A large European survey reported that one-third of the chronic pain patients were not receiving any treatment and 40% were inadequately managed.

Medications are widely employed for the treatment of chronic pain and pharmacists, being experts in pharmacotherapy, have a potential role in chronic pain management by ensuring the safe and effective use of medicines. Sub-optimal use of analgesics (Hanlon et al., 1996), inadequate monitoring of repeat prescriptions (The Accounts Commission for Scotland, 1999), and self-medication with over the counter (OTC) analgesics in combination with prescribed analgesics resulting in overdosing (polypharmacy) (Porteous et al., 2005) have been reported in the literature, and pose a threat to the successful management of chronic pain.

Medication review is a structured critical examination of a patient's medicines with the aim of optimising medicines use, preventing medication-related problems and reducing waste, in an agreement with the patient (Taskforce on Medicines Partnership and The National Collaborative Medicines Management Services Programme, 2002). Medication review has the potential to overcome all the above mentioned obstacles in the management of chronic pain. Theoretically, pharmacist-led medication review may improve pain-related outcomes by optimising the choice and dose of analgesics, improving adherence to prescribed medication, reducing adverse effects and resolving drug-related problems (DRPs). However, limited and inconsistent clinical and research evidence is available to support these claims in the context of chronic pain (Suh et al., 2004, Weitzel et al., 2004, McDermott et al., 2006, Phelan et al., 2008). A well conducted systematic review has the potential to generate conclusive quality evidence to support, or refute, the effectiveness of pharmacist-led medication review in chronic pain management. However, to date, no systematic review has evaluated the effectiveness of pharmacist-led medication review for chronic pain management. This systematic review was

undertaken to fulfil this important research gap and to resolve controversies surrounding the effectiveness of pharmacist-led medication review in chronic pain management.

3.2.1 Aim and objectives

As highlighted earlier, the aim of this systematic review was to evaluate the effectiveness of pharmacist-led medication review in chronic pain management in adult patients. The specific research questions were:

- 1) Does pharmacist-led medication review decrease pain intensity?
- 2) Does it reduce medication-related adverse effects?
- 3) Does it improve patients' physical functioning and quality of life?
- 4) Are patients satisfied with the service provided by pharmacists?

3.3 Methods

3.3.1 Study selection

The following databases were searched using pre-defined search strategy. The searches were conducted during April-June 2012.

- MEDLINE (via Ovid)(1946 to June 2012),
- EMBASE (via Ovid)..... (1947 to April 2012)
- Cochrane Central Register of Controlled Trials..... (Issue 6 of 12, June 2012)
- Cumulative Index to Nursing and Allied Health Literature (CINAHL) (via EMBSCO)..... (1960 to June 2012),
- PsycINFO..... (1806 to June 2012)
- International Pharmaceutical Abstracts (via Ovid)..... (1970 to June 2012)

Randomised controlled trials (RCTs) and non-randomised studies (quasi-experimental, controlled before-and-after study) having at least one control group were considered for inclusion. Non-randomised studies were only to be considered for inclusion if less than three randomised controlled trials were eligible for inclusion (Karjalainen et al., 2003). Waiting list controls, usual care, attention only and any other active control were accepted as appropriate controls. Studies were considered for inclusion if one of the arms received either pharmacist-led medication review delivered independently, or as part of more complex multidisciplinary interventions, provided that the pharmacist was part of the multidisciplinary team. In addition to database searches, websites of American, Canadian and Royal (British) Pharmaceutical societies were also searched together with the reference lists of the retrieved articles to identify any additional eligible studies. Studies published only in English language (full text or abstract) were considered. The corresponding authors of the included studies were contacted to obtain additional information where required and to identify any other unpublished studies. An example of the search strategy is presented in Appendix I.

The search strategy was developed in consultation with an experienced health science librarian. The process of study selection involved three steps 1) The author ran the pre-defined specific search strategy on each of the chosen databases. All the searched results were exported to an Endnote file. 2) Study titles and abstracts of the studies were screened independently by the author and one of his supervisors (DPA). Disagreements were resolved through discussion and if agreement was not reached, another supervisor (MB) was consulted. Full texts of all studies considered potentially relevant studies were

retrieved. 3) Finally, the author and one of his supervisors (DPA) independently selected studies meeting the pre-defined and pilot-tested inclusion criteria.

3.3.2 Types of participants

Studies involving chronic pain patients 18 years and older were included regardless of their gender, type and aetiology of chronic pain. In this systematic review, The International Association for the Study of Pain (IASP) definition of chronic pain: *“Pain without apparent biological value that has persisted beyond the normal tissue healing time (usually taken to be 3 months)”* was used (International Association for the Study of Pain, 1986). Studies involving patients with malignant or cancer pain were excluded as these would have introduced clinical heterogeneity.

3.3.3 Outcome measures

The primary outcome measure was pain intensity measured using a validated scale (e.g. numerical rating scale). The secondary outcome measures included: 1) reduction in adverse effects; 2) physical functioning measured using a validated scale (e.g. Brief Pain Inventory); 3) patient satisfaction using a validated scale; and 4) quality of life measured using a validated scale (e.g. SF-36).

3.3.4 Assessment of risk of bias

The risk of bias was assessed for all the included studies by the author and checked by one of his supervisors (SJC) using a standardised form (Appendix II). Bias is a *“systematic error or deviation from the truth, in results or inferences”* (Higgins and Green, 2011, P.188). Bias attributed to a particular design deficiency (e.g. lack of allocation concealment) may inflate the effect size in one study and deflate it in another (Higgins and Green, 2011). A number of

scales and checklists exist in the literature to assess 'quality' or risk of bias in randomised controlled trials but the use of these quality scales and checklists is discouraged (Higgins and Green, 2011) as the scales give unreliable assessments of validity (Jüni et al., 1999) and lack transparency (Higgins and Green, 2011). Therefore, the risk of bias was assessed using the Cochrane Collaborations' tool for assessing risk of bias (Higgins and Green, 2011), a domain-based evaluation rather than a checklist or scale, covering the following criteria: 1) random sequence generation; 2) allocation concealment; 3) blinding of participants and personnel; 4) blinding of outcome assessment; 5) incomplete outcome data and; 6) selective reporting and other bias (e.g. baseline differences between control and active arms, use of invalid questionnaires). For cluster randomised controlled trials, risk of bias was assessed across additional domains including loss of clusters and appropriate statistical analysis. Each domain was assessed and categorised into low risk of bias, high risk of bias or unclear risk of bias based on the recommendations of Higgins and Green (2011). Disagreements were resolved through discussion and if consensus was not reached a third reviewer (MB) was consulted.

3.3.5 Data extraction

Data was extracted by the author (MAH) and checked by one of his supervisors (MB) using a standardised data collection form. The data collection form was pilot tested. Disagreements were resolved through discussion, and if no consensus was reached, opinion of a third reviewer (SJC) was requested.

3.3.6 Data synthesis

The data was analysed using the Cochrane Collaboration's software Review Manager (RevMan 5.1). For all continuous variables (e.g. pain intensity), mean difference (MD) was calculated when outcomes were

measured using the same scale and standardised mean difference (SMD) when different scales were used with corresponding 95% confidence intervals. For dichotomous variables, relative risk (RR) with 95% confidence intervals was calculated. Pooling of data using meta-analysis was performed depending on the clinical homogeneity in terms of the population, intervention, outcome measures and timing of outcome measures.

Clinical heterogeneity was determined by discussion among the author and his supervisors, and clinically heterogeneous trials were not combined statistically. Statistical heterogeneity was determined by using chi-square (χ^2) and I^2 statistic. Statistical heterogeneity determined the choice of using random-effects model or fixed-effects model for meta-analysis. A χ^2 P value of greater than 0.1 and an I^2 value of less than 50% was used to indicate statistical homogeneity (Higgins and Green, 2011). Random-effects model was used to combine clinically homogeneous but statistically heterogeneous clinical trials, whereas clinical and statistical homogenous trials were combined using the fixed-effects model.

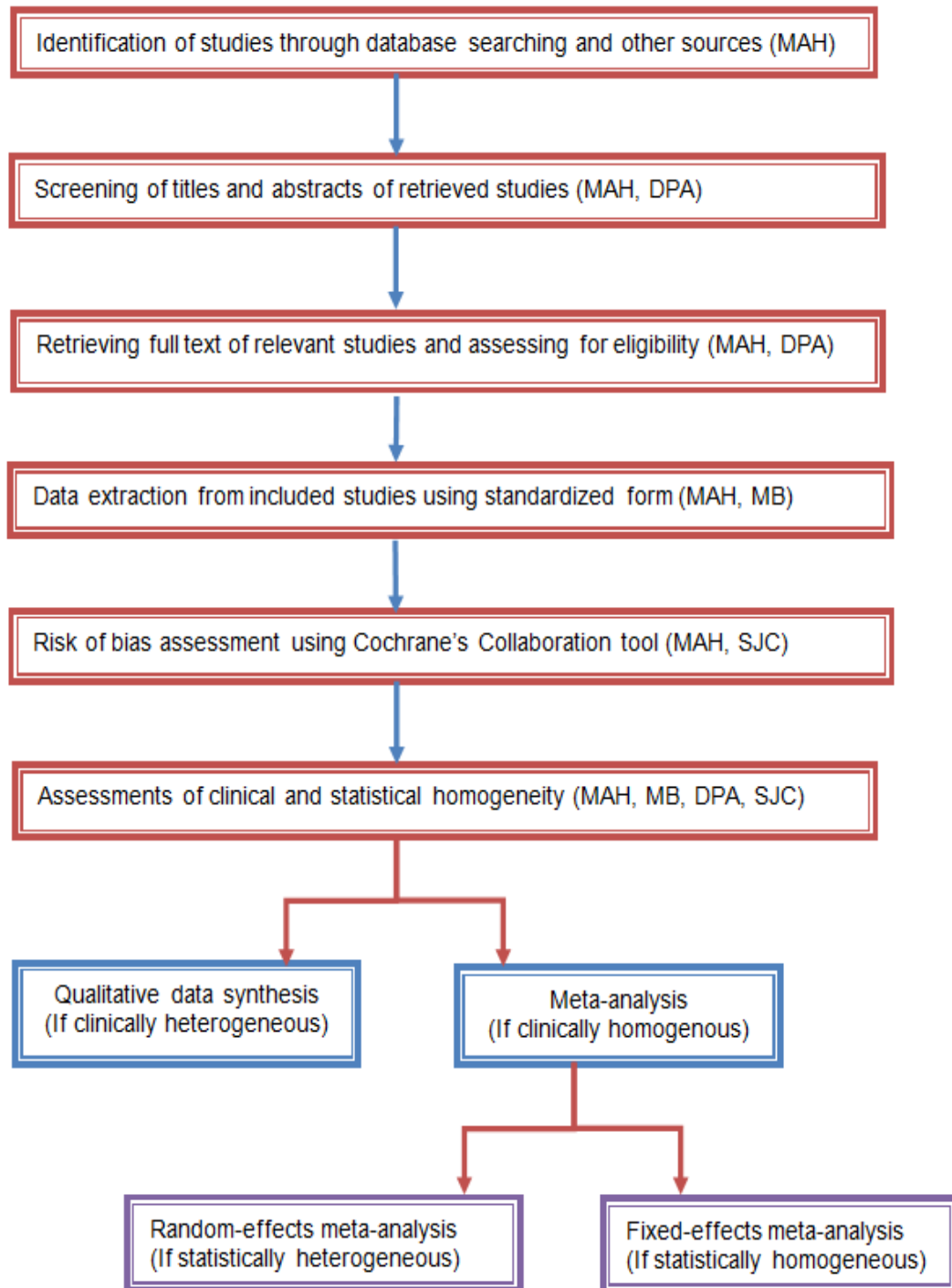


Figure 3.2. Work flow of this systematic review

3.4 Results

3.4.1 Study characteristics

Six hundred and sixty-four articles were retrieved through database searches (578 after deduplication). Of these 578 articles, 27 were considered relevant to the review after initial title and abstract screening. An additional five articles were found through other sources including two each through author contact and reference list searching, and one through website searching. Of these 32 articles, nine reports from five studies met the inclusion criteria for review (Marra et al., 2008, Bruhn et al., 2011b, Phelan et al., 2008, Hoffmann et al., 2008, Hay et al., 2006, Bond et al., 2011, Bruhn et al., 2011a, Marra et al., 2012, Gammaitoni et al., 2000). Figure 3 shows a PRISMA flow diagram to explain the search process and the reasons for exclusion from the review. Two trials were conducted in the UK (Hay et al., 2006, Bruhn et al., 2011a) and one each in Canada (Marra et al., 2012), Germany (Hoffmann et al., 2008) and the USA (Gammaitoni et al., 2000) .

The included studies consisted of three individually randomised (Hay et al., 2006, Gammaitoni et al., 2000, Bruhn et al., 2011a) and two cluster randomised controlled studies (Marra et al., 2012, Hoffmann et al., 2008) randomising 1035 patients in total. All trials followed up the patients for at least 3 months. Three trials followed-up patients for 6 months and one trial for 12 months. All studies had their first follow-up at 3 months except for Hoffman et al study (2008) where the first (and the last) follow-up was made at 4 months. In total, 131 patients (12.7%) were lost to the first follow-up. Two trials included patients with chronic pain of various aetiologies (Bruhn et al., 2011a, Gammaitoni et al., 2000), another two involved patients with knee pain

associated with osteoarthritis (Hay et al., 2006, Marra et al., 2012) and one trial involved chronic headache and migraine patients (Hoffmann et al., 2008). In four trials where gender was reported, the majority of the participants were females (61.8%). The mean age of participants varied between 62.7 years (SD \pm 9.2) in Marra et al. (2012) study, 67.9 years (SD \pm 8.2) in the Hay et al. (2006) study and 42.70 years (SD \pm 13) in the Hoffman et al. (2008) study. The study by Bruhn et al. (2011) did not report age and participants in the Gammaitoni et al. (2000) study ranged from 35-64years.

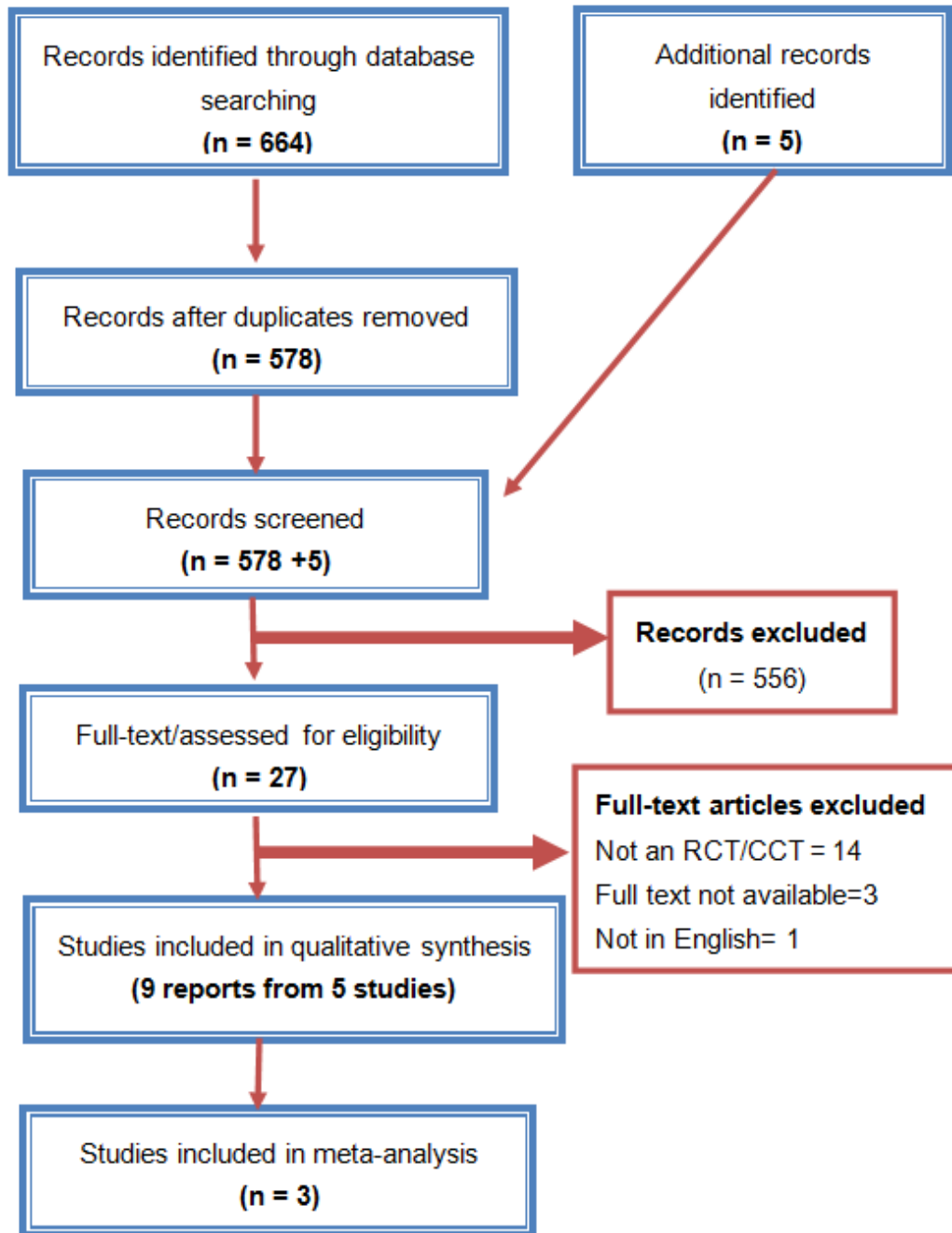


Figure 3.3. PRISMA flow diagram

3.4.2 Nature and delivery of intervention

In three trials (Bruhn et al., 2011a, Hay et al., 2006, Hoffmann et al., 2008), the intervention group received pharmacist-led medication review alone where as in the other two trials (Marra et al., 2012, Gammaitoni et al., 2000) the intervention group received medication review as part of a multi-component intervention. In the Gammaitoni et al. trial (2000), the intervention comprised of two components. The first component was a specialised prescription service provided by a palliative care pharmacy company (PainRxperts) which delivered patients' medication to their home or to the clinic, when requested. The aim of the service was to improve accessibility to pain medicine and to reduce the burden of managing medication treatment for clinical practice. The second component was proactive monitoring of patients' medication therapy for any potential or actual drug related problem (DRP) by a palliative care trained pharmacist, with an access to patients medical records, to ensure that the drug therapy was achieving desired patient outcomes (i.e. improvement in quality of life). In total, 81 phone calls were made by the pharmacist including 45 to patients (mean 1.2 calls per patient) and 36 to the clinic staff. Majority of the calls were made for patient monitoring/administration of Brief Pain Inventory (BPI) (n=36), questions related to medication use (n=22) and delivery of medications (n=11). On average, each contact with the patient lasted 12 minutes and 9 minutes for clinic staff. Fifteen out of sixteen recommendations made to the clinic staff were accepted which included: addition of an adjuvant (n=4), change drug (n=2), change dose (n=3), change frequency (n=2), dosing conversion (n=5) The control group received usual care as prior to study with the exception of filling in questionnaires at baseline and 3 months follow-up.

In the Marra et al. study (2012), the intervention comprised of two components as well (medication review and physiotherapist guided exercise). The patient had a face to face consultation with a pharmacist who educated patients on various aspects of osteoarthritis (OA), conducted medication review to ensure safe use of analgesics, referred patients to a physiotherapist-guided exercise programme (second component) and requested patients' primary care physicians to approve their inclusion. It was not made clear whether the pharmacists had an access to patients' electronic medical records or not. Over the 6 months follow-up period, 297 patient-pharmacist contacts were recorded resulting in 255 comments and recommendations, including 49 medication-related recommendations to patients' primary care physician. The pharmacist also followed-up with the patients each month for six months to monitor their progress. The physiotherapist recommended an individualised home exercise programme after a one-hour consultation with each patient. The participants attended an exercise class twice per week for six weeks. Participants in the control group received an educational leaflet on knee OA developed by the Canadian Arthritis Society

In the Hay et al. study (Hay et al., 2006, Phelan et al., 2008), there were two independent intervention groups: pharmacy review group and community physiotherapy group. Data of the pharmacy review group were only extracted for this systematic review. Together with an education leaflet, participants in the pharmacy review group received an enhanced pharmacy review by an experienced community pharmacist in general practice surgeries with access to patients' medical records. The trial protocol permitted three to six sessions of approximately 20 minutes each over 10 week period. The pharmacist used a pre-defined set of questions for initial assessment and optimized/changed drug

therapy, if necessary, based on an algorithm after accounting for personnel preferences and clinical needs. In total, 335 pharmacist-patient consultations took place (mean 3.2 per patient; range 2-5). The mean amount of time spent per patient was around 63 minutes in 3 sessions. Participants in the control group received the same education leaflet and a telephone call from a rheumatology nurse to reinforce the advice on the leaflet within seven days of randomization.

In the Hoffmann et al. study (2008), participants in the intervention group received an individualised counselling session by trained community pharmacists with the aim of optimising pharmacotherapy, promoting self-management, goal setting and pacing activities. It was not clearly reported whether the community pharmacists were given access to patients' electronic medical records or not. During intervention phase, each patient received approximately two hours of counselling and each pharmacy counselled 4.6 ± 3.06 patients on average (range 1-15). Participants in the control group continued to receive usual pharmaceutical consultations with pharmacists who were not formally trained in headache/pain management.

In the Bruhn et al. study (Bruhn et al., 2011a, Bruhn et al., 2011b, Bond et al., 2011), there were two independent intervention groups as well: pharmacist medication review with recommendations to the GP and pharmacist medication review with pharmacist prescribing. Pharmacists in the intervention arms had access to patients' medical records. Further data on the nature and duration of the intervention were not available at that time. Authors were contacted to obtain additional data but the request was declined due to restrictions from the funding agency.

Table 3.1. Characteristics of included studies

Study/Year country	Trial design	Setting	Sample recruited (completed)	Follow up (months)	Intervention	Dose of intervention	Pharmacist trained in pain management
Gammaitoni et al/ 2000 (USA)	I-RCT	University pain clinic	N=74 I=38 (20) C=36(21)	3	MR through telephone interviews, and a specialized prescription delivery service.	81 phone calls (45 to patients and 36 to clinic staff managing patients) were made in 12 weeks. Mean 1.2 calls per patient.	Yes
Hay et al/2006 (UK)	I-RCT	General practice	N=325* I=108(100,103,99) C=108(92,98,90)	3, 6 and 12	MR and advised patients face-to- face individually based on leaflet	3 to 6 sessions of 20min each over 10 weeks	Not known
Hoffmann et al/2008 (Germany)	CRCT	Community pharmacy	N=410 I=201 (163) C=209 (194)	4	Face-to-face MR plus advice on pacing activities and goal setting.	Each pharmacy counselled on average 4.6±3.01 patients (range 1- 15) for 2hrs/per patient.	Yes

Bruhn et al/2011 (UK)	I-RCT	General practice	N=196* I=70(60,58) I**=63(50, 49) C=63(54,55)	3 and 6	MR plus recommendations to the GP	Data not available	Yes
Marra et al/2012 Canada	C-RCT	Community pharmacy	N=139 I=73(72) C=66(65)	3 and 6	MR + education+ Physiotherapist guided exercise	297 pharmacist-patient follow ups were performed over 6 months resulting in 355 recommendations to patients' primary care physicians (4.8 recommendations/patient)	Yes

*Two intervention groups in trial. ** The second intervention group also received medication review as part of intervention. Data for only one intervention group is presented here. I-RCT=Individual randomised controlled trial, C-RCT= Cluster randomised controlled trial, MR= Medication review, GP=General Practitioner, I=Intervention group, C=Control group.

3.4.3 Risk of bias

Three trials (Marra et al., 2012, Hay et al., 2006, Gammaitoni et al., 2000) described adequate methods for random sequence generation (Figure 3.4). Hay et al. (2006) used a random number generator which allocated the participants in intervention and control groups in pre-determined sequence blocks of six by general practice. The study statistician generated values from a uniform (0, 1) distribution in the Marra et al. (2012) study and a computer programme was used to randomly assign the names to either the intervention group or the control group in the Gammaitoni et al. (2000) trial. However, Gammaitoni et al. (2000) did not describe how the selection of 107 patients from pain clinics was undertaken prior to this random allocation to groups. Methods of random sequence generation were not adequately explained by Bruhn et al. (2011a) and Hoffman et al. (2008). Only Hay et al. (2006) described an adequate method of allocation concealment (sequentially numbered opaque envelopes). Since Marra et al. (2012) and Hoffmann et al. (2008) were cluster randomised trials, allocation concealment was not possible and is not considered an issue (Higgins and Green, 2011).

In all the trials, it was impossible to blind pharmacists delivering the intervention and the participants receiving it due to the nature of intervention. However, it would have been possible to blind outcome assessors of the allocation of participants to minimize detection bias. Outcome assessors were blinded in two trials only (Marra et al., 2012, Hay et al., 2006). Hoffmann et al. (2008) collected data through a computer aided, standardised telephone interview but it was not made clear whether people who handled and analysed the data were blinded or not.

All trials (Hay et al., 2006, Marra et al., 2012, Hoffmann et al., 2008, Bruhn et al., 2011a) except one (Gammaitoni et al., 2000) used the intention to treat principle for analysing their data thus minimizing attrition bias. There was low risk of selective reporting of an outcome across four trials (Hay *et al.*, 2006; Marra *et al.*, 2012; Hoffmann *et al.*, 2008; Gammaitoni *et al.*, 2000) and unclear risk in one of the trials (Bruhn *et al.*, 2011a). Although, the study protocol was available for only one study (Marra *et al.*, 2012), the decision was made to assign low risk to other trials based on the fact that the authors reported outcomes with non-significant P-values as well.

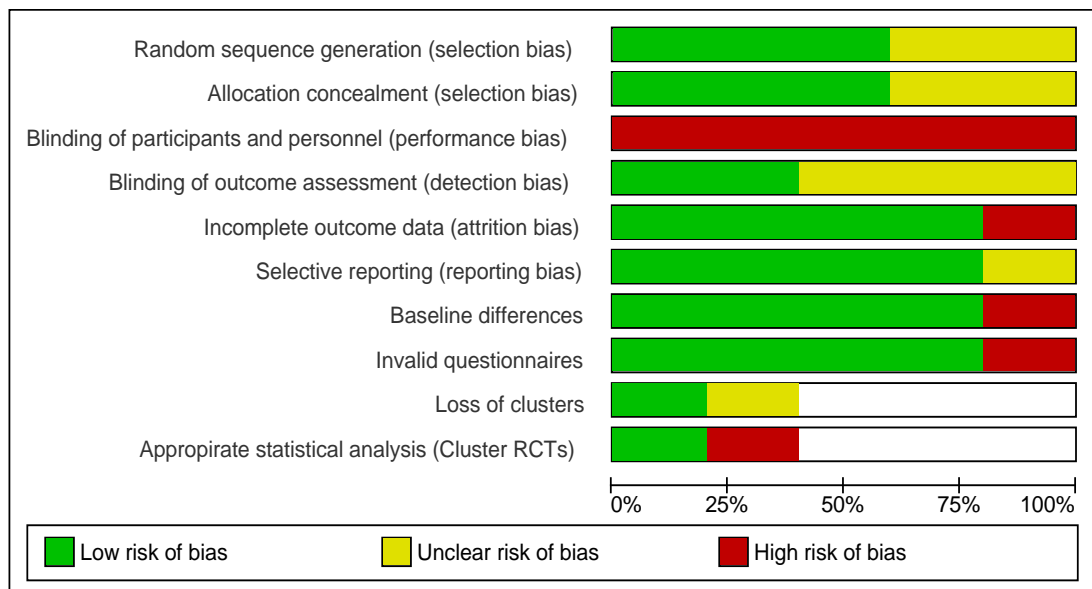





Figure 3.4. Risk of bias in included trials across each domain

There were no baseline differences between intervention and control groups in any of the trials except one (Marra et al., 2012). In the Marra et al. (2012) trial, there were significant differences at baseline in pain scores measured by the Health Utilities Index-3, a generic instrument to measure quality of life, between intervention and usual care groups but there were no significant differences in pain scores when measured by the Western Ontario

and McMaster Universities Osteoarthritis Index (WOMAC) pain subscale. Furthermore, participants in the intervention group were slightly more educated (86% reported more than high school education compared to 79%), belonged to higher socioeconomic class (71% reported an income over \$50,000 compared to 59%) and were of Asian origin (21% compared to 9%) compared with the usual care group.

Only one patient was lost to follow up in each group in the Marra et al. (2012) study and the authors took “clustering” into consideration in sample size calculation and data analysis. However, in the cluster randomised controlled trial by Hoffmann et al. (2008), the authors did not use appropriate statistical techniques and did not allow for the clustering effect in sample size calculation and data analysis.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Baseline differences	Invalid questionnaires	Loss of clusters	Appropriate statistical analysis (Cluster RCTs)
Bruhn 2011	?	?	-	?	+	?	+	+		
Gammaitoni 2000	+	?	-	?	-	+	+	-		
Hay 2006	+	+	-	+	+	+	+	+		
Hoffman 2008	?	+	-	?	+	+	+	+	?	-
Marra 2012	+	+	-	+	+	+	-	+	+	+

Figure 3.5. Risk of bias across individual trials.  = unknown risk,  = high risk  = low risk

3.4.4 Outcomes assessment

3.4.4.1 Pain intensity

Pain intensity was reported in all the trials but used different scales. Gammaitoni et al. (2000) measured pain intensity on a 0 to 10 numerical rating scale where 0 = no pain and 10 = pain as bad as you can imagine as part of the Pharmacotherapeutic Pain Inventory (PhPI), a survey instrument derived from the Brief Pain Inventory (Cleeland and Ryan, 1994) and the Health Background Questionnaire-Initial Patient Visit (Gallagher, 2000). Hay et al. (2006) reported pain intensity on a 0 to 10 numerical rating scale where 0 = no pain and 10 = pain as bad as you can imagine and on a 0 to 20 subscale of WOMAC (Bellamy, 1996). Bruhn et al. (2011b) assessed pain intensity using the pain intensity subscale of the chronic pain grade questionnaire (CPG), a 7-item questionnaire to measure pain intensity, severity and functional disability (Von Korff et al., 1992). Marra et al. (2012) measured pain intensity on a 0 to 10 pain subscale of WOMAC while Hoffman et al. (2008) measured it on a 1 to 10 numerical rating scale where 1 = no pain and 10 = pain as bad as you can imagine. Although pain intensity was measured using different scales in Gammaitoni et al. (2000), Hay et al. (2006) and Marra et al. (2012), all the scales ranged from 0 to 10 where 0 = no pain and 10 = pain as bad as you can imagine.

Of the five trials, four reported statistically significant reduction in pain scores at follow-up (Hay et al., 2006, Hoffmann et al., 2008, Bruhn et al., 2011b, Marra et al., 2012). Gammaitoni et al. (2000) reported a reduction in pain scores which was not statistically significant ($p=0.67$) at 3-month follow up. Although, Hay et al. (2006) reported a statistically significant reduction in pain scores at 3-month follow-up ($p=0.04$), the pain scores were statistically non-significant at 6

($p = 0.3$) and 12 months ($p=0.5$). However, Marra et al. (2012) reported a statistically significant reduction at both 3 and 6 months follow-ups (both $p<0.05$). In the study by Hoffmann et al. (2008), there was a significant reduction in 'untreated' pain intensity in both intervention ($p<0.001$) and control group ($p<0.001$); however, reduction in 'treated' pain intensity remained non-significant in both intervention ($p=0.52$) and control groups ($p=0.92$) at 4-month follow-up.

Pain scores were pooled using meta-analysis. Since the study by Hoffmann et al. (2008) involved patients with chronic headache and migraine it was deemed clinically heterogeneous and not combined statistically. The data reported by Bruhn et al. (2011b) were insufficient for meta-analysis. Therefore, data from three RCTs only were pooled statistically. As described earlier, pain intensity was measured on different scales therefore the standardised mean difference (SMD) and corresponding standard error was calculated for each of the three studies. For the purpose of meta-analysis, change in score from baseline rather than final score was used as the former is more efficient and powerful as it eliminates between-person variability (Higgins and Green, 2011). But if the 'adjusted' change in score derived from regression model accounting for baseline measurements was reported, it was preferred over the crude change in score to calculate SMD, as statistically, adjusted scores are considered most precise and least biased (Higgins and Green, 2011). Meta-analysis was undertaken at 3 and 6 month follow-ups.

Compared to the control group, there was a significant reduction in pain intensity in the intervention group with SMD of -0.37 (95% confidence interval $-0.58, -0.16$) (Figure 3.6). This corresponds to a 0.83 point reduction on a 0 to 10 numerical rating scale where 0=no pain and 10 pain as bad as you can

imagine (95% confidence interval -1.28, - 0.36). There was no heterogeneity in the result ($I^2=0\%$). Only two studies (Hay et al., 2006, Marra et al., 2012) reported pain intensity at 6-months. At 6 months, there was also a significant reduction in pain intensity in the intervention group compared to the control with SMD – 0.31 (95% CI -0.53, - 0.09) corresponding to a 0.7 point reduction on a 0 to 10 numerical rating scale (95% CI -1.19, - 0.20). There was slight heterogeneity in the result ($I^2=39\%$) [$\text{Chi}^2=1.64$, $\text{df}=1$, $p=0.20$] which is statistically considered non- significant (Higgins and Green, 2011).

3.4.4.2 Physical functioning

Physical functioning was assessed as an outcome measure in all the studies. Marra et al. (2012) and Hay et al. (2006) assessed physical functioning using a 0 to 10 and 0 to 68 physical functioning subscale of WOMAC respectively (Bellamy, 1996). Higher scores on the WOMAC subscale represented worse (limited) physical functioning. Hoffmann et al. (2008) and Bruhn et al. (2011b) used the physical health subscale of SF-36 (Ware and Sherbourne, 1992) and SF-12 (Ware Jr et al., 1996) respectively to assess physical functioning. Gammaitoni et al. (2000) assessed pain interference with various daily activities (general activity, mood, waking, normal work, relationships, sleep and enjoyment of life) as part of PhPI, a survey instrument derived from the BPI (Cleeland and Ryan, 1994) and the Health Background Questionnaire-Initial Patient Visit (Gallagher, 2000). But instead of reporting a recommended summary score calculated from these seven interference items (Cleeland and Ryan, 1994), the authors reported each item individually.

Marra et al. (2012) reported a statistically significant improvement in physical functioning at 3-months [-0.65; 95% CI (-1.20 to -0.10)] and 6-months [-0.84; 95% CI (-1.45 to -0.24)] in the intervention group compared to the control.

Hay et al. (2006) reported a non-significant improvement in functioning at 3-months [-2.12; 95%CI(-0.5 to 4.8)], 6 months [-0.96 ; 95% CI(-4.0 to 2.1)] and 12 months [-0.39; 95% CI (-3.8 to 3.0)] in the intervention group. Compared with the control group, Gammaitoni et al. (2000) reported non-significant improvement in pain interference with mood ($p=0.07$), general activity ($p=0.37$), walking ($p=0.92$), work ($p=1.00$), relationships ($p=0.72$), sleep ($p=0.62$) and enjoyment of life ($p=0.76$) at 3-months follow up. Similarly, Hoffmann et al (2008) reported a non-significant improvement in physical health ($p=0.85$) at the end of the 4-month study period. Bruhn et al (2011b) also reported a non-significant improvement in physical health ($p=0.75$) at 6-months follow-up.

Data were pooled using meta-analysis for three studies excluding Hoffman et al. (2008) for clinical heterogeneity and Bruhn et al. (2011b) for insufficient data. Meta-analysis was undertaken at 3 and 6 months follow-up. At 3-month follow-up there was a statistically significant improvement in the intervention group with SMD of -0.38 (95% CI -0.58, -0.18) compared to the control group (Figure 3.7). This effect is equivalent to 4.84 points (95% CI -7.38, -2.29) on a 0 to 68 point function subscale of WOMAC. There was no heterogeneity in the result ($I^2=0\%$). Only two trials (Marra et al., 2012, Hay et al., 2006) reported physical functioning status at 6-months. Meta-analysis showed a significant improvement in physical functioning at 6-month follow-up as well in the intervention group compared to the control group with SMD -0.30 (95% CI -0.51,- 0.09) corresponding to -3.82 points (95% CI -6.49, -1.14) on WOMAC 0 to 68 function subscale. There was non-significant heterogeneity in the result ($I^2=33\%$).

3.4.4.3 Patient satisfaction

Three studies (Gammaitoni et al., 2000, Hay et al., 2006, Bruhn et al., 2011b) reported patient satisfaction as an outcome. Gammaitoni et al. (2000) assessed patient satisfaction with different components of the service using the Treatment Helpfulness Questionnaire (THQ), a validated measure to assess patient satisfaction with chronic pain management service (Chapman et al., 1996). The questionnaire was modified to include measures regarding satisfaction with the pharmaceutical care programme. The questionnaire assessed satisfaction with the following components of the programme: access to medication, pharmacy service, delivery of medication, pharmacist phone calls, time spent obtaining medications, pharmacist medication counselling and information provided by the pharmacist. Each item was ranked on a 11 point scale ranging from -5 (extremely harmful) to +5 (extremely helpful). Hay et al. (2006) assessed satisfaction as a dichotomous outcome (satisfied, not satisfied). In the case of Bruhn et al. (2011b), patient satisfaction was reported in another linked abstract by Bond et al. (2011). Patient satisfaction was assessed at the end of 3 months using Likert scale ratings of statements about their pain and pharmacist consultation, and open ended questions on good and bad things about pharmacist consultations (Bond et al., 2011).

In the Gammaitoni et al. study (2000), patients in the intervention group were significantly more satisfied with various components of the pharmaceutical care programme including pharmacy service ($p=0.001$), delivery of medication ($p=0.001$), pharmacist phone calls ($p=0.003$), time spent in obtaining medications ($p<0.001$), pharmacist medication counselling ($p=0.003$), and information provided by the pharmacist ($p=0.013$). However, there was no significant difference in satisfaction with the whole programme domain ($p=0.72$)

of the patient satisfaction survey. In the control group, patients were not significantly satisfied with any component of the service except for psychological assessment and treatment ($p < 0.05$). It should be noted here that Gammaitoni et al. (2000) only compared the difference in patient satisfaction from baseline to 3-month study period in both intervention and control groups independently, but did not compare control with the intervention group. In the Hay et al. study (2006), compared to the control group, patients in the intervention group were significantly more satisfied with the received treatment at 3-month [-20%; 95% CI (-33 to -6)] and at 12-months-[-19%; 95%CI (-32 to -4)] follow-up but not at 6-month [-14%; 95%CI (-28 to 1)]. Bond et al. reported that 85% (38/46) of the patients in the prescribing arm were totally satisfied with the received treatment. Patient satisfaction rates were not reported for the other intervention (medication review alone) and control groups.

Data for patient satisfaction were pooled for two studies only (Figure 3.8). Meta-analysis showed significant patient satisfaction in the intervention group compared to the control group with SMD -0.39 [95% CI (-0.68, -0.10)]. Using the universal rule of thumb, this effect size corresponds to 'small to moderate effect' (Cohen, 1988, Higgins and Green, 2011).

3.4.4.4 Quality of life

Three studies assessed quality of life (QoL) (Marra et al., 2012, Hoffmann et al., 2008, Bruhn et al., 2011b). Hoffmann et al. (2008) assessed quality of life using the Medical Outcomes General Health Survey (SF-36). While Bruhn et al. (2011b) assessed QoL using SF-12, a validated shorter version of SF-36. Marra et al. (2012) assessed QoL using WOMAC (global) and Health Utilities Index-3 (HUI-3), a generic and preference-scored instrument for measuring health

status and health related quality of life. Higher scores on HUI-3 indicate better health.

In the Hoffmann et al. (2008) trial, compared to the control group, there was no significant difference in the intervention group in the physical health subscale ($p=0.85$) of SF-36 but a statistically significant difference was found in the mental health subscale ($p=0.02$) of SF-36 at the end of the 4-month study period. Similarly, Bruhn et al. (2011a) reported a significant improvement in the mental health component of SF-12 ($p=0.04$) but not on the physical health component ($p=0.75$) at 6-months follow-up. Marra et al. (2012) reported a significant improvement in WOMAC (Global) at 3-months [-1.99; 95% CI (-3.45, -0.54)] and 6-months [-2.40; 95% CI (-4.10,-0.71)] in the intervention group compared to the control. However, HUI-3 failed to measure significant differences in QoL between the intervention and control group at 3-months [0.04; 95% CI (-0.03, 0.12)] and 6-months [0.01; 95%CI (- 0.06, 0.10)].

Meta-analysis was not undertaken as clinical heterogeneity and insufficient data ruled out Hoffmann et al. (2000) and Bruhn et al. (2011a) studies respectively.

3.4.4.5 Adverse effects

Surprisingly, none of the studies except Phelan et al. (2008), linked to the Hay et al. (2006) trial, reported adverse effects. The authors reported adverse effects in 30 patients including constipation (10), drowsiness (8), gastro intestinal upset (8) and others (4) from prescribed analgesics at the initial consultation. During follow-up the side effects were reduced or stopped in 25 patients by altering, adding or substituting their medication. The remaining five

patients continued with their medication unchanged as the medications were effective and the side effects were tolerable.

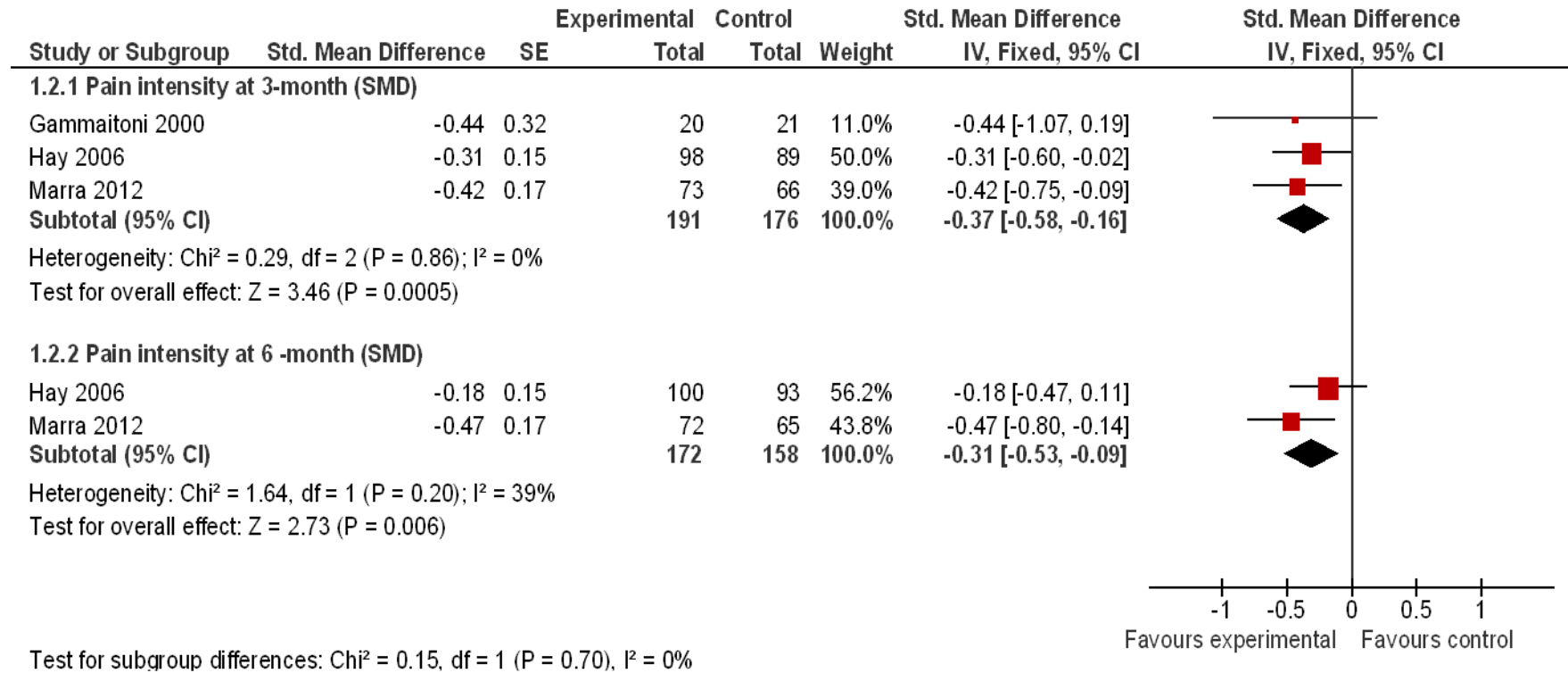


Figure 3.6. Meta-analysis of pain intensity at 3-month and 6-month

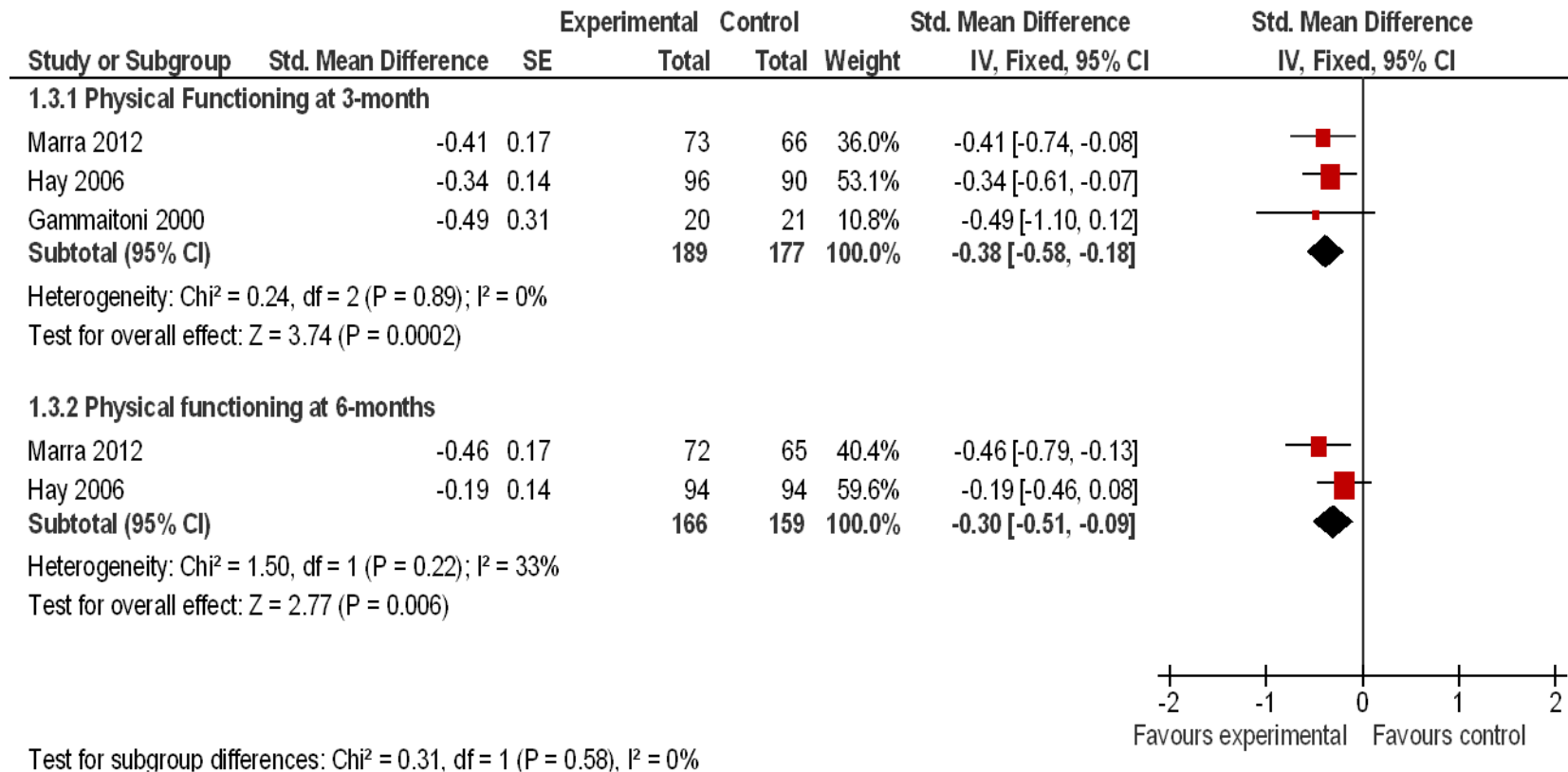


Figure 3.7. Meta-analysis of physical functioning at 3-month and 6-month

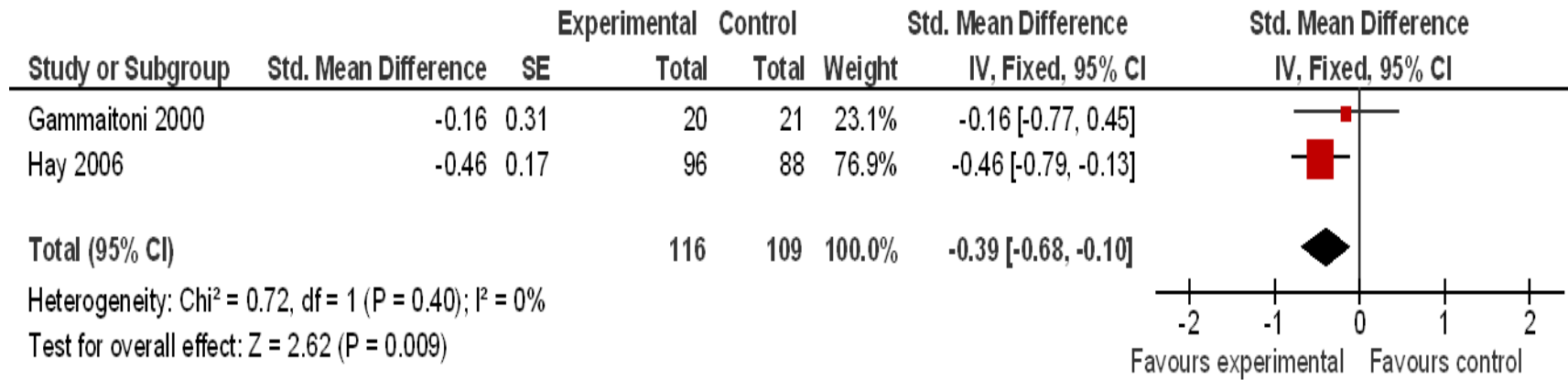


Figure 3.8. Meta-analysis of patient satisfaction at 3-month

3.5 Discussion

3.5.1 Main results

The search strategy identified five studies which met the inclusion criteria including three individually-randomised (Gammaitoni et al., 2000, Hay et al., 2006, Bruhn et al., 2011a) and two cluster-randomised controlled trials (Hoffmann et al., 2008, Marra et al., 2012). The 'grey-literature' was not searched and studies published only in the English language were included in the systematic review. The potential implications of restricting the searches to databases and websites, and English language are discussed in the limitations section (section 3.6). Pharmacists delivered interventions in different settings such as community pharmacies (Hoffmann et al., 2008, Marra et al., 2012), general practices (Hay et al., 2006, Bruhn et al., 2011a) and university pain clinic (Gammaitoni et al., 2000) indicating that the intervention can potentially be delivered in multiple settings. Furthermore, the included trials involved patients with various chronic pain aetiologies, demonstrating that the pharmacist-led medication review may be effective for different types of chronic pain conditions.

Two trials originated from the UK (Hay et al., 2006, Bruhn et al., 2011a) and one each from the USA (Gammaitoni et al., 2000), Canada (Marra et al., 2012) and Germany (Hoffmann et al., 2008) indicating that there is growing interest in evaluating the role of pharmacists in chronic pain management in the developed world. This may be due to the high disease burden of chronic pain and a growing necessity to involve other healthcare professionals such as pharmacists and nurses actively in direct patient care to reduce the workload on general practitioners (GPs)/primary care physicians (PCPs) in these countries. A survey conducted among GPs in the UK reported that the GPs were

dissatisfied with their management of chronic pain patients and they were worried about the long waiting time for secondary care appointments (Stannard and Johnson, 2003). Therefore, the growing number of independent nurse and pharmacist prescribers can potentially fill this gap and improve patient care, especially for chronically ill patients.

The risk of bias was assessed for all of the included studies. There was low or unclear risk of bias across all the domains except for blinding of participants and personnel where there was high risk of bias across all trials. Due to the nature of the intervention, it was practically impossible to blind the pharmacists conducting medication reviews and the patients receiving them as, in most instances, the medication review was conducted face-to-face. Although the nature and mode of delivery of intervention prevented blinding of participants and personnel, outcome assessors were blinded in two of the three trials involved in the meta-analysis, and in the third trial the outcome assessments were carried out using a standardised computer aided interview minimising detection bias. The research evidence suggests that, on average, lack of blinding in RCTs is associated with a 9% increment in the intervention effect when measured as odds ratio (Pildal et al., 2007). Trials with more subjective outcomes, such as pain trials, are likely to be affected more than those which measure objective outcomes (Wood et al., 2008). Concealment of allocation is necessary to limit selection bias but allocation concealment may not be possible for cluster-randomised controlled trials. Among the included trials, only one study by Hay et al. (2006) described adequate method for concealment of allocation (opaque envelopes). However, treatment allocation was disclosed to study nurse by 15 of 325 participants (4.6%). A meta-epidemiologic study of 16 meta-analyses involving osteoarthritis patients

reported statistically significant differences in effect sizes in 46 trials with adequate allocation concealment compared with 112 trials with inadequate or unclear concealment of allocation (difference -0.15; [95% CI, -0.31 to 0.02]) (Nüesch et al., 2009). However, there was no statistically significant difference in effect sizes in trials involving non-pharmacological interventions -0.05 [95% CI (-0.22 to 0.12)] (Nüesch et al., 2009).

Clinical homogeneity was considered before pooling data statistically. Data from a study by Hoffmann et al. (2008) were not considered for meta-analysis as the study involved patients with chronic headache and migraine, which is a neurological condition and has an episodic nature (National Institute of Neurological Disorders and Stroke, 2012) unlike other chronic pain conditions. Furthermore, it requires a different therapeutic approach. The full report of Bruhn et al. (2011a) study was not available at that time and the data reported in conference abstracts (Bond et al., 2011, Bruhn et al., 2011a, Bruhn et al., 2011b) was not enough to be pooled statistically. The corresponding author was contacted to obtain additional data but unfortunately the author declined the request due to restrictions by the funding agency. Other trials were relatively similar in terms of nature of intervention, patient follow-up and patients' pain scores. Meta-analysis was conducted at two time points; 3-months and 6-months because the studies included in the systematic review reported follow-up results ranging from 3-months to 12-months. Combining short with long term trials is not recommended as it produces larger treatment effect than combining longer term trials alone (Moore et al., 2010a). Furthermore, the response to placebo tends to be larger in longer trials (Quessy and Rowbotham, 2008) and research evidence also suggests that the efficacy of interventions, especially of less effective interventions decrease over 2-12 weeks (Moore et al., 2010b).

Therefore, meta-analysis was conducted at two time points to limit any bias arising from combining short-term trials with long-term trials.

The included trials measured the same outcomes using different scales therefore data were pooled using SMD for each outcome. The potential problem with SMD is that it expresses the intervention effect in standard units rather than the original units of measurement making clinical interpretations difficult for patients and practitioners (Higgins and Green, 2011). To interpret SMD, in line with the Cochrane's guidance (Higgins and Green, 2011), it was re-expressed in the units of a specific measurement scale for two of the three outcome measures that were statistically combined, pain intensity and physical functioning. This was achieved by multiplying SMDs for pain intensity and physical functioning with the standard deviation of the numerical rating scale (0 to 10) and physical functioning subscale of WOMAC (0-20) respectively. Both of the standard deviations were obtained as pooled standard deviations of baseline scores from the Hay et al. study (2006). Only the summary measure of effect was back-transformed to enhance clinical interpretation. For the third outcome measure, patient satisfaction, SMD was re-expressed using rules of thumbs for effect sizes (Cohen, 1988, Higgins and Green, 2011) as one of the trials (Hay et al., 2006) measuring patient satisfaction reported it as dichotomous outcome measure and the other trial (Gammaitoni et al., 2000) used an adapted and modified version of a validated questionnaire thus compromising its validity and reliability .

Meta-analysis showed that there was a statistically significant reduction in pain intensity and statistically significant improvement in physical functioning in the intervention group compared to the control group. However, the clinical significance of these findings is arguable and needs careful consideration. The

use of average results of continuous data (e.g. pain intensity) can be misleading (McQuay et al., 1996) as it is argued that the population distributions of pain scores and/or pain relief are usually 'U-shaped' (as opposed to being normally distributed) therefore patients tend to have either very good or very poor pain relief. Consequently, it has been suggested that pain scores/pain relief should be reported as percentage of patients responding to the treatment instead of average pain scores to reflect the actual number of patients who have improved or deteriorated. All the trials included in the systematic review reported average pain scores only rather than reporting percentages of patients responding to the treatment. As a result, making clinical recommendations about the effect size of the effectiveness of the pharmacist-led medication review in chronic pain management is difficult due to the nature of reported data. The evidence from the meta-analysis indicates potential benefit for patients; however, there is uncertainty around the clinical significance of this benefit which limits wider clinical implementation. Furthermore, medication review was conducted as part of multi-component interventions in three of the five included studies and consequently, the "active ingredient" of the intervention is not known. However, the impact of the intervention on other drug-related outcomes such as the reduction in side effects documented by Phelan et al. (2007) linked to Hay et al. (2006), the reduction in the use of non-steroidal anti-inflammatory drugs documented by Hay et al. (2006) and the high acceptance of pharmacists' recommendations as documented by Gammaitoni et al. (2000), Hoffmann et al. (2008) and Marra et al. (2012) suggest that pharmacist-led medication review is an important component in overall pain management and can improve patient reported outcomes.

3.5.2 Implications for pharmacy practice and policy

Medications are widely used in chronic pain management with two-thirds of chronic pain patients receiving prescription medicines and half of them taking non-prescription medicines (Breivik et al., 2006). Therefore, the safe and effective use of analgesics is critical to ensure optimum analgesia, prevention of adverse effects and drug related problems, and abuse of analgesics. In the USA, in 2007, almost 12,000 cases of unintentional drug poisoning involved prescription analgesics (Centers for Disease Control and Prevention, 2010) and in 2008, 14,800 people died due to overdoses of opioid analgesics (Centers for Disease Control and Prevention Analysis: Morbidity and Mortality Weekly Report (MMWR), 2011). The report also suggested that, in 2009, misuse and/or abuse of prescription analgesics resulted in more than half a million emergency Department visits (Centers for Disease Control and Prevention Analysis: Morbidity and Mortality Weekly Report (MMWR), 2011). Given these alarming negative consequences of inappropriate use of analgesics and the potential for abuse of opioid analgesics, regular review of medicines is important to optimise pain relief whilst ensuring safe use of analgesics.

With the advancement of the concept of pharmaceutical care (Mikeal et al., 1975), the focus of pharmacist-led services has shifted from being product-centred to patient-centred. A number of pharmacist-led services have been developed both in hospital and community settings to improve patient care. Research evidence to support the effectiveness for such services is critical for their sustainability. The present systematic review has identified and synthesised data which demonstrates the effectiveness of pharmacist-led medication review in chronic pain management. The findings have raised two questions which need to be considered by service commissioners and policy

makers before a wider role for pharmacists in chronic pain management is put into practice. Firstly, certain issues related to delivery of the intervention such as 'how much', 'how often', 'how long', must be carefully considered as limited exposure to the service may not be adequate to achieve desired outcomes and prolonged use of the service may not be cost-effective and may put an additional burden on healthcare systems. Furthermore, it is still unknown whether the pharmacist-led medication review benefits all types of chronic pain patients or only certain types of patients. However, it can be argued that medication review by an expert pharmacist should be able to reduce drug-related problems and adverse effects in all patients irrespective of the pain aetiology. Secondly, short-courses/programs/residency training must be developed to provide specialised education and training in pain management to all the pharmacists in order to achieve maximum clinical benefit. In the past, the need for specialised training programmes has also been advocated in the literature (LaPerriere, 1994). However, to date, such training programmes are not widely available for pharmacists especially outside the USA. Some examples include specialised pain management residency programmes for pharmacists in the USA (Department of Pharmacy, 2012) with palliative care as a key focus area and pharmacotherapy traineeship in pain management among geriatric patients offered by American Society of Consultant Pharmacists (ASCP) Foundation (2012). Some universities in the UK also offer 'generic' postgraduate programmes (MSc/Post-Graduate Diploma) and short courses (2-3 days) in pain management but no specialised training programmes for pharmacists are currently available in the UK. Training programmes to produce skilled pharmacy human resource in pain management is essential to ensure sustainability and clinical effectiveness of pharmacist-led pain management service.

With regard to the developing countries, the findings of the systematic review may not be transferable as the pharmacy profession is undergoing transition from 'industry-oriented' to 'patient-oriented'. Over the past decade, changes in undergraduate curriculum have been made together with the development of clinical oriented postgraduate programs (Hadi et al., 2010) to equip pharmacists with necessary clinical knowledge to meet growing needs of the patients (Hadi, 2010, Hadi and Awaisu, 2010). However, there is still a long way to go before these changes can make significant impact in transforming pharmacy practice and relevant policies in these countries.

3.5.3 Implications for future research

High prevalence of chronic pain and its associated burden on healthcare systems and societies across the globe calls for high quality research to improve both diagnosis and management of chronic pain. However, the literature suggests that research into chronic pain is not well funded (The Mayday Fund Special Committee on Pain and the Practice of Medicine, 2009). In 2008, in the USA, less than one percent of National Institutes of Health (NIH) budget was given for pain research (National Institutes of Health, 2008). Underfunding of pain research is concerning and it may damage initiatives to improve pain management due to a lack of research evidence. A survey in the USA reported that almost six in ten adults (57%) were willing to pay one dollar more per week in taxes to increase federal funding for the research into pain.

The purpose of a systematic review is not only to synthesise research evidence but also to identify the limitations of current knowledge and propose directions for future research (Higgins and Green, 2011). The role of pharmacists in chronic pain management is still relatively new and requires further exploration. The current evidence suggests that pharmacist-led

medication review is effective in reducing pain intensity, medication-related adverse effects and improve physical functioning. Future research must evaluate the optimum and cost-effective mode/method and duration of delivery of the intervention to achieve maximum clinical benefit. Standardisation of the intervention may not be possible due to the individualised needs of the patients especially those taking opioid analgesics may need a more frequent medication review to limit abuse and ensure safety.

There is a need to improve the quality of reporting of clinical trials involving chronic pain patients. In addition to CONSORT guidance on the conduct and reporting of clinical trials (Moher et al., 2010), the researchers should also adhere to the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) guidance (Turk et al., 2003, Dworkin et al., 2005, Moore et al., 2010a) in designing, conducting and reporting their findings. The IMMPACT group has developed consensus reviews and recommendations for improving the design, conduct, reporting and interpretation of clinical trials of treatments for pain. A list of core outcome domains and their respective measurement scales have also been developed to allow meaningful comparisons among different patient populations, treatments and settings (Turk et al., 2003). As discussed earlier, the researchers instead of reporting average pain scores only should always report percentages of patients achieving minimally important, moderately important and substantial clinical difference in accordance with the recommendations of IMMPACT group (Dworkin et al., 2008).

Trials involving only non-malignant pain patients were included as the inclusion of trials involving cancer pain would have introduced clinical heterogeneity and complicated clinical interpretation of the findings. It would be

interesting to evaluate the effectiveness of pharmacist-led medication review among patients with cancer pain as effective management of cancer pain is very important in overall cancer management, especially in end of life care. Finally, the cost-effectiveness of pharmacist-led medication review in chronic pain management is yet to be evaluated. In the present global financial environment, healthcare systems across the world are taking measures to reduce healthcare costs and data demonstrating cost-effectiveness of an intervention is important in the commissioning of services.

3.6 Limitations

In terms of the design of the systematic review there were two major limitations. Firstly, studies reported only in English language were included in the systematic review, which might have led to language bias (Moher et al., 1996). One study (Marti et al., 2005) was excluded during screening of full-texts of included studies as it was published in the Spanish language. However, conflicting results have been reported in the literature examining the extent of the effect of language bias on the findings of the systematic review (Higgins and Green, 2011). In a study, Jüni et al. (2002) reported that trials published in non-English languages were more likely to produce significant results and, on average, the intervention effects were 16% (95%CI 3% to 26%) greater in these trials compared to trials published in English. On the contrary, Moher et al. (2003) did not report any significant effect of excluding non-English trials on the results of meta-analysis. Furthermore, Galandi et al. (2006) reported a decline in publishing clinical trials in German-language indicating a shift from using non-English language to English-language in disseminating clinical trials. It was decided during protocol development not to include non-English studies as the review team lacked expertise in translating non-English studies in English and

had no funds to hire services of professional translators. Secondly, publication bias may have been introduced as no attempt was made to locate unpublished trials (grey literature). The findings of the research evaluating the impact of inclusion or exclusion of 'grey' literature in meta-analysis of RCTs are inconsistent. Hopewell et al. (2007) in a review reported, on average, a 9% larger intervention effect in published trials than grey trials. The problems associated with the inclusion of unpublished trials include (Higgins and Green, 2011): difficulty in locating such studies, data acquisition from the study investigators, and absence of peer-review. Furthermore, the methodological quality of unpublished trials has been reported to be lower than published trials in terms of allocation concealment and blinding outcome assessment (Egger et al., 2003). On the contrary, Hopewell et al. (2004) did not find such methodological limitations. The major issue with data acquisition is that only investigators with positive results may be willing to share their results which may introduce bias in to the systematic review. Finally, the located studies may only be a small part and 'unrepresentative' (Page 309) of all the unpublished studies (Higgins and Green, 2011). Systematic review authors in future may consider including studies published in non-English languages and unpublished studies to overcome the above mentioned limitations.

3.7 Conclusion

Pharmacists can play an important role in improving chronic pain management. Pharmacists can deliver interventions independently and as part of multidisciplinary teams in both community and hospital settings. The present systematic review suggests that pharmacist-led medication review is effective in reducing pain intensity and improving physical functioning. Furthermore, patients were generally satisfied with the service provided by the pharmacists.

There is also weak evidence of preventing/stopping adverse effects associated with the use of medicines among chronic pain patients. The clinical significance of these findings remains to be established. Future clinical trials evaluating the effectiveness of pharmacist-led interventions in chronic pain must adhere to the IMMPACT guidance (Turk et al., 2003, Dworkin et al., 2005) in designing, conducting and reporting their findings in addition to the CONSORT guidance (Moher et al., 2010). This will ensure selection of the recommended uniform outcome domains and measures, and quality reporting of the trial results facilitating not only clinical interpretation but also data synthesis in future. As the focus of care shifts from secondary to primary care, pharmacists especially community pharmacists have the potential to reduce the chronic pain burden on healthcare system and society by ensuring the safe and effective use of medicines.

CHAPTER 4

METHODOLOGY

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METHODOLOGY

4.1 Introduction

This chapter outlines the research methodology used to guide this research project and answer the research questions related to the second aim of the research presented in this thesis. The chapter begins with a brief introduction to various research methodologies commonly used in healthcare research. Then the strengths and weaknesses of these methodologies are discussed and in particular, mixed-methods. Following that, the selection of a particular mixed-methods design for the present study is also debated and justified.

Whilst conducting the literature review for the present study, the author found that mixed-methods designs are infrequently used by pharmacy practice researchers and recognised a need to advocate the use of mixed-methods research in pharmacy practice. Furthermore, the quality of reporting of mixed-methods research was also deemed to be suboptimal. Consequently, two papers highlighting various aspects and challenges of mixed-methods research and a framework to improve its reporting were published in a peer reviewed journal (Hadi et al., 2013, Hadi et al., 2014).

4.2 Research methodology

Research methodology is an approach to systematically solve/answer the research problem/question and it may be considered as the science of exploring how research is conducted scientifically (LINGAYAS Institute of Management and Technology, 2012). Broadly, there are three research methodologies available to researchers in health sciences namely qualitative, quantitative and mixed-methods. A number of research designs are available within these three methodologies. There are specific philosophical assumptions, advantages, applications and limitations associated with each research methodology. Therefore, the choice of a particular methodology should be based on the nature of the research question. In the following sections, each of these three methodologies and some important research designs within these methodologies are explained briefly.

4.2.1 Qualitative research methodology

There is little agreement between methodologists on a single definition of qualitative research, probably because qualitative research encompasses a diverse range of methods (Holloway, 2005). In general, qualitative research is a collection of interpretative methods which aim to describe, understand and explain people's experience of a certain phenomenon with non-numerical data (Holloway, 2005, Denzin and Lincoln, 2005). Qualitative research, in its structured form, was first used by sociologists and anthropologists in the early 20th century (Al-Busaidi, 2008). In healthcare research, after receiving significant criticism and resistance in the 1980's and 1990's, qualitative research is now widely used to inform healthcare practice and policy.

Qualitative inquiry, in contrast to quantitative inquiry, explores the meaning people attribute to their experiences and explains the process of social construction that shape these meanings (Popay, 1992). There are four specific characteristics of qualitative research (Avis, 2005): Firstly, it obtains and analyses textual (interview transcripts, diaries, observation notes, photographs, videos) rather than numeric data. Secondly, since qualitative research aims to view the social world through participants' eyes, it involves extensive interaction with the study population, referred to as 'field work' (Creswell, 2007). Engagement with study participants ensures that instead of merely studying the participants, the researcher learns from them (Spardley, 1979) and develops a common understanding. Thirdly, it has a 'flexible plan of inquiry' – the design evolves as the study progresses. Finally, it is 'context bound'- it studies participants in their natural environment rather than experimental settings, referred to as 'naturalism'. The researchers cannot disengage themselves from the research process and therefore constantly need to critically reflect on their own role in the process of generating data.

There are at least forty different research designs under the umbrella of qualitative research (Tesch, 1990). It is beyond the scope of this thesis to provide a description of each of these methods. However, a brief introduction of a few methods which are important and relevant to healthcare research is described below.

Phenomenology aims to describe the shared lived experiences of groups of individuals of a particular phenomenon rather than a single individual. Phenomenology advances a collective in-depth description of the essence of the experience of all the study participants (van Manen, 1990). The data analysis involves finding "significant statements" or quotes, a process called

horizontalisation. Researchers then develop themes from these statements and together with the statements, these themes provide a textual description of the experience. Alongside the textual description, a structural description is provided that refers to context and settings that have influenced the experience.

Grounded theory study, as the name indicates, aims to generate or discover a theory which is 'grounded' in the views of participants who have experienced the phenomenon (Strauss and Corbin, 1990). The development of theory provides an in-depth explanation of participants' practices (Creswell, 2007). The concept of grounded theory was proposed by Glaser and Strauss in 1967 (Glaser and Strauss, 1967) but the authors later disagreed about the procedures of conduct of grounded theory research leading to the development of two variants of the grounded theory approach (Strauss, 1987, Glaser, 1992). Charmaz (2006) introduced another variant by proposing the concept of constructivist grounded theory. Creswell (2007) described data collection and analysis in grounded theory as a 'zigzag' process as it occurs simultaneously – the researcher undertakes fieldwork to collect data and then analyses it in the office, and then returns to the field to collect more data.

Ethnography aims to describe shared beliefs, views, values and behaviours of a culture sharing group (Harris, 1968). Data are often collected through participant observation and interviews and therefore, the researcher spends a significant amount of time with the group to understand their beliefs and cultural values. The concept of ethnography was first introduced in the early 20th century in the field of cultural anthropology (Creswell, 2007). There are many variants (types) of ethnography but the most commonly used are: realist ethnography (Van Maanen, 1988) and critical ethnography (Thomas, 1993).

Case study methodology has been defined in a number of ways and what constitutes a case study is also widely debated among researchers (Hammersley, 1992, Wolcott, 2002, Yin 2009). Yin defined case study as “*an empirical inquiry about a contemporary phenomenon (e.g., a “case”), set within its real-world context—especially when the boundaries between phenomenon and context are not clearly evident*” (Yin, 2009, P. 18). It involves studying a phenomenon in its context (e.g. traditional ethnographies). Broadly, there are two types of case studies, single case study and multiple case study. It typically involves multiple sources of evidence and data is collected through documentation, archival records, interviews, direct observations, participant observation and physical artefacts (Yin, 1994). Case studies, whether single or multiple, typically answer either a descriptive question (e.g. what is happening?) or an exploratory question (e.g. how or why something happened?). However, questions about the effectiveness of an intervention and prevalence are not best answered using case study design (Yin, 2009). Since the aim of the study was to investigate the effectiveness of the pain clinic and explore patients’ satisfaction with the service, case study was not considered suitable

Qualitative description is not often described as a distinctive method in the literature (Sandelowski, 2000, Sandelowski, 2010) but it is widely used in practice disciplines (Sullivan-Bolyai et al., 2005, Julion et al., 2007, Van Hulle and Gaddy, 2009). This is probably because qualitative description draws heavily on the principles of phenomenology, ethnography and grounded theory, but compared to these traditional approaches it is less interpretative. However, as the name may suggest, it is not free of interpretation. Sandelowski (2000, P.335) described the interpretive nature of qualitative description as “*All inquiry entails description, and all description entails interpretation.*” A variant of

qualitative description is 'interpretive description' (Thorne et al., 1997). Qualitative description, being the chosen qualitative design, is explained in detail later in the chapter.

4.2.2 Quantitative research methodology

Quantitative research uses statistical procedures to test a theory and relationship among the variables, measured in numbers, with an aim to establish or refute the generalizations of the theory (Creswell, 2003). Quantitative research designs have dominated healthcare research because their findings are often generalizable and they have the ability to address a wide range of clinical topics (e.g. risk factors, diagnosis, prognosis and treatment choice) through a systematic process. Quantitative approaches are often associated with a positivist worldview – that there is a 'single reality' which can be studied objectively. In contrast to qualitative research, the researcher remains independent of the research process and does not bring his values and beliefs into the research (Leedy and Ormrod, 2001, Creswell and Plano Clark, 2011). The generation of knowledge is based on cause-and-effect, reductionism, comprehensive observations, measures of variables, and testing and refining of hypotheses and theories (Slife and Williams, 1995). Broadly, quantitative research designs are divided into observational and experimental designs.

In *observational studies*, the researcher does not intervene in the care of the patient and only observes what happens (Seers and Critelton, 2001). There are three major types of observational studies: cross-sectional surveys, case-control studies and cohort studies (Creswell, 2003). *Cross-sectional surveys* are mostly descriptive in nature and are undertaken at a single point in time or over a short period of time. Data are usually collected through structured

questionnaires. They are used to assess the burden of disease(s) and/or the health needs of a population and are particularly useful in informing the planning and allocation of health resources (Rothman, 2002). *Case-control* studies are typically retrospective as they look back in time to find an association, if any, between a previous exposure with an outcome of interest. Case-control studies are relatively quick, inexpensive, and easy to carry out. They are particularly appropriate for investigating disease outbreaks and studying rare diseases or outcomes (Rothman, 2002). *Cohort studies* are typically prospective as they follow-up individuals over time until the outcome of interest appears or the study time ceases. Since cohort studies involve patient follow-up over a long period of time, they are expensive and time-consuming. They are particularly useful in studying causes, natural history and prognosis of diseases (Rothman, 2002).

In *experimental studies*, the researcher intervenes in the care of patients and evaluates the effectiveness of the intervention (Seers and Critelton, 2001). Experimental studies include quasi-experimental studies, controlled clinical trials (CCTs), and randomised controlled clinical trials (RCTs). The overall aim of experimental designs is to evaluate the effectiveness of an intervention. *Controlled Clinical trials* and *randomised controlled trials* are similar in terms of their design except that in RCTs the assignment of participants to control and intervention groups is random. RCTs are considered the gold standard for evaluating the effectiveness of healthcare interventions as they are considered the least biased (Rothman, 2002). Quasi-experimental designs, also known as “before-after intervention” and “pre-post intervention”, are also frequently used in healthcare research when conducting RCTs or CCTs is not possible (Harris et al., 2004). Quasi experimental studies may or may not have a control group.

Being the chosen design, quasi-experimental designs are discussed in more detail later in the chapter.

4.2.3 Mixed-methods research methodology

Since mixed-methods methodology has been used to guide this research, it is described in more detail. Mixed-methods research, as the term indicates, entails both qualitative and quantitative components. Although a number of definitions exist in the literature, what constitutes a mixed-methods study and, how and when qualitative and quantitative components should be combined remain open for debate. Tashakkori and Creswell (2007) defined mixed methods research as “*research in which the investigator collects and analyses data, integrates the findings, and draws inferences using both qualitative and quantitative approaches or methods in a single study or program of inquiry (Page 4).*” Johnson et al. (2007, P. 123) reviewed 19 definitions of mixed-methods and concluded with the following definition: “*Mixed-methods research is the type of research in which a researcher or team of researchers combines elements of qualitative and quantitative research approaches (e.g., use of qualitative and quantitative viewpoints, data collection, analysis, inference techniques) for the purposes of breadth and depth of understanding and corroboration.*” It is noteworthy that mixed-methods research should not only be used as a tool to collect qualitative and quantitative data, but the two datasets should be meaningfully integrated (Creswell and Plano Clark, 2011).

Mixed-methods research combines the strengths of the two methodologies to overcome their respective limitations. It allows researchers to choose and merge different methodologies to develop ‘the best possible method’ to comprehensively answer a specific research question (Creswell and Plano Clark, 2011). Mixed-methods research can potentially answer different

research questions within a single study that addresses the same research problem, but requires different methodologies. Nonetheless, if the research problem requires a mono-method study design to answer the question then it should be chosen bearing its limitations in mind.

4.2.3.1 Typologies of mixed-methods research

Broadly, mixed-methods designs are either fixed or emergent (Creswell and Plano Clark, 2011). In fixed designs, the use of qualitative and quantitative methods is pre-planned and executed accordingly. Emergent designs arise when data from a single method is insufficient to comprehensively answer the research question and a second approach (qualitative or quantitative) is added to an on-going study (Morse and Niehaus, 2009). Various classifications or typologies of mixed-methods designs exist in the literature (Greene et al., 1989, Greene, 2007, Tiddie and Tashakkaori, 2009, Morse and Niehaus, 2009, Creswell and Plano Clark, 2011). However, it should be noted that no classification system is superior to another. Choosing an appropriate research design is one of the most complex and challenging issues in mixed-methods research (Teddlie and Tashakkori, 2006).

Four basic mixed-methods research designs proposed by Creswell and Plano Clark (2011) are briefly described below.

The Convergent parallel design also known as 'current triangulation' (Creswell et al., 2003), 'simultaneous triangulation' (Morse, 1991a), and 'parallel study' (Tashakkori and Teddlie, 1998), involves conducting qualitative and quantitative components concurrently. Both components are given equal priority and are kept independent during data collection and analysis, and mixing occurs during interpretation. The convergent design is best suited for 'obtaining

different but complementary' data on the same topic (Creswell and Plano Clark, 2011); overcoming weaknesses of one method; triangulating findings for confirmation and validation; and developing a complete understanding of the research problem.

The explanatory sequential design involves two distinct interactive phases. In the first phase, quantitative data are collected, analysed and given priority in answering the research question. Following this, qualitative data are collected with the purpose of explaining the findings of the quantitative phase.

The exploratory sequential design also has two distinct sequential phases. However, unlike the explanatory design, it prioritises qualitative data collection and analysis which occur in the first phase. The quantitative phase builds on the results of qualitative data analysis to test or generalize its findings.

The embedded design was first described by Caracelli and Grenne in 1989 (Greene et al., 1989). In embedded design there is one principal method (qualitative or quantitative) and it is given priority depending on the purpose of the research and the other method provides supportive data. Qualitative and quantitative data can be collected concurrently or sequentially. The embedded design is particularly useful when a single dataset is not sufficient and different questions requiring different methodologies need to be answered within a single study.

Advanced mixed-methods designs include transformative design and multiphase design. In the following sections, first the rationale for choosing a mixed methods approach is presented and then the choice of embedded design is debated and justified in depth.

4.3 Rationale for choosing mixed-methods design

The rationale for choosing a mixed-methods approach should always be presented since not all research problems require mixed-methods research methodology (Creswell and Plano Clark, 2007). The essence of mixed-methods research is to allow the research question to dictate the choice of the method rather than the inclination towards a specific “quantitative only” or “qualitative only” methodology. Greene et al. (1989) identified five reasons for conducting mixed-methods research including triangulation, complementarity, development, initiation and expansion. In 2006, Bryman expanded the list and identified 16 reasons for conducting mixed-methods research including triangulation, offset, completeness, process, different research questions, unexpected results, instrument development, sampling, credibility, context, illustration, utility or improving usefulness of findings, confirm and discover, diversity of views, and enhancement or building upon quantitative and qualitative findings (Bryman, 2006).

For the present study, the decision to use mixed-methods methodology was made based on the nature of the research question(s). The rationale for choosing mixed-methods methodology is justified by reflecting on the reasons identified by Bryman (2006) for conducting mixed-methods research. Choosing among the 16 reasons identified by Bryman (2006), the rationale to use a mixed-methods approach for this particular study included: different research questions; offset; utility and illustration. Each of these are explained in detail in the following paragraphs.

The primary reason for using mixed-methods methodology was its ability to answer different research questions requiring different methodologies. This

author believes that no methodology is superior to another and no single methodology can answer all the research questions within the context of healthcare research. Broadly there were two components to the inquiry: one focused on the evaluation of 'effectiveness' of the nurse-pharmacist managed pain service requiring a quantitative approach; and the other looked at exploring patients' experiences, satisfaction and views about the service requiring a qualitative approach. Patient satisfaction is a multidimensional phenomenon with clinical outcomes, relationship with healthcare professionals, and bureaucratic and environmental issues being the three key areas (Wensing et al., 1994, Gray, 1997). Patient satisfaction is considered an indicator of quality of healthcare (Fitzpatrick, 1990, Fitzpatrick, 1991, May, 2000). Patient satisfaction is associated with increased compliance with medical advice (Fitzpatrick and Hopkins, 1981), continuity of care (Orton et al., 1991) and health status improvement (Fitzpatrick et al., 1983). Both structured questionnaires and qualitative interviews have been used in literature to assess patient satisfaction (Williams et al., 1998, May, 2000, Kleefstra et al., 2010, Xiao and Barber, 2008). Questionnaires accessing patient satisfaction have been criticized for not being reliable and valid (Sitzia, 1999). Furthermore, questionnaires designed by clinicians might not truly reflect patients' opinions and preferences on quality and satisfaction (Locker and Dunt, 1978, May, 2000). This shortcoming can be overcome by using a qualitative approach. The use of mixed-methods allowed the author to use both quantitative and qualitative methods simultaneously within a single study in order to answer the different research questions.

Offset refers to the "*suggestion that the research methods associated with both quantitative and qualitative research have their own strengths and*

weaknesses so that combining them allows the research to offer their weaknesses to draw on the strengths of both" (Bryman, 2006, P. 106). In the past, methodologists have argued and debated about the respective usefulness and limitations of qualitative and quantitative methodologies in answering "clinical" and "biopsychosocial" questions and gave an impression that 'one method fits all research problems' (Berkwits and Aronowitz, 1995, Pope and Mays, 1995, Armstrong, 1996, Poses and Isen, 1998). Mixed-methods research recognises and appreciates the strengths and weaknesses of both qualitative and quantitative research designs. Qualitative research best fits a research question which aims to explore participants' subjective experiences including behaviours, attitudes, perceptions, expectations, motivations and interactions, often grouped under the "biopsychosocial" dimension (Pope and Mays, 1995, Gilchrist and Engel, 1995). In the present study, as explained earlier, the author was not only interested in evaluating the effectiveness of the clinic but also keen to explore patients' experience of the service. The use of structured questionnaires (quantitative approach) in evaluating patient satisfaction would have merely generated statistically significant or non-significant p-value without giving the patients an opportunity to reflect on their overall experiences.

Utility or improving the usefulness of findings refers to "*a suggestion, which is more likely to be prominent among articles with an applied focus, that combining the two approaches will be more useful to practitioners and others*" (page 106) (Bryman, 2006). This is a commonly cited reason for using a mixed-methods approach in practice disciplines. In the present study, the use of mixed-methods research generated both numerical and textual data and provided a more comprehensive picture of what was happening in the clinic. The use of a qualitative approach provided a 'voice to the patients' and

generated more in-depth data on patient satisfaction, and general experience of living with chronic pain. It was anticipated that patients' words would enlighten the healthcare professionals engaged in managing chronic pain in relation to the 'needs' of their patients. Understanding patients' needs and expectations will hopefully enable practitioners to improve the care provided.

Illustration refers to "*the use of qualitative data to illustrate quantitative findings, often referred to as "putting meat on the bones" of "dry" quantitative findings" (page 106) (Bryman, 2006)*. This is perhaps one of the most useful applications of a mixed-methods approach, particularly in health services evaluation studies, because a "quantitative only" study can only generate P values and effect sizes which may not be enough for a holistic service evaluation. Integrating P-values with "words" in the present study, made it possible to answer questions like: What were the useful components of the service? How do they see the role of the pharmacist in a chronic pain service? How can the service be improved? Answering these questions through qualitative research can give meaning to numerical results generated through quantitative research.

4.4 Rationale for choosing embedded design

A brief introduction of the embedded design has been provided earlier in this chapter. In the following paragraphs, the earlier introduction is expanded with an aim to justify the choice of the embedded design for this particular study.

As mentioned earlier, a number of mixed-methods designs are available to healthcare researchers and choosing a particular design is perhaps the most complex and challenging step in designing a mixed-methods study (Teddlie and Tashakkori, 2006). Since each research design within mixed-methods

methodology has particular strengths and weaknesses and a different purpose and procedure of integrating qualitative and quantitative datasets, the choice should always be primarily based on the research question (Creswell and Plano Clark, 2011).

The primary objective of this study was to evaluate the effectiveness of the nurse-pharmacist managed pain clinic. A secondary objective was to explore patients' experience of the service provided by the clinic. Keeping in mind these research objectives, an embedded design was used because it was best suited to answer the different research questions which required a different method within the single study (Creswell and Plano Clark, 2011). The embedded design enabled the author to choose a quantitative method to answer the "effectiveness question" and a qualitative method to "explore patients' experience and satisfaction with the service". It should be noted here that the qualitative method in the embedded design answers a different research question, in contrast to the convergent parallel design, where the researcher uses both quantitative and qualitative methods to answer a single overarching question. As mentioned earlier, in an embedded design study, one method is dominant and the other plays a supportive role and answers a different research question. In the present study, the main question (effectiveness) required a quantitative approach and therefore it was the principal method. The qualitative method was used to explore patients' views and experience with the service and had a supportive role.

One of the challenges of using mixed-methods designs is that the researcher or the research team requires the necessary knowledge and skills to collect, analyse and interpret both qualitative and quantitative data (Creswell and Plano Clark, 2011). To enhance qualitative research skills, as part of PhD

training, the author attended specialised workshops at the University of Oxford, UK on qualitative interviewing and data analysis. Various training courses in statistical analyses were also attended to improve quantitative data analysis skills.

The embedded design in the present study consisted of a quasi-experimental (quantitative) and qualitative description (qualitative). The rationale for choosing these particular designs is justified below.

4.4.1 Rationale for choosing quasi-experimental design

As mentioned earlier, the aim of the quantitative research question was to evaluate the effectiveness of a nurse-pharmacist managed pain clinic. Ideally, a well-designed and conducted RCT would be the best study design to evaluate the effectiveness of an intervention. But practically it is not always possible to conduct a RCT for logistic or ethical reasons and in such cases quasi-experimental studies best serve the purpose (Harris et al., 2004, Harris et al., 2005). Compared to RCTs, the major weakness of quasi-experimental studies is the lack of randomization and, in some quasi-experimental designs, lack of a control group. A number of quasi-experimental designs exist and a hierarchy of these designs with respect to their ability to establish causal relationships has been proposed (Cook and Campbell, 1979, Shadish et al., 2002). Broadly, in the social science literature, quasi-experimental designs are classified into four types (Cook and Campbell, 1979, Shadish et al., 2002): quasi-experimental designs without control groups; quasi-experimental that use control groups but no pre-tests; quasi-experimental designs that use control groups and pre-tests; and interrupted-time-series designs. In general, among quasi-experimental designs, interrupted time series studies are at the top of the hierarchy followed by studies with pre-tests and control groups (Harris et al., 2004). Studies without

control groups are at the bottom end of the hierarchy but this hierarchy is not absolute as it is not always possible to find a suitable control group (Harris et al., 2004). Since there was no suitable control group available for this study, a prospective single group pretest-posttest design was used. Two post-tests (upon discharge and 3-month follow-up) were performed instead of one originally proposed by Harris et al. (2004). The modification was made to document small to medium term effects of the pain management interventions at NPMPC.

In the present study, a RCT design was not chosen for two major reasons: lack of information on the clinical characteristics of patients referred to the clinic and lack of a suitable control group. The reasons are interlinked as it is important to know the clinical characteristics of the patients receiving the intervention in order to identify a suitable control group. The unavailability of suitable “controls” was a major problem in designing the RCT. A typical RCT evaluating a non-pharmacological intervention in chronic pain management may have either one of two controls: waiting lists controls or usual care controls. Active-treatment controls are less frequently used in service evaluation studies. Recently, the suitability of waiting lists controls in chronic pain has been questioned as a waiting time of six months or more has been associated with deterioration of HRQoL and an increase in depression scores (Lynch et al., 2008). Furthermore, waiting lists controls would have been unsuitable for the present study because of the nature of the service. Once referred by the GP, it takes only 6-8 weeks for patients to have their initial appointment at the clinic and usually patients remain in the service for 12-weeks to one year. Therefore, the wait-time for treatment was not enough to constitute a control group.

At the time of the commencement of this project (and to date) there was no mechanism to identify and recruit patients receiving “usual care” through general practitioners. McDermott et al. (2006) in Aberdeenshire, Scotland, UK used a Microsoft Access based Audit tool (NIMROD) to search the General Practice Administrative System for Scotland (GPASS) to identify chronic pain patients receiving usual care from their GPs in a single practice. However, the author was not aware of any such tool applicable to general practices in the local Primary Care Trust and therefore the idea of using a usual-care control group was dropped.

The pilot study (Briggs et al., 2008) provided only limited information about the nature and clinical characteristics of the patients that were referred to the pain clinic. Therefore one of the objectives of the present study was to examine the clinical characteristics of the patients. The design and evaluation of complex interventions (interventions that contain several interacting components) such as this is a stepwise process as per the framework proposed by the UK Medical Research Council (MRC) (2008). These steps include (Campbell et al., 2000, Medical Research Council, 2008): a preclinical or theoretical phase to explore relevant theory underpinning the possible usefulness of the intervention; modelling (Phase I), identifying the components of intervention which may influence outcomes; an exploratory trial (Phase II) to test the acceptability and feasibility of the intervention; a definitive randomised controlled trial (Phase III) to establish the effectiveness of the intervention; and long term implementation (Phase IV) to determine whether the intervention and results are replicable. The preclinical or theoretical phase is related to the development of the intervention rather than the evaluation of its effectiveness. The rest of the four phases are associated with the evaluation of the

intervention. More information was required about the population, nature of intervention, and how the intervention impacts the target population before designing a RCT. For these reasons designing a RCT was neither practical nor logical and therefore a quasi-experimental design was chosen. Findings of this study could be used to inform the design of a RCT in the future.

4.4.2 Rationale for choosing qualitative description

So far, in this chapter, the rationale for choosing a mixed-methods approach, an embedded design and a quasi-experimental design have been explained. In this section, the rationale for choosing a particular qualitative design, qualitative description, is presented.

The selection of a particular qualitative design was challenging. Nurse researchers have been criticised for misunderstanding, misinterpreting and wrongly labelling their studies as “phenomenology” in the past (Crotty, 1996, Paley, 1997). Finding the right label for a qualitative research design within the context of healthcare/practice research is challenging probably because: qualitative research is a relatively new method of inquiry in healthcare research; different schools of thought exist within qualitative research; lack of clear understanding of theoretical and philosophical principles underpinning different qualitative designs among practice researchers; and the objective(s) of doing qualitative research in health services/practice research is often different to the disciplines of sociology and anthropology- where qualitative research originated.

Sally Thorne and colleagues (1997) recognised the need for a discipline specific qualitative design and proposed the idea of “*Interpretive Description*”- a non-categorical qualitative alternative for developing nursing knowledge. They proposed the concept of interpretive description as a “generic” nursing

adaptation of grounded theory, phenomenology and ethnography (Thorne et al., 1997) and that is why it is labelled as a non-categorical (non-distinctive; non-independent) method. In 2000, Sandelowski, inspired partly by interpretive description, proposed “qualitative description” as a distinctive method (Sandelowski, 2000). Compared to traditional qualitative research designs such as ethnography, grounded theory, or phenomenology, qualitative description is considered the least theoretical, but not a-theoretical, and probably on the lowest rank of the qualitative research hierarchy (Sandelowski, 2000, Sandelowski, 2010). In general, principles of naturalistic inquiry guide qualitative descriptive studies. Naturalistic inquiry implies: studying something in its natural state or as close as possible; no a-priori commitment to any theoretical view of a target phenomenon, and no pre-selection of variables to study (Lincoln and Guba, 1985). Sandelowski’s qualitative description (Sandelowski, 2000) differed from interpretive description (Thorne et al., 1997) in three basic aspects: She considered qualitative description as a distinctive categorical method as opposed to a “non-categorical” alternative. Secondly, she believed that qualitative description is neither a new method, although unacknowledged, nor a nursing adaptation of grounded theory, phenomenology or ethnography as proposed by Thorne et al. (1997). However, a researcher whilst conducting a qualitative description may employ one or two techniques associated with phenomenology, ethnography or grounded theory as necessary (Sandelowski, 2000). Finally, Sandelowski considered qualitative description as less interpretive than “interpretive description”. However, this author believes that the degree of interpretation should be left to the discretion of the researcher as the demarcation between less and more interpretation is very subjective. Furthermore, the nature of the research project rather than the label of qualitative approach should dictate the degree of interpretation.

The research question, to explore patients' experience and views with the service provided at the pain clinic, guided the author to choose the appropriate design. The process began with matching the research question to the goal(s) of the five most commonly used qualitative research designs identified by Creswell (2007) namely case study, ethnography, grounded theory, phenomenology and narrative research. After extensive reading of the literature, consultations with colleagues, supervisors and other qualitative researchers, it was concluded that none of these approaches were a good fit to answer the research question. This author realised that it is difficult to apply traditional qualitative designs to practice-based research questions. Learning from the criticism of nurse phenomenologists, the author was reluctant, although tempted, to label his approach as phenomenology as it would have cast doubts in the minds of the readers and questioned the credibility of the study. Interpretative description and qualitative description were the best labels for the qualitative approach being used in the present study. Although the approaches are similar in a number of ways, as described in the above paragraphs, the study design was labelled as qualitative description: because, the author does not see the method as "non-categorical" and believes that interpretation by the researcher is the essence of all research methods. Furthermore, findings produced by qualitative descriptive studies are data-near – which is what this author wanted. Sandelowski pointed out that qualitative description should not be seen as a "quick-fix, data to go, smash-and-grab" type of research. The rationale behind all the decisions made during sampling, data collection and data analysis should be presented (Sandelowski, 2010). To ensure rigour, in the following chapter (Chapter 4), all the choices made during data collection and analysis have been debated and justified.

CHAPTER 5

METHODS

CHAPTER 5

METHODS

5.1 Introduction

In the previous chapter, research methodologies available to healthcare researchers were described and the choice of mixed-methods methodology in guiding this research study was justified. Following that, the rationale for choosing an embedded design in relation to answering the research question(s) was discussed. Finally, the selection of quasi-experimental and qualitative descriptive designs were debated and justified.

In this chapter, the methods used within the quasi-experimental and the qualitative description are explained. The chapter begins with an explanation of the process of obtaining ethical and governance approval for the present study, and steps taken to ensure the ethical conduct of the research. The chapter consists of two interlinked sections: In the first section, procedures for sample size calculation, sampling and subject recruitment, data collection, and data analysis for the quasi-experimental design are explained. In the second section, the same issues for the descriptive qualitative study are discussed. In both sections, alternative approaches considered at each stage are also discussed and the choices made are justified.

5.2 Research ethics and governance approval

In modern day medical research, it has become the norm for any research activity involving human participants, human tissues or their clinical data, given its sensitive nature, to obtain ethical approval by an independent ethics committee. This is to limit abuse of research participants and to safeguard their rights. All leading medical and healthcare journals will only publish studies for which ethical approval has been granted, where applicable.

In this study, the ethics application was submitted to the Leeds West Research Ethics Committee using the Integrated Research Application System (IRAS). The University of Leeds acted as the sponsor for the study. After completing the online application, the supporting documents including research protocol, invitation letters (Appendices III and IV), GP information sheet (Appendix V), patient information sheets (Appendices VI and VII), patient consent forms (Appendices VIII and IX), data collection forms (baseline and discharge) (Appendices X, XI and XII), and curriculum vitae of the research team were sent to the committee in the post. The meeting was attended by the author and one of his supervisors (MB). The committee members, during the meeting, sought clarification on the process of patient recruitment, use of multiple questionnaires, and the author's experience of conducting interviews. The committee gave provisional favorable opinion subject to minor corrections in the consent forms, patient information sheet and protocol. All suggested corrections were made and revised documents were submitted for approval. Subsequently, favorable ethical opinion was granted (Appendix XIII) by the committee.

Following the successful ethics application, research governance approval was sought from the NHS for the research to be conducted at Leeds Community Healthcare NHS Trust. Subsequently, permission was granted (Appendix XIII) and a letter of access for research (Appendix XV) was issued by the relevant authorities. Participant recruitment began only after obtaining research governance approval.

During the course of the study, a few changes were deemed necessary in the protocol and consequently a notice of substantial amendment, generated through IRAS, was submitted to the Leeds West Research Ethics committee for review. The committee gave favorable ethical opinion to the amendments (Appendix XVI). The amendments included: a reduction in the sample size from 105 to 79; only two questionnaires (BPI and HADS) were used for 3-months follow-up instead of four (BPI, HADS, SF-36, CPG); 3-months follow-up questionnaires posted to only the first 30 patients discharged from the service. The reasons for all these changes are provided later in this chapter.

In the following paragraphs, the key steps taken to ensure ethical conduct of research in line with the University of Leeds, Research Ethics Policy and Data Protection Act 1998 are explained.

5.2.1 Informed consent

The process of obtaining informed consent has two components: 1) providing participants with the necessary information; 2) signing of consent forms. Since there were two phases of the study, two patient information sheets, one general (Appendix VI) and one specifically for the qualitative phase (Appendix VII), were developed to provide patients with the necessary information to make an informed decision whether or not to participate in the

research. The general information sheet and a letter of invitation were sent together with the clinic appointment letter to patients at least two weeks ahead of their clinic appointment. This was to ensure that patients had sufficient time to read, understand and discuss the study with their family and friends. Contact details were also provided at the end of the patient information sheet, so that patients could contact the author to obtain further information, if required.

5.2.2 Right of withdrawal

The patients were informed of their right to withdraw at any stage without giving any reason in the patient information sheet. This information was reiterated verbally before signing the consent forms before both phases. The participants were assured that withdrawing from, or not taking part in, the research would have no negative consequences on the care provided by the health professionals. During the qualitative interviews, patients were allowed to stop the interview at any time without providing any reason. Only one patient withdrew from the study, a few days after enrolling in the study.

5.2.3 Confidentiality and data protection

All necessary measures were taken to ensure the confidentiality of research participants and data protection. To mask the identity of patients, a pseudonym and a serial number were assigned to all the patients enrolled in the study. The master list was kept electronically on a password-protected online University server. Only members of the research team had access to the master list. Personal identifiable data were not collected in any of the questionnaires. All paper-based data were kept under lock and key in a secure room at the pain clinic. After the completion of baseline data collection, all the paper-based data were then transferred to the author's office at the University and placed in a filing cabinet protected by lock and key. Audio data, gathered through qualitative

interviews, were downloaded on a password protected online University server after every interview. Once downloaded, the audio data were deleted from the recorder prior to the next interview.

5.3 Quasi-experimental study

As mentioned earlier, a number of quasi experimental designs exist in the literature and a single group pretest-posttest design was used. In the following sections, procedures related to patient recruitment, data collection and analysis are described in detail.

5.3.1 Patient recruitment

All the patients referred to the pain clinic between 31st January 2012 and 31st September 2012 were sent a letter of invitation (Appendix III) and a patient information sheet (Appendix VI) together with the clinic appointment letter by the secretarial staff at the pain clinic. The patients were screened for eligibility, based on the information provided in the referral notes by the GP, against the inclusion and exclusion criteria (described below). Patients meeting the inclusion criteria were asked verbally by the author or the clinical nurse specialist (KM) about their willingness to participate in the research study. Patients were given additional information pertaining to their participation in the research, if requested. Once all the information was provided, written consent was obtained by the author or the clinical nurse specialist (KM). The author attended the clinic on Wednesdays for the purpose of patient recruitment, since almost all of the new patients were invited for their first appointment on that day as routine practice. The patients' GP(s) were also informed about their participation in the research through a letter (Appendix V), if agreed by the patient.

5.3.1.1 Inclusion criteria

Patients meeting the following inclusion criteria were recruited:

- Age \geq 18 years.
- History of chronic pain for > 3 months.
- Adequate ability to read and understand English.

5.3.1.2 Exclusion criteria

The following patients were excluded:

- Patients with malignant pain.
- Patients with organic brain disease or psychiatric disorders.
- Pregnant women.
- Patients who required acute medical/surgical intervention for their pain relief.

5.3.2 Sampling

In medical research a representative sample is usually chosen from the desired population as studying the whole population is often not practical. Findings from an unbiased and sufficiently large sample can then be generalized to the whole population (Zodpey, 2004).

Broadly, there are two types of sampling techniques: probability sampling and non-probability sampling. Probability sampling is an umbrella term for a number of sampling techniques in which all the members of the population have an equal chance of being recruited in the sample (Zodpey, 2004). The key advantages of probability sampling include: the sample is representative of the population; statistical inferences are generalizable to the population; and it minimizes the selection bias. Because of these advantages, probability

sampling techniques are considered ideal for quantitative research (Zodpey, 2004). Probability sampling techniques include: simple random sampling; stratified random sampling; cluster sampling and systematic sampling (Zodpey, 2004).

In non-probability sampling, individuals in a population do not have an equal chance of being recruited. Since not all the individuals in the population have an equal chance of being recruited, the sample may not be representative of the population and statistical inferences made are not often generalizable to the population. Consequently, non-probability sampling is considered to be inferior to probability sampling in quantitative research (Castillo, 2003). Non-probability sampling techniques are often employed when probability sampling is not possible for practical reasons. Non-probability sampling is quicker, cheaper and easier compared to probability sampling (Castillo, 2003). Non-probability sampling encompasses a number of sampling techniques and the commonly used techniques include: quota sampling; consecutive sampling; convenience sampling; purposive sampling; and theoretical sampling (Castillo, 2003).

In this study, a consecutive sampling technique was used to recruit patients. Consecutive sampling, a non-probability sampling technique, aims to include all the accessible subjects. Ideally a probability sampling technique, either simple random or systematic sampling would have been used to limit selection bias. However, consecutive sampling is considered the best non-probability sampling technique (Castillo, 2003) as it gives an opportunity to all the participants to be recruited thus minimizing the selection bias. Consecutive sampling, as opposed to simple random or systematic sampling, was chosen due to a limited pool of potential participants as well as slow discharge rate.

Being a pretest-posttest study, baseline assessment was necessary; therefore, only new patients could have been recruited. On average, 150 to 200 new patients used to attend the clinic and were usually discharged after 6 to 8 months. Furthermore, a three month follow up was also planned to document short to medium term outcomes of the intervention. Given the nature of the study design and discharge rate of the clinic, employing a probability sampling technique would have required more time to recruit research participants. Since the research was undertaken as part of a PhD dissertation, the author had a maximum of one year to complete the data collection in order to ensure timely completion of the degree. Furthermore, the issue of selection bias was not substantially important as there was no control group and all patients referred to the clinic were invited to participate in the study, rather than based on the author's personal preference.

5.3.3 Sample size

One of the most important issues in a quantitative study design is a careful estimation of sample size (Emanuel et al., 2000). Irrespective of how robust the study design is, if the sample size is smaller than required, it is highly likely that the study may fail to detect a difference in the presence of a real difference (Type II error) (Zodpey, 2004). Furthermore, underpowered trials are considered "scientifically useless" (Altman, 1980) and therefore unethical (Halpern et al., 2002). However, meta-analysis of clinically homogenous studies can overcome the said problem. In practice, it may not be always possible to recruit the required number of participants in the research study. On the other hand, recruiting more participants than required is also unethical and would result in wastage of time and resources (Zodpey, 2004).

In this study, pain intensity was the primary outcome and the sample size calculations were based on the pain scores measured by the numerical rating scale (NRS). Initially a sample size of 105 was calculated using an online webulator (Montelpare, 2011) after accounting for a 15% dropout rate. The calculation was based on an assumed rather than actual standard deviation (SD). After recruiting the first 30 patients, the SD was calculated and the sample size was recalculated based on the new SD value using the formula (explained below). After accounting for the 15% drop out, the new sample size was calculated to be 79.

The sample size was calculated using the following formula (Eng, 2003):

$$N = \frac{4\sigma^2 (Z_{crit} + Z_{pwr})^2}{D^2}$$

Where N= total sample size; σ = Standard deviation (σ value = 1.60 obtained from the first 30 patients); Z_{crit} = Standard normal deviate corresponding to the selected significance criteria and confidence interval (Z_{crit} value = 1.96 corresponding to 95% confidence interval and significance criteria of 0.05) ; Z_{pwr} = Standard normal deviate corresponding to selected statistical power (Z_{pwr} value = 0.842 corresponding to 80% power); D = minimum expected difference. In this study, pain intensity is the primary outcome measure measured on an 11-point, 0-10 numerical rating scale (NRS). For NRS a 10% to 20 % (1.1 to 2.2 point) decrease is considered to be the minimum clinically important difference (Dworkin et al., 2008). In order to ensure that the study is powered to detect the minimum clinically important difference, a D value of 1.1 was chosen for the calculation of sample size.

The recalculation of sample size prevented over recruitment and unnecessary burden on patients. As mentioned earlier, the sample size was

recalculated because the earlier calculation was based on an assumed SD rather than the actual SD. As per the requirement of ethics approval, any change in the protocol should be brought to the attention of the committee. Therefore, a notice of substantial amendment was submitted to the REC to highlight the change in the sample size, together with the other above mentioned changes, for review. The reason for the change in the sample size was also explained in the application. Subsequently, favorable ethical approval was obtained (Appendix XVI).

5.3.4 Data collection

Once the written informed consent was obtained from the patients, they were requested to fill in the questionnaires (the Brief Pain Inventory, the SF-36, the Hospital Anxiety and Depression Scale, and the Chronic Pain Grade questionnaire) prior to their first consultation with the nurse and/or the pharmacist as part of the baseline assessment (pretest; T_0). It should be noted here that, as a routine clinical practice, all the patients referred to the pain clinic were asked to complete the BPI and the HADS. For the purpose of this study, participants completed two additional questionnaires (SF-36 and CPG). The rationale for choosing these specific outcome measures and their respective instruments is explained in the next section of this chapter. Sociodemographic and clinical data were also collected on a structured questionnaire (explained below) by the author from patients' clinical notes and patient interview.

Two post-tests were undertaken: upon discharge from the pain clinic, and at 3-month post-discharge. The decision to discharge patients from the service was made by the clinical nurse specialist (KM) in consultation with the patient after assessing their clinical needs. Upon discharge, after the last consultation, patients were asked to complete the same set of questionnaires

(BPI, HADS, SF-36, CPG) by the clinical nurse specialist (KM). The patients completed the questionnaires at the pain clinic. For the 3-month follow-up, questionnaires (BPI and HADS) were posted to the patients' home addresses together with a letter of invitation (Appendix IV) to complete the 3-month follow-up and a self-addressed pre-paid envelope. Patients were requested to complete the questionnaires and return them within one week of receiving them. For each patient enrolled in the study, the date of discharge and a due date for 3-month follow-up were recorded and kept under lock and key by the author at the pain the clinic. The process of data collection is shown in Figure 5.1.

As mentioned previously (section 5.2), two changes were made in the initial protocol in relation to the 3-month follow-up: Firstly, instead of requesting the patients to fill in all four questionnaires (BPI, CPG, SF-36, HADS), the patients were asked to complete only two questionnaires (BPI and HADS). There were two interlinked reasons to make this change: to reduce patient burden; and to improve response rate. During the baseline assessment, a number of patients expressed concerns about the length of the questionnaire especially the SF-36. Furthermore, a low response rate with postal questionnaires is well documented in the literature and it was a concern that the patients might not fill in and return the questionnaires because of their length. Secondly, only the first 30 patients discharged from the service were invited to take part in the 3-month follow-up assessment as opposed to all the 79 patients, initially proposed. There were two main reasons for reducing the sample size for the 3-month follow-up: Firstly, slow recruitment of patients in the study as the research team was only able to recruit less than half of the patients meeting the inclusion criteria,. Secondly, a slow discharge rate from the service was also observed. While designing the study, it was assumed that patients would be

discharged after 4 to 6 months but in practice it was realized that most of the patients were taking more than six months to be discharged from the service. Given the limited time to complete data collection, being a PhD research project, all of the above mentioned factors necessitated a reduction in the sample size for 3-month follow-up. . The ethics committee was notified about these changes through a notice of substantial amendment, generated through IRAS. The committee gave favorable ethics opinion after the review of the application (Appendix XVI).

The follow-up data collection was stopped when the service was decommissioned by the local PCT in December 2012, effective March 2013. However, no new patients were seen at the clinic since December 2013. The existing patients were either referred to a local Musculoskeletal service or discharged back to their GPs. The implications of decommissioning of the service in relation to the findings of this study are discussed in section 8.5.

5.3.4 Outcome measures

The following outcome measures and respective scales were selected based on demonstrated validity and reliability in chronic pain clinical trials. The selection of outcome domains is supported by the recommendations of the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) group, an initiative to improve the design, conduct and reporting of clinical trials on pain. All the scales described below can be self or interviewer administered.

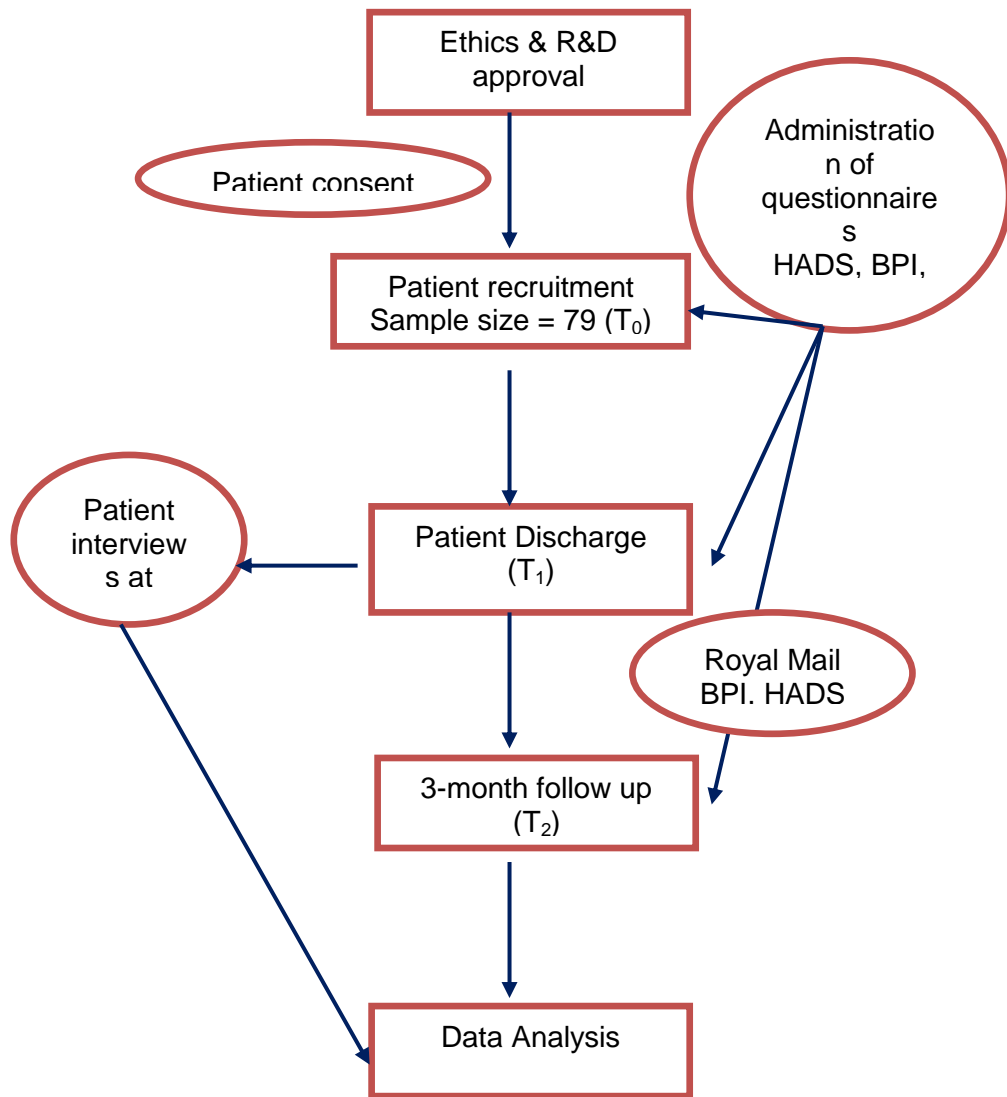


Figure 5.1. The research process

5.3.4.1 Sociodemographic and clinical data

Sociodemographic data (age, gender, ethnicity, and employment status etc.) and history of chronic pain (pain sites, duration of pain, and referral to pain specialist in the past) were collected through a structured questionnaire (Appendix X) by the author. Additionally, at baseline, data on co-morbidities, route of referral and medication history were collected on another structured data collection form (Appendix XI). The discharge data collection form (Appendix XII) was used to gather data on the change in medication based on recommendations made by the clinical nurse specialist and/or the pharmacist, the number of visits to the pain clinic and the nature of consultation. The author designed these data collection forms. Three senior academics (MB, SJC, DA) reviewed the data collection forms for accuracy, adequacy, face and content validity. The clinical nurse specialist (KM) was also consulted for the appropriateness and practicability of the forms. Subsequently, changes were made to the forms in light of the feedback. Finally, the data collection forms were pilot-tested on 3 patients.

5.3.4.2 Pain intensity

Pain intensity is a quantitative estimate of severity or magnitude of pain. Both generic and disease specific questionnaires exist in the literature to measure pain intensity (Dworkin et al., 2005). Since various types of chronic pain patients are referred to the pain clinic, the use of a disease specific questionnaire was deemed inappropriate. The numerical rating scale (NRS), visual analogue scale (VAS) and visual rating scale (VRS) are the most frequently used generic instruments to measure pain intensity (Dworkin et al., 2005). NRS is an 11-point scale ranging from 0 = no pain to 10 = 'pain as bad as you can imagine' (Cleeland and Ryan, 1994). Typically, a VRS categorises

pain intensity into one of the four categories: none, mild, moderate, and severe. VAS consists of a 10 cm line with no pain at one end and worst imaginable pain at the other (McCormack et al., 1988). All three instruments have demonstrated validity and reliability. However, no single scale has persistently established greater responsiveness in detecting improvements in pain treatment (Jensen and Karoly, 2001). In terms of patient preference, VAS is least preferred compared to NRS and VRS (Jensen and Karoly, 2001). VAS is associated with greater missing and incomplete data compared to NRS as NRS is relatively easy to administer. Furthermore, patients with old age or who take opioid analgesics have difficulty in filling in VAS (Jensen and Karoly, 2001). Similarly, patients with cognitive impairment find NRS difficult to respond to (Jensen and Karoly, 2001).

After careful consideration of the advantages and disadvantages of each of these scales and reviewing the recommendations of The IMMPACT group (Dworkin et al., 2005), an 11 point (0-10) numerical rating scale (NRS) ranging from 0 = no pain to 10 = 'pain as bad as you can imagine' was selected. NRS was administered as part of the Brief Pain Inventory (BPI) (Cleeland and Ryan, 1994). NRS is simple and, easy to administer and score (Jensen and Karoly, 2001, Dworkin et al., 2005).

5.3.4.3 Physical functioning

Chronic pain restricts daily life activities and physical functioning. Theoretically, pain relief should be complemented with an improvement in physical functioning but studies have shown that pain intensity and physical functioning are not significantly associated (Turk, 2002). For this reason, using measures of physical functioning in trials assessing the effectiveness of interventions in chronic pain management is recommended (Dworkin et al.,

2005). Both generic, such as the BPI (Cleeland and Ryan, 1994) and the Multidimensional Pain Inventory (MPI) (Kerns et al., 1985), and disease specific measures, such as WOMAC (Bellamy, 1996) and the Roland and Morris Back Pain Disability scale (Roland and Morris, 1983), for assessing physical functioning exist in the literature. The IMMPACT group recommends the use of a disease specific tool for assessing physical functioning in studies where a well-established and validated tool is available for that particular disease (Dworkin et al., 2005). However, disease-specific measures of physical functioning do not exist for all types of chronic pain. Therefore, generic measures should be used when the study population consists of patients with different types of chronic pain conditions (Dworkin et al., 2005).

Since patients with a variety of chronic pain conditions were referred to the pain clinic, only generic measures were considered for selection. The IMMPACT group recommends either pain interference items of BPI (Cleeland and Ryan, 1994) or MPI (Kerns et al., 1985). MPI is a 9-item questionnaire which assesses a number of dimensions of chronic pain experience, including pain intensity, emotional distress, cognitive and functional adaptation, and social support. On the other hand, BPI is a 7-item instrument and measures pain interference with seven daily life activities including general activity, walking, work, mood, enjoyment of life, relations with others and sleep (Cleeland and Ryan, 1994, Cleeland et al., 1996). The validity and reliability of both instruments have been documented in different settings and languages (Dworkin et al., 2005). Unlike BPI, MPI does not assess pain interference with sleep, an important outcome; therefore, a valid and reliable measure is required to assess the impact of pain on sleep if MPI is used (Dworkin et al., 2005).

BPI was chosen for the present study because it is shorter and unlike MPI it precludes the necessity of using another questionnaire to assess the impact of pain on sleep, preventing an undue burden on the patients. In the BPI, each of the seven interference items is scored on an 11-point (0-10) scale ranging from 0 = does not interfere to 10 = completely interferes (Appendix XVII). BPI pain interference is calculated as the mean of the seven interference items. This mean can be used if more than 50%, or four of seven, of the total items have been completed on a given administration (Cleeland and Ryan, 1994).

5.3.4.4 Emotional functioning

Mood disturbances, anxiety, anger and depression are well reported consequences of chronic pain (Fernandez, 2002). Depression combined with physical illness has greater adverse outcomes than physical illness alone (Stein et al., 2006). However, assessment of emotional functioning in chronic pain patients is a challenge because some of the symptoms of depression such as fatigue, reduced libido and weight gain are also associated with chronic pain itself and medication used for its treatment (Gallagher and Verma, 2004).

A number of instruments to measure emotional functioning exist in the literature such as the Hospital Anxiety and Depression Scale (HADS) (Zigmond and Snaith, 1983), Beck Depression Inventory (BDI) (Beck et al., 1961), the Patient Health Questionnaire (PHQ-9) (Spitzer et al., 1999), the General Health Questionnaire (GHQ-28) (Goldberg and Williams, 1988), the Centre of Epidemiology Studies-Depression (CES-D) (Radloff, 1977), the Geriatric Depression Scale (GDS) (Yesavage et al., 1983), and the Profile of Mood States (McNaire et al., 1971). Each of these instruments has their own advantages and disadvantages and explaining all these tools individually is beyond the scope of this thesis. The IMMPACT group recommends the use of

the BDI or the POMS (Dworkin et al., 2005), as both instruments are reliable, validated and widely used. BDI is a 21-item questionnaire that can be divided into two subscales: the cognitive-affective (items 1 to 13) and the somatic-performance (items 14 to 21) (Beck and Steer, 1993). POMS assesses six mood states: tension-anxiety, depression-dejection, anger-hostility, vigor-activity, fatigue-inertia, and confusion-bewilderment (McNaire et al., 1971). Limitations of the BDI include (Richter et al., 1998): high item difficulty, lack of representative norms leading to uncertainty in the objectivity of interpretation, debatable factorial validity and poor discriminant validity against anxiety. Nevertheless, BDI has high internal consistency, high content validity, high discriminant validity in differentiating between depressed and non-depressed individuals, and sensitivity to change (Richter et al., 1998).

Since HADS (Zigmond and Snaith, 1983) was routinely used in the pain clinic to assess emotional functioning, it was decided to continue its use in the present study. Asking patients to fill in another questionnaire to assess the same outcome would have put patients under unnecessary burden. Substituting HADS with BDI or POMS would have affected the routine clinical practice which was undesirable. Furthermore, HADS is shorter as than BDI and has well documented validity and reliability (Bjelland et al., 2002). It was developed to identify possible cases of anxiety and depression among patients in non-psychiatric clinics. It consists of two subscales; Anxiety subscale (HADS-A) and a Depression subscale (HADS-D). Each subscale consists of 7-items and each item has four numerical response options from 0 to 3 with a minimum score of 0 and a maximum of 21 for each subscale. The mean cut-off score for HADS-A and HADS-D is 8 (Bjelland et al., 2002). A review by Bjelland and colleagues

(2002) concluded that HADS is a valid and reliable tool to detect anxiety and depression and assess their symptom severity in primary care.

GL assessment holds exclusive copyright of HADS. An agreement with GL assessment was signed and license fees were paid to ensure lawful use of the questionnaire (Appendix XVIII).

5.3.4.5 Quality of life

Chronic pain adversely affects the quality of life of patients. The IMMPACT group has not identified Health-related quality of life (HRQoL) as an 'independent outcome domain', but it recommends the use of a generic HRQoL measure (e.g. SF-36) in trials evaluating the effectiveness of an intervention in chronic pain (Dworkin et al., 2005). The use of a generic HRQoL measure has been recommended because: it allows a meaningful comparison with other disease conditions; and the data could be used in cost-effectiveness analyses.

HRQoL instruments can be divided into three categories with each type having its own specific clinical and research use: generic measures, condition-specific measures, and preference-based measures (Vetter, 2007). The ten most cited generic and preference based QoL measures include (Vetter, 2007): the SF-36 (Ware and Sherbourne, 1992), the EuroQoL Scale (EQ-5D) (Rabin and de Charro, 2001), the Nottingham Health Profile (NHP) (McEwen and McKenna, 1993), the SF-12 (Ware Jr et al., 1996), the Sickness Impact Profile (SIP) (Bergner et al., 1981), the Health Utilities Index (HUI) (Furlong et al., 2001), the World Health Organization Quality of Life Scales (WHOQOL) (The WHOQOL Group, 1995), the Dartmouth COOP and Dartmouth COOP/WONCA Charts (Nelson et al., 1996), the Quality of Well-Being Scale (QWB) (Kaplan et al., 1993) and the SF-6D (Brazier et al., 2002).

In the present study, HRQoL of life was used as an independent outcome measure because, arguably the improvement in physical functioning and pain relief should also be reflected in the improvement in overall quality of life. The Medical Outcomes Study-Short Form version 2 (SF-36v2)[®] was used for measuring the HRQoL (Ware and Sherbourne, 1992). Initially, while designing the research project, the length of the questionnaire was a source of concern and shorter alternatives such as SF-12 and SF-8 were considered. But unlike the SF-36, both the SF-12 and the SF-8 do not have pain items in the questionnaire therefore SF-36 was chosen. Furthermore, the IMMPACT group also recommends the use of SF-36 as a generic HRQoL tool. SF-36 consists of eight subscales: Physical Functioning (PF), Role-Physical (RP), Bodily Pain (BP), General Health (GH), Vitality (VT), Social Functioning (SF), Emotional Role (ER) and Mental Health (MH) (Appendix XIX). Scores for each variable are summed then transformed into a Likert scale ranging from 0 (worst) to 100 (best) (Ware et al., 2005). Various studies have documented the validity and reliability of the SF-36 in different settings and languages (Sersic and Vuletic, 2006, Leung et al., 2010, Chia et al., 2006, Almborg and Berg, 2009, Kosinski et al., 1999). It is suitable for adults ≥ 18 years of age and can be self, telephone or interviewer administered.

Quality Metric Incorporated (QM), Lincoln RI, USA has the exclusive copyright for SF-36. A non-commercial license agreement was signed between the Office of Grants and Scholarly research (OGSR), Quality Metric Incorporated and the author to enable the use of SF-36 in this research project. Under the agreement 360 copies of SF-36v2 together with the e-manual and scoring software v4 were provided by QM free of cost.

5.3.4.6 Chronic Pain Grade questionnaire (CPG)

The Chronic Pain Grade (CPG) questionnaire was used, in addition to as an outcome measure, to assess pain severity among patients referred to the pain clinic. The World Health Organization's International Classification of Functioning Disability and Health (ICF), provides a standard framework for the comparison and understanding of health outcomes, and has identified three main outcomes for chronic pain namely, impairment (I), activity limitation (A) and participation restrictions (P) (World Health Organization, 2001). The CPG measures all three of these ICF outcomes (Dixon et al., 2007) (Appendix XX).

The CPG is a seven-item questionnaire and measures pain severity in three dimensions: persistence, intensity and disability (Von Korff et al., 1990). Three questions (questions 1 to 3) measure pain intensity, each item using an 11-point numerical rating scale (NRS) ranging from 0 = no pain to 10 'worst pain you can imagine'. Another three (questions 5 to 7) measure pain related disability, each item using an 11-point numerical rating scale (NRS) ranging from 0 = no pain to 10 'worst pain you can imagine'. One question (question 4) gives disability points based on the number of days in the past six months the respondent was unable to do his/her regular work because of pain (0-6 days 0 points; 7-14 days 1 point; 15-30 days 2 points; ≥ 31 days 3 points). Based on the pain intensity score, disability score and disability points, CPG classifies chronic pain patients into one of the five hierarchical categories according to pain severity: Grade 0, Pain free; Grade I, low disability-low intensity; Grade II, low disability-high intensity; Grade III, high disability-moderately limiting; and Grade IV high disability-severely limiting. The questionnaire was originally proposed by Von Korff et. Al. (1992) and has been validated in the UK general population (Smitha et al., 1997). The method proposed by Von Kroff et al.

(1992) was used for the scoring and classification of patients in the above mentioned chronic pain grades.

5.4 Data analysis

The Statistical Package for Social Sciences (SPSS) for Windows version 20 (Chicago, IL, USA) was used for data analyses. All quantitative data were coded numerically (e.g. for gender; male was coded as 1 and female was coded as 2) and entered into SPSS. Subsequently a codebook was prepared. As mentioned earlier (section 4.3.4.5), quality of life (SF-36) data (both baseline and discharge) were entered into the scoring software provided by the Quality Metric Incorporated (QM), Lincoln RI, USA. Once scoring was completed the results were exported to SPSS for further analyses. For the Chronic Pain Grade (CPG), data were entered into Microsoft Excel and the scoring of the questionnaire was conducted based on the algorithm proposed by Von Korff et al. (1992). Data were then exported to SPSS for further analyses. Patients were then classified into IV groups, described above, based on the severity of chronic pain (Von Korff et al., 1992).

Descriptive statistics such as measures of central tendency and spread were used to summarise and present data. Since parametric tests have more statistical power and produce more accurate and precise estimates, they were preferred over non-parametric tests if data were continuous and normally distributed (Siegel and Castellan, 1988). However, if the assumptions of parametric tests were not met, for example, if the data were skewed, non-parametric tests were used. Data were considered normally distributed if the skewness value was between +1 and -1, calculated using SPSS. (Altman, 1991). Data are reported as mean and standard deviation, if normally distributed and as median and intra-quartile range (IQR), if not normally distributed.

Since data were paired (repeated measures; pretest-posttest study design), either the paired t-test (comparing means) or its non-parametric equivalent the Wilcoxon Signed-Rank test (comparing medians) was used based on the distribution of the data. The Wilcoxon Signed-rank test was used for comparing baseline and discharge scores of pain intensity, physical functioning, anxiety and depression, and pain intensity and disability (measured by CPG). The paired t-tests were used for comparing quality of life data. The Wilcoxon signed rank test was preferred over the Sign test, an alternative test for two related samples, because the Wilcoxon Signed-rank test is statistically more powerful. This is because in addition to assigning positive or negative ranks to the observations according to where they lie above or below some hypothesized value, it also takes magnitude of the observation into account unlike the sign test (Siegel and Castellan, 1988). In the results chapter (Chapter 6), to enhance clarity, the name of the statistical test used to calculate the P-value is also given at the bottom of each table, where applicable. A two-tailed P-value of less than 0.05 was considered statistically significant.

5.5 Descriptive qualitative study

The primary objective of the qualitative phase was to explore patients' views around their experiences and satisfaction with the service provided by the nurse-pharmacist managed pain clinic. The rationale for choosing a descriptive qualitative design has been explained in chapter 3. In the following sections, procedures for subject recruitment, sampling, data collection and data analysis are explained. Alternative approaches, where available, are also presented and the rationale for choosing a particular approach is justified.

5.5.1 Selection of patients

As mentioned earlier, an embedded design was used for this study and therefore, the process of patient recruitment for the qualitative phase was nested within the process of recruitment for the quantitative phase (see section 5.3.2). Within the consent form for the quasi-experimental study (quantitative phase), patients were also asked about their willingness to participate in the qualitative interview upon discharge from the service. Patients who indicated their willingness constituted the sampling frame for the descriptive qualitative study. However, patients were allowed to withdraw their consent and refuse to participate in the interview at any stage before, or upon, discharge from the service. Whilst discharging patients, the clinical nurse specialist (KM) sought their willingness to take part in the interview. If willing, the contact details (name and telephone number) of the patient were communicated to the author. The author then arranged the time and date of the interview based on the patients' preference. In addition to the inclusion and exclusion criteria for the quasi-experimental phase, the following inclusion and exclusion criteria were applied for the qualitative descriptive study.

5.5.1.1 Inclusion criteria

- Discharged from the service within the study period.

5.5.1.2 Exclusion criteria

- Referred to secondary care after the first consultation.
- Discharged from the service due to nonattendance at two consecutive consultations without informing the clinic staff.

- Patients deemed unsuitable for an interview due to communication or medical issues (e.g. speaking/listening disability, patients with psychiatric disorders) identified by the clinical nurse specialist.

5.5.2 Sampling

Like quantitative research, sample selection can profoundly affect the quality of qualitative research (Coyne, 1997). In the past, qualitative researchers had been criticized for not describing the sampling strategy adequately resulting in difficulties in interpretation and study replication (Kitson et al., 1982). Unlike quantitative research, the aim of sampling in qualitative research is not to recruit a statistically representative sample of respondents in order to generalize findings to the population (Pope et al., 2000). But instead, as Morse (1991b) pointed out, sampling in qualitative research is based on the principle of appropriateness that requires purposeful sampling and a “good” informant (i.e. one who is articulate, reflective, and willing to share with the interviewer)’ (p. 127) (Morse, 1991b). The sample size for qualitative study is usually small as the focus of qualitative research is to provide an in-depth understanding of the phenomenon under study rather than statistical generalization (Crouch and Mckenzie, 2006). The principles of quantitative sampling are not applicable to qualitative studies for both practical and theoretical reasons (Marshall, 1996). Firstly, random sampling only produces a representative sample only if the study variables are normally distributed within the population. But qualitative studies explore attitudes, beliefs and values which are not normally distributed within the population (Marshall, 1996). Secondly, it is well known among the qualitative researchers that some participants are “richer” than others and such participants are more likely to provide an in-depth insight on the research question therefore choosing someone at random may be inappropriate

(Marshall, 1996). On the other hand, purposeful sampling may enable a researcher to find a rich-informant. It can also be argued that the qualitative researchers should not waste their time and resources in doing random sampling as the aim of qualitative sampling techniques is not to select a statistically representative sample, a desired characteristic of random sampling techniques.

A number of sampling strategies are available in qualitative research and the selection is based on the type of qualitative design and research question (Miles and Huberman, 1994). According to Patton (1990), all sampling techniques in qualitative research can be encompassed under the umbrella of purposeful sampling. Purposive sampling refers to selecting individuals who are likely to generate 'appropriate and meaningful data' (Green and Thorogood, 2009). The aim of purposive sampling is to recruit 'information rich cases for in depth study' (Patton, 1990) (Page 169). Patton (1990) identified 15 different sampling techniques within purposeful sampling including extreme or deviant case sampling, intensity sampling, maximum variation sampling, homogenous, typical case sampling, stratified purposeful sampling, critical case sampling, snow ball sampling, criterion sampling, theory based or operational based sampling, confirmation and disconfirmation cases, opportunistic sampling, sampling politically important cases and convenience sampling. Patton described theoretical sampling, described by Strauss and Corbin (1990) as a three stage process consisting of open sampling, relational and variation sampling and discriminate sampling associated with grounded theory studies, as a variant of purposeful sampling. Morse (1991b) and Sandelowski (1995) endorsed Patton's view (1990) and also recognized theoretical sampling as a variant of purposeful sampling. Whether theoretical sampling is an independent

method or encompassed under purposeful sampling is a debated topic among qualitative researchers (Patton, 1990, Strauss and Corbin, 1990, Morse, 1991b, Sandelowski, 1995, Coyne, 1997). However, this author believes that, whether a qualitative study aims to generate a theory or not, all qualitative researchers aim to recruit 'information rich' participants therefore all the sampling techniques can be broadly encompassed under purposeful sampling.

In this study, a combination of two purposeful sampling techniques, namely convenience sampling and maximum variation sampling were used. In convenience sampling participants are selected because of their convenient accessibility and proximity to the researcher. Maximum variation sampling aims at *"capturing and describing the central themes or principal outcomes that cut across a great deal of participant or program variation"* (Page 172) (Patton, 1990). Initially for the first five interviews, convenience sampling was used and patients meeting the inclusion/exclusion criteria and consenting for an interview were recruited. In order to ensure representation of different types of patients referred to the clinic, the remaining 14 interviewees were recruited using maximum variation sampling. Maximum variation sampling is the most frequently used technique (Sandelowski, 1995).

A framework for maximum variation sampling was developed based on pain scores on discharge, duration of chronic pain and gender (Figure 4.2). In the first step, patients were classified into two groups based on pain scores on discharge: pain score < 7 (mild to moderate pain) and pain score \geq 7 (severe pain). Following that, based on duration of chronic pain, the patients were stratified into two groups: pain duration \leq 3 years; and pain duration > 3 years. Finally, each of these four groups was further stratified based on gender.

However, any patient meeting the inclusion criteria, who expressed interest in participating in the interview was recruited.

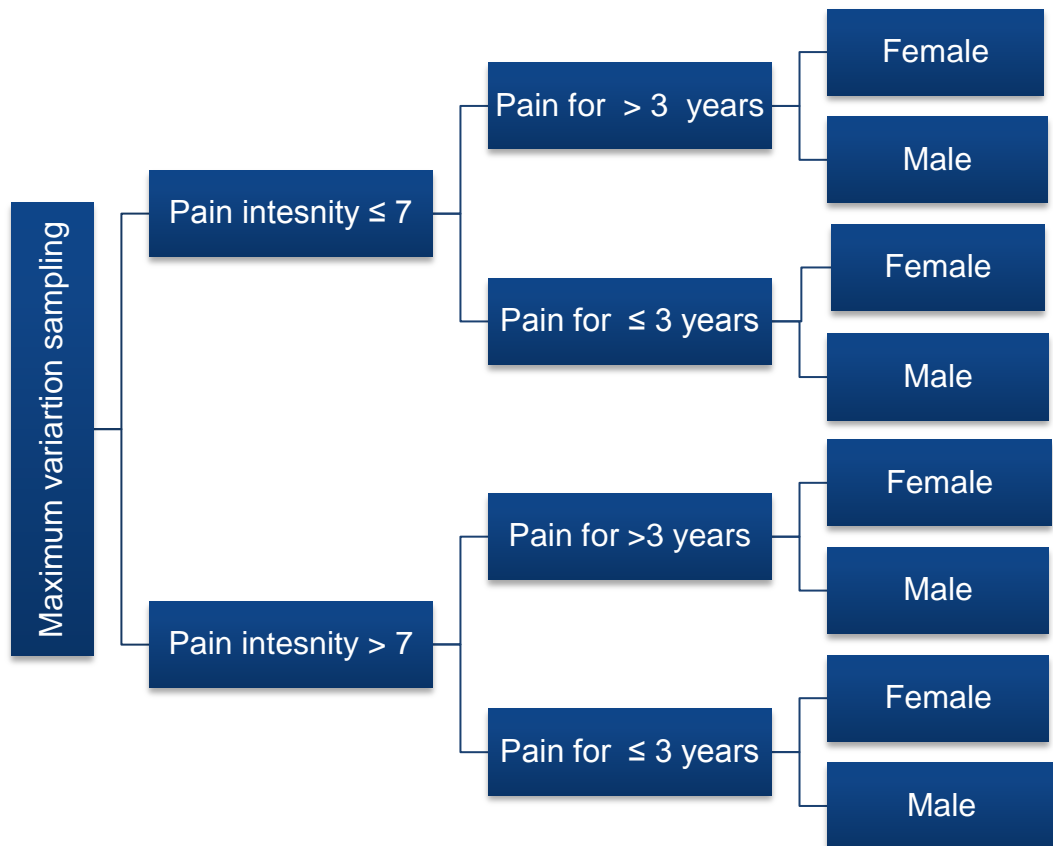


Figure 5.2. Framework of maximum variation sampling

5.5.3 Sample size

Unlike quantitative research, in qualitative research there are neither rules nor *a priori* methods to calculate sample size. Sample size in most of the published qualitative research is often determined by data saturation (informational redundancy) (Lincoln and Guba, 1985) or theoretical saturation (Strauss and Corbin, 1990). However, reported sample sizes are often too small to support either informational redundancy or theoretical saturation (Sandelowski, 1995). The concepts of informational redundancy and theoretical saturation are, although related, different from each other. Informational redundancy is said to occur when no new information is obtainable from newly sampled units, and the information obtained therefore becomes redundant (Patton, 2002). Similarly, Sandelowski (1995) described informational redundancy as the point when a researcher feels that he has seen and heard the same thing repeatedly and collecting more data will add no further interpretive value to existing data. On the other hand, theoretical saturation, associated with grounded theory inquiry, is said to occur when gathering more data adds no value to the properties of a theoretical category (Strauss and Corbin, 1990). It should be noted here that in contrast to informational redundancy, theoretical saturation is associated with the data interpretations rather than data collection and it is the endpoint of theoretical sampling and is achieved via constant comparison analytic technique.

In general, sample sizes in qualitative research should neither be too small to achieve data saturation nor too large to limit in-depth case-oriented data analysis (Sandelowski, 1995). The principle of data saturation offers mainly conceptual guidance rather than practical guidance for sample size estimation before data collection (Guest et al., 2006) and judgment and experience of the

qualitative researcher eventually determines the number of participants in the majority of qualitative research. Several factors which influence saturation have been highlighted in the literature including the study aim, nature of topic, heterogeneity of the population, methods of data collection, groups of special interest requiring intensive study, study design and quality of data (Morse, 2000, Ritchie et al., 2003, Charmaz, 2006). Based on the type of qualitative research design, different guidelines on the sample size have been proposed by researchers ranging from 5 to 50 (Creswell, 2007, Morse, 2000, Ritchie et al., 2003). Morse (1994) suggested that at least six participants are required when the goal of the study is to understand the essence of experience. Green and Thorogood (2009) suggested that for an interview based study saturation usually occurs after 20 interviews.

In this study, data saturation or informational redundancy was used to guide sample size. In total, 19 patients were interviewed. The author continued to interview patients until no new information was coming out during the interview. The author started to sense data saturation after 17 interviews but conducted two additional interviews to ensure data saturation. As mentioned earlier, unlike theoretical saturation, it is not necessary to analyse data concurrently with data collection to ascertain data saturation. The author listened to each interview afterwards and made notes of key points. In addition to listening to the same information repeatedly, this guided the researcher in establishing data saturation - when the author felt that there was repetition of the information and key points.

5.5.4 Interviews

Data for qualitative research is gathered through interviews (one to one and group interviews), observations and reviewing documentary sources (public

records, personal documents, mass-media outputs and research outputs). A researcher may choose one or a combination of two or more techniques (e.g. interviews + participant observation) for generating qualitative data. Each data collection technique has its unique advantages and disadvantages and the choice of a particular method is governed by the study aim and objectives. Interviews are the most widely used data collection method in qualitative research. The purpose of a qualitative interview is to gather descriptions of the life-world of the interviewee (Kvale, 1983). Interviews can be of different types: structured, semi-structured, in-depth, narrative and informal interviews (Green and Thorogood, 2009). Keeping in mind the aim of the qualitative phase, semi-structured interviews were chosen because in semi-structured interviews, the interview agenda is determined by the researcher but the interviewee's responses determine the nature and depth of information unlike the structured interviews where participants' responses are fixed (Green and Thorogood, 2009).

Interviews can be conducted face to face, via telephone, internet (email, Skype and MSN Messenger) individually or in groups and each has its advantages and disadvantages (Opdenakker, 2006). There are different types of group interviews namely consensus panel, community interviews and participatory methods, focus groups and natural groups (Green and Thorogood, 2009). For the present study, all interviews were conducted face-to-face. Individual face-to-face interviews were selected as they allow more confidentiality and freedom to express individual experience and feelings and are not influenced by group interaction and dynamics (Gibbs, 1997). Group interviews are often difficult to arrange, manage and the researcher has less control over the data produced (Morgan, 1988). Furthermore, focus groups were

not practical for this study due to the nature of the research design and working of the clinic. The author aimed to interview patients within two weeks of their discharge from the pain clinic and patients were discharged from the service from weeks to months apart, making arrangement of focus groups impossible. Conducting focus group interviews would have inconvenienced patients into travelling to the interview location from different parts of the city, which considering the physical disability associated with chronic pain, was not appropriate. It was also anticipated that recently discharged patients in the group would have a fresh memory of their experience compared to those patients discharged months ago; the former might tend to dominate and influence the group which was not desirable. The major limitation of using interviews as a data collection tool is that they only provide access to what people say but not to what they do in their lives (Green and Thorogood, 2009). However, the study aim was not to document participants' behavior rather to explore their views about services at NPMPC for which interviews were best suited.

As mentioned earlier, interviews were conducted either at the patients' home or at the clinic based on the patients' preferences as interview setting influences the nature and quality of data generated (Green and Hart, 1999). One interview was conducted at the patient's work place during a lunch break, at her request. Patients were explained the purpose of the interview and measures (such as assigning pseudonyms, not using personal identifiable data in any publication, and keeping data on a password protected server) taken to ensure confidentiality. Following this, patients were explained the format of the interview and informed about the expected length of the interview. Once explained, patients were asked to sign the consent form. Permission was also

obtained to audio record the interview. Interviewees lasted between 15-45 minutes and interviews were audio taped using two digital audio recorders

A topic guide (Appendix XXI) was prepared to ensure uniformity, based on the literature review and study objectives. Topic guide, frequently used in semi-structured interviews, contains topics and questions that the interviewer can ask in different ways for different participants (Lindlof and Taylor, 2002). As mentioned earlier (Chapter 4, section 4.3), patient satisfaction is a multidimensional phenomenon therefore the topic guide was designed to cover the following areas: expectations from the service; efficacy of the service (did it help? How?); interaction with nurse and pharmacist (time given for consultation, engaging patient in discussion and designing of therapeutic plan, listening to and understanding the problem); understanding of chronic pain and self-management; and overall satisfaction (experience compared to other services in past, aspects of the service which need improvement etc.) with the service. In addition, in the beginning of each interview, patients were asked about their history of chronic pain and its impact on daily life including physical functioning, emotional functioning and quality of life. Interviewees were given a chance to express any additional views at the end of the interview. Once prepared, the author discussed the topic guide with his supervisors, who have substantial experience of conducting qualitative research, and amended it in light of their recommendations. A trial interview was also conducted with another PhD student.

5.5.5 Data management

After each interview, data from both audio recorders were transferred to a password protected university server. All consent forms were kept under lock and key in the author's office at the university. Once transferred, the audio

recordings were deleted from both recorders. All interviews were transcribed verbatim by a professional transcribing company registered with the University of Leeds. For the purpose of transcribing, the audio files were uploaded on a secure online server, which were only accessed by the assigned transcriber. All the interviews were transcribed by a single transcriber. Once transcriptions were received, the author listened to the audio recordings to check the transcriptions for accuracy.

5.5.6 Data analysis

A variety of qualitative data analysis methods are available and the selection of an appropriate method is guided by the study objectives. These methods can be broadly divided into three categories (Smith and Firth, 2011): Sociolinguistic methods (discourse and conversation analysis), grounded theory, and thematic analysis.

Thematic analysis *“is a method for identifying, analysing and reporting patterns (themes) within data”* (page 78) (Braun and Clarke, 2006). Thematic analysis is often seen as a ‘tool’ or a process used within other qualitative data analysis techniques rather than a specific method on its own. This is because identifying themes is an integral component of most, if not all, qualitative data analysis techniques such as grounded theory and interpretative phenomenological analysis (IPA). However, Braun and Clarke (2006) have argued that thematic analysis is a definite method in its own right. This author believes that thematic analysis can be used for either of the above mentioned purposes, it can be used as a core component of other qualitative data analysis methods (e.g. grounded theory) and it can be an independent method, depending on the overall research objective. For this study, keeping in mind the research objectives, thematic analysis was used as an independent method.

Unlike IPA and grounded theory analysis, methods which are tied to a specific theoretical stance, thematic analysis offers flexibility as it is not tied to any particular theory and can be applied across different theoretical stances (Sandelowski, 2000). This is what made it the method of choice for the present study, keeping in view the pragmatic approach of the author.

5.5.6.1 Process of data analysis

Although thematic analysis is widely used, there is no consensus on how to undertake a thematic analysis rigorously (Braun and Clarke, 2006). One of the contributing reasons for the said problem is the fact that the process of data analysis is often not described in detail in the published qualitative reports. Braun and Clarke (2006) proposed a six step procedure in an attempt to give structure to thematic analysis and ensuring transparency. The same six steps, detailed below, were followed by the author to undertake thematic analysis. However, it should be noted here, as also highlighted by Braun and Clarke (2006), that these steps are not sequentially fixed and the researcher is allowed to move back and forth as needed.

- Familiarising with data (Phase 1) - Familiarisation with the data is the first and the most important step of conducting thematic analysis. The author familiarised himself with the data through a number of ways: Firstly, the interviews were conducted by the author which gave slight flavour of the data; Secondly, each transcript was checked against the main interview recoding to check the accuracy of the transcription, providing more in-depth information about the data; and finally the author read and re-read interview transcripts before formally beginning the coding of data.

- Coding of data (Phase II) – A code is *“the most basic segment, or element of the raw data or information that can be assessed in a meaningful way regarding the phenomenon”* (page 63) (Boyatzis, 1998). Data were coded manually. Interview transcripts were printed using wide margins, allowing the author to write notes. “Post-it” notes were also used as required. All interview transcripts were coded line by line and segments of the transcripts against each code were highlighted using different color highlighters. The process of coding continued until all the transcripts were coded. A few examples of coding from an interview are shown in Table 6.4. The initial coding framework was checked by two senior qualitative researchers (MB, SJC) for accuracy and completeness by reviewing two coded interview transcripts.

Table 5.2. Example of coding

Data extract	Code
<i>Medication, that was it really, which seemed inadequate most of the time...I didn't feel that it was doing a lot of good at the time but in retrospect and also now I wouldn't like to be without it....."</i>	Helpfulness of medication
<i>"I had undergone various physiotherapies to try and get rid of it none of which worked, it was still there, and has been."</i>	Usefulness of physiotherapy
<i>Well our marriage has more or less broken and I think that's a lot of it is to do with me becoming less and less able to cope with life in general"</i>	Inability to cope
<i>"I can'tI 'm in enough pain not to be able to tolerate people who are telling me its not real, you know, because it is real"</i>	Frustration on disbelieving
<i>"Up to now, although the pain is still there, they have taken steps to help the emotional side, which that's, you know sort of getting out and meeting people. And [the nurse] picked on that very quickly, very, very quickly..."</i>	Emotional support at the pain clinic
<i>"I have more ideas about what I can do to try and control it. So I do feel a little bit more positive because I don't have to just sit and be in pain....."</i>	Self-management

- Searching for themes; Reviewing themes; Defining and naming themes (Phase III, IV, V)

Although Braun and Clarke (2006), have described these as individual phases, in practice, these phases are interlinked and not independent, especially the later two. Since these phases ran concurrently, for clarity and easy comprehension, the phases have been merged into a single phase in the following explanation.

The process began with the searching for themes. Once all the interviews were coded, a list of all the codes was generated. The author read through the list of initial codes and removed any duplication. It should be noted that only duplicated codes were removed but not the data extracts. Following that, different codes were sorted into potential themes. The relevant data extracts were collated within these potential themes. As the new themes emerged, old ones were reviewed and sometimes renamed in the light of emergence of new themes. Mind maps were used for collating codes into themes.

Once the initial set of potential themes was developed, then the process of reviewing and, if required, amending the themes began. Where deemed appropriate, two themes were collapsed to form a single theme and where there was not enough data to support a potential theme, that theme was abandoned. The concepts of internal homogeneity and external heterogeneity proposed by Patton (1990), for judging criteria for categories, guided this process. Internal homogeneity means that the data within each theme should be coherent with each other, while external heterogeneity means that each theme should be clearly different from each other.

This to-and-fro process continued until the set of themes was finalized and named. The research objectives guided the data analysis process. An example of the above mentioned process is shown in Figure 5.3.

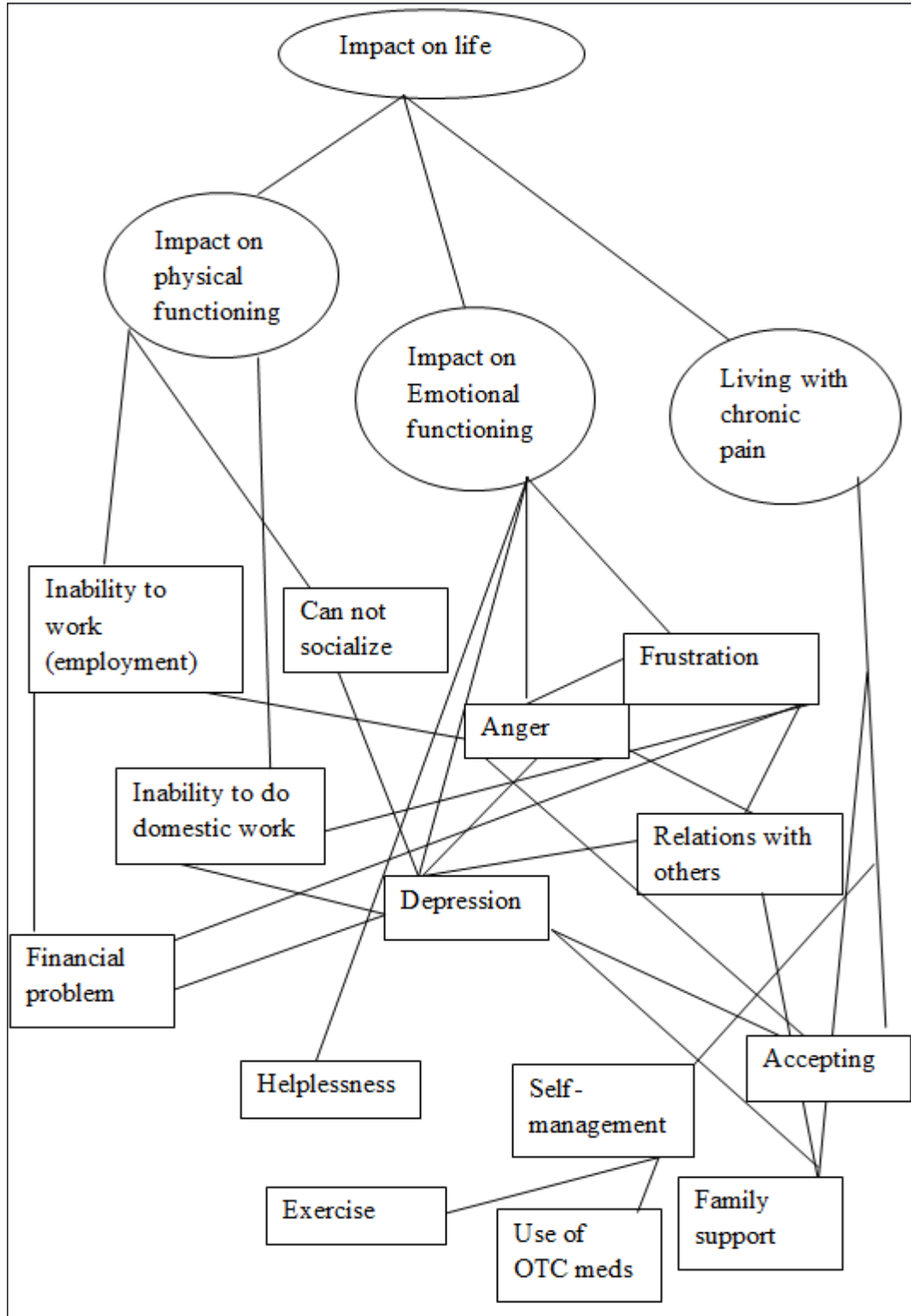


Figure 5.3. Mind map of “impact on life” theme

- Producing a report (Phase VI) - As with other forms of data analysis, the final step was writing qualitative results. The findings are presented in chapter 6 in detail. Data extracts have also been provided to demonstrate the prevalence of themes and sub-themes.

5.5.6.2 Rigour in qualitative data analysis

In the past, qualitative research in general and qualitative data analysis in particular have been criticized for lacking rigor and transparency (Poses and Isen, 1998, Laubschagne, 2003). Like quantitative studies, although in a different context, rigour and validity are of key importance in qualitative studies. The appropriateness of using positivist terminologies such as validity and reliability in qualitative research has been debated among qualitative researchers (LeCompte and Goetz, 1982, Lincoln and Guba, 1985, Lather, 1993, Sandelowski, 1993), some suggesting to abandon their use and use alternatives (Ely et al., 1991). Lincoln and Guba (1985) introduced the concept of trustworthiness in qualitative research and proposed the terms credibility, transferability, dependability and conformability as qualitative equivalents for internal validity, external validity, reliability and objectivity respectively. Whitemore et al. (2001) proposed 29 strategies to ensure 'trustworthiness' in a qualitative study, covering various aspects from study design to final report writing. Creswell and Miller (2000) outlined eight strategies frequently used by qualitative researchers including prolonged engagement, triangulation, peer review or debriefing, negative case analysis, researcher reflexivity, member checking, rich thick description, and external audits. Creswell (2007) suggested that at least two strategies should be used in a qualitative project.

For this qualitative study, peer review/debriefing and providing rich thick description (Lincoln and Guba, 1985) were used to ensure credibility and transferability of the findings. Peer review/debriefing was carried out by the author's supervisors (SJC and MB). From study design to report writing, the author held regular meetings with his supervisors (SJC, MB, DPA) and discussed various aspects of data collection and analysis. A supervision meeting report was produced by the author, after each supervision meeting, detailing the matters arising and decisions made during the meeting. All the reports were electronically signed by the main supervisor and where necessary comments were added.

"Rich thick description" means that a detailed account of the study settings, participants, sampling technique, and data analysis method should be provided to ensure transferability of the findings. A detailed account of all aspects of data collection (sample size, inclusion/exclusion criteria, interview guide, and data analysis) has been made in the earlier sections of this chapter to ensure transparency and enabling reading to establish the transferability of findings to other settings. In addition to these steps, as mentioned earlier, two senior qualitative researchers (MB and SJC) independently reviewed the codes and themes against the transcripts.

CHAPTER 6

RESULTS OF QUANTITATIVE PHASE

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6.1 Introduction

The results of the quasi-experimental phase (quantitative) are presented in this chapter. As mentioned in the previous chapter, both descriptive and inferential statistics have been used to analyse the data. Figures and tables have been used and embedded in the text to facilitate reading and comprehension.

The chapter begins with the description of sociodemographic and clinical characteristics of participants included in the study. Following that, comparison of all outcome measures at baseline, discharge and 3-month follow-up are presented. Then, the recommendations, both medicine-related and non-pharmacological, made to the patients and GPs are described. The chapter concludes with the summary of key findings. Where findings are statistically significant P-values are presented in bold text. In addition to reporting measures of central tendency and spread of data for the outcome variables, where appropriate, clinically important differences have also been reported, in line with the recommendations of the IMMPACT group (Dworkin et al., 2008).

6.2 Sociodemographic characteristics of the patients

As per the calculated sample size, seventy nine patients were enrolled in the study. After completing baseline assessment, one patient withdrew from the study for personal reasons before discharge. The mean age of the patients was 46.5 years SD \pm 14.5 (range 22-86). Almost half of the patients were between 36 to 50 years of age (Figure 6.1). Approximately two thirds of the patients were female (67.1%) and more than half of the participants were married or living with partner. About a quarter of the patients were working in the private sector (24.1%) and slightly more than a quarter (25.3%) was unemployed due to pain. Sixty-seven (84.6%) patients were white (British) while six (7.6%) were Asian/Asian British. Twenty-nine (36.7%) patients were educated up to secondary school level. Almost half of the patients, 48.1% and 44.3%, did not disclose their alcohol and smoking status respectively. Details of sociodemographic characteristics of patients are presented in Table 6.1

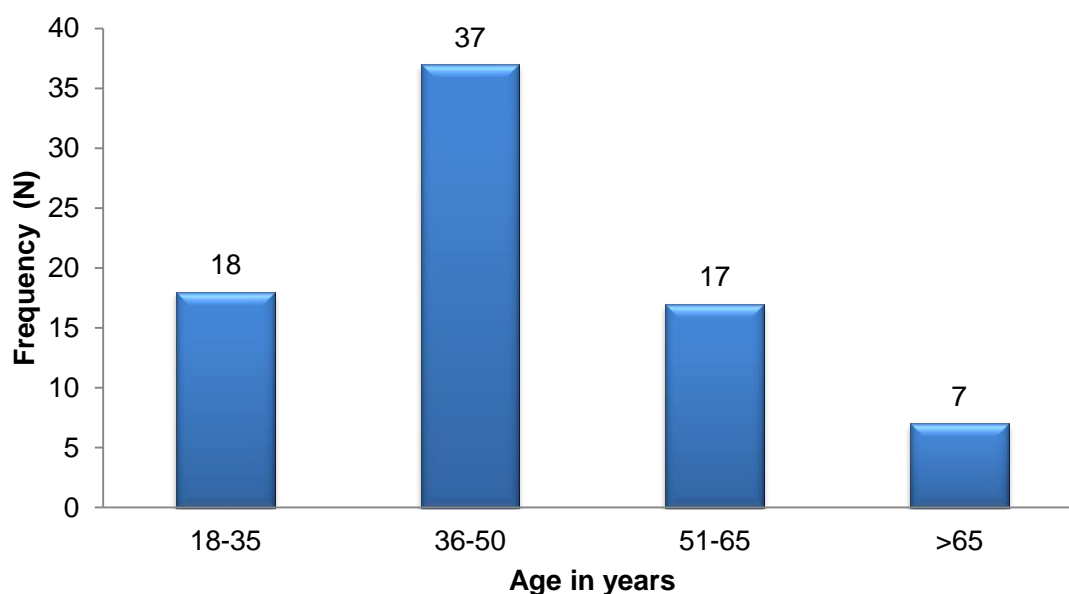


Figure 6.1. Stratification of patients in various age groups

Table 6.1. Sociodemographics of patients

Characteristic	N (%)
Age	
<i>(Mean: 46.49 ; SD:14.5) Range (22-86)</i>	
18-35	18 (22.8)
36-50	37 (46.8)
51-65	17 (21.5)
>65	7 (8.9)
Gender	
Male	26 (32.9)
Female	53 (67.1)
Marital Status	
Single	24 (30.4)
Married/living with partner	45 (57.0)
Divorced/separated	6 (7.6)
Widowed	3 (3.8)
Undisclosed	1 (1.3)
Living arrangement	
Alone	21 (26.6)
With partner/children	58 (73.4)
Employment status	
Public	3 (3.8)
Private	19 (24.1)
Self-employed	3 (3.8)
Retired	14 (17.7)
Unemployed (pain)	20 (25.3)
Unemployed (other reason)	14 (17.7)
Student	2 (2.5)
Undisclosed	4 (5.1)
Ethnicity	
White	67 (84.8)
White others	3 (3.8)
Asian/Asian British	6 (7.6)
Arab	2 (2.5)
Undisclosed	1 (1.3)

<i>Education level</i>	
Undisclosed	10 (12.7)
GCSE/O-Level	29 (36.7)
A-level/NVQ	19 (24.1)
Diploma	5 (6.3)
Degree	10 (12.7)
Postgraduate	6 (7.6)
<i>Alcohol status</i>	
Yes	16 (20.3)
No	25 (31.6)
Unknown	38 (48.1)
<i>Smoking Status</i>	
Yes	17 (21.5)
No	27 (34.2)
Unknown	35 (44.3)

6.2 History of chronic pain and other medical problems

More than a quarter of the patients (26.6%) reported suffering from chronic pain for one to three years while nine (11.4%) patients had chronic pain for more than 10 years (Figure 6.2). Low back (68.4%) followed by lower limb (58.2%) were the most commonly reported pain sites by the patients (Figure 6.3). It should be noted that patients were allowed to choose more than one pain site. The number of pre-existing co-morbidities ranged from zero to four among patients. Almost half, 34 (43.0%) of the patients, had no other pre-existing co-morbidity while 19 (24.1%) had at least one comorbidity. Among the patients with pre-existing comorbidities, sixteen (20.3%) patients had asthma while nine (11.4%) had Diabetes Mellitus (DM). The majority of patients 56 (70.9%) reported to have never been referred to a pain clinic/ pain consultant in the past. In terms of source of referral to the pain clinic, as per the referral guidelines, all patients were referred by their GPs. However, for 12 patients (15.2%) a hospital

physician/consultant requested referral and nine (11.4%) of the patients were referred on the request of physiotherapists (Figure 6.4). Thirty-five (44.3%) patients had their first consultation with both the nurse and the pharmacist while 44 (55.7%) patients had their first consultation with the nurse only.

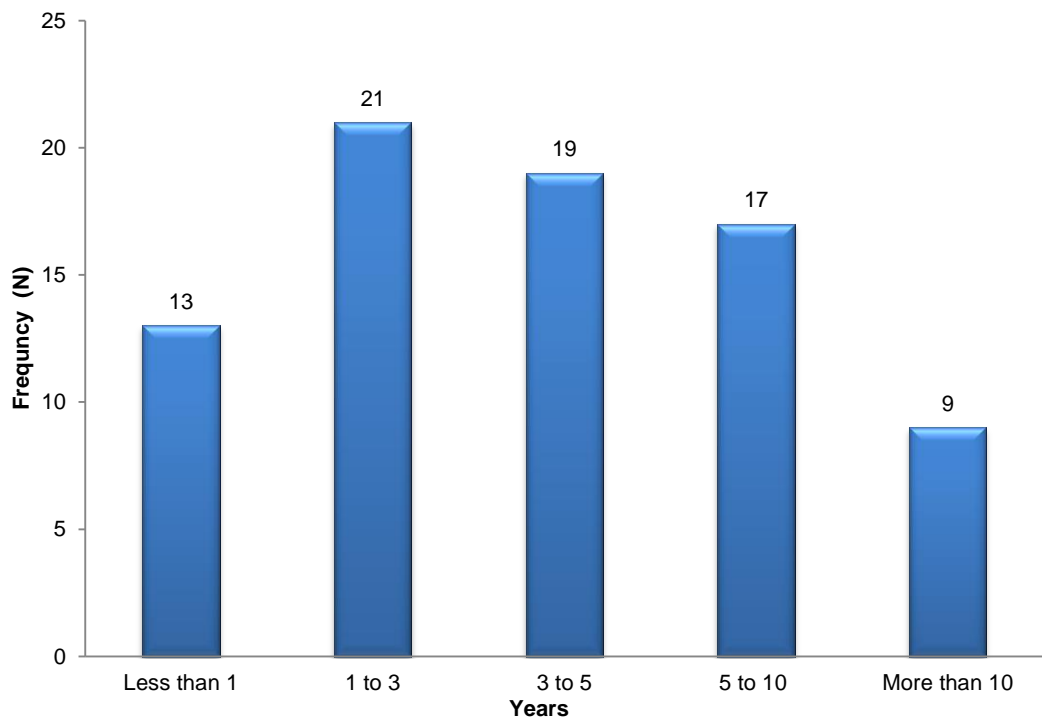


Figure 6.2. Stratification of patients based on pain duration in years

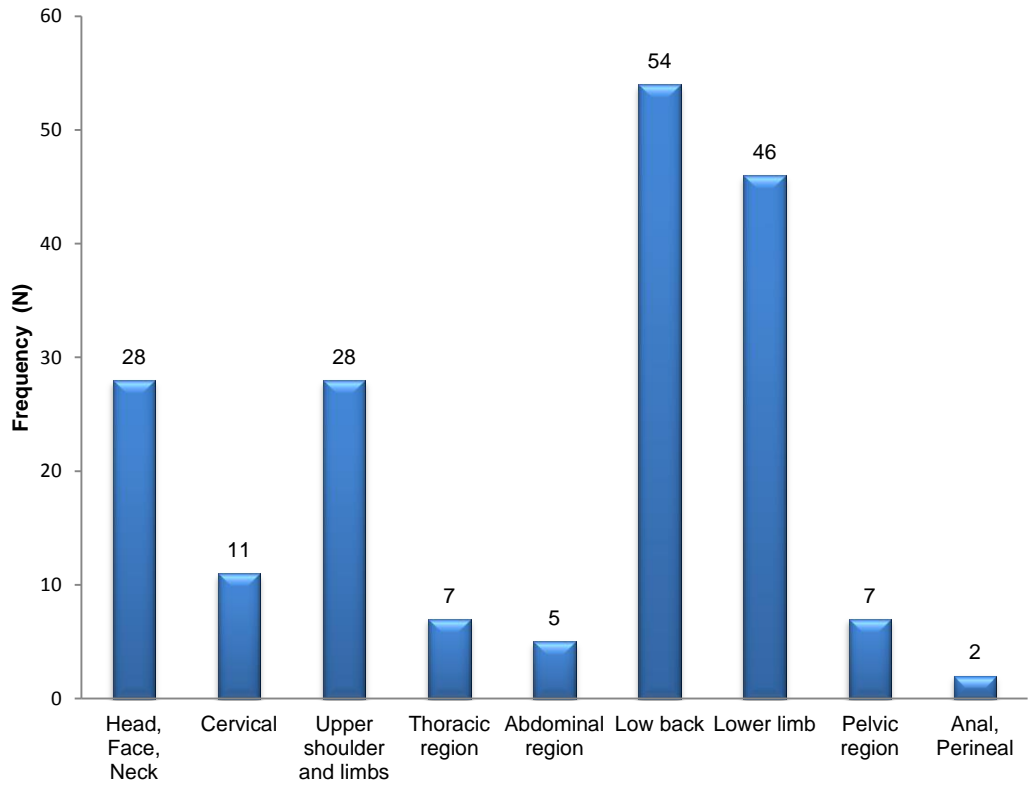


Figure 6.3. Chronic pain sites in patients referred to the pain clinic

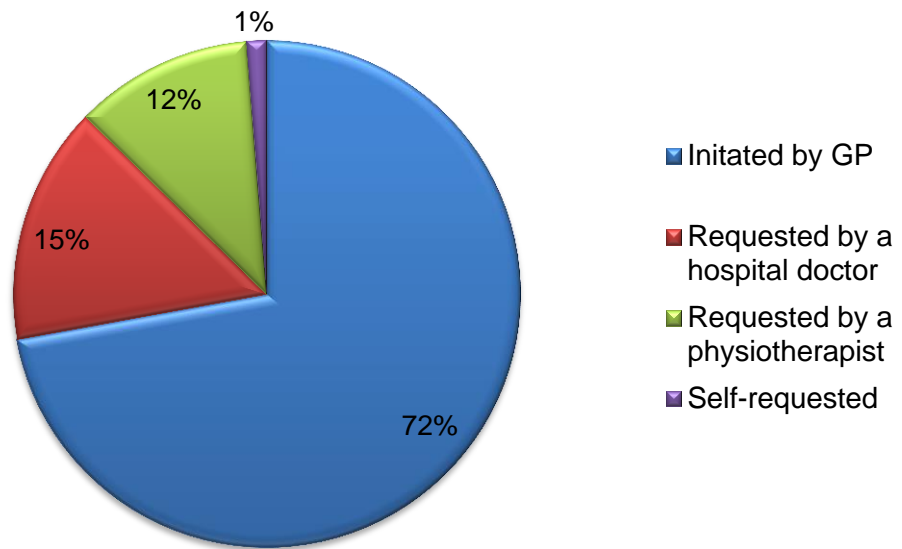


Figure 6.4. Source of referral to the pain clinic

Table 6.2. Pain and other medical history of patients

Item	N (%)
<i>Pain Duration (Years)</i>	
< 1 year	13 (16.5)
1 to 3	21(26.6)
3-5	19 (24.1)
5-10	17 (21.5)
>10	9 (11.4)
<i>Comorbidity</i>	
Diabetes Mellitus	9 (11.4)
Hypertension	8 (10.4)
Asthma	16 (20.3)
Hypothyroidism	6 (7.6)
Ischemic Heart Disease	6 (7.6)
Others	30 (38.0)
<i>Number of comorbidities</i>	
None	34 (43.0)
1	19 (24.1)
2	15 (19.0)
3	10 (12.7)
4	1(1.3)
<i>Past visit of pain clinic/consultant</i>	
No	56 (70.9)
Yes	23 (29.1)
<i>Route of referral</i>	
GP	57 (72.2)
Hospital Doctor	12 (15.2)
Physiotherapist	9 (11.4)
Self	1 (1.3)
<i>Healthcare professional seen</i>	
Nurse only	44 (55.7)
Nurse and pharmacist	35 (44.3)

6.3 Outcome measures

6.3.1 Pain intensity

As mentioned in the methods chapter, pain intensity was measured using an 11-point NRS, administered as part of the BPI. Patients were asked to rank the worst pain, least pain and average pain that they had experienced in the past 24 hours. Patients were also asked to rank “pain right now” as well using the same 11-point NRS.

For baseline, pain intensity scores were available for all 79 patients. However, at discharge pain scores were available for 35 patients only. Since pain intensity data were not normally distributed therefore the data are expressed as medians with respective interquartile ranges (IQR). At baseline, the median values (IQR) of worst pain, least pain, average pain, and pain right now were 8 (7; 9), 5 (3;7), 7 (5; 8), and 7(5; 8) respectively. Upon discharge, there was a statistically significant reduction for worst pain ($P = 0.02$) and average pain ($P = 0.02$). However, for least pain and pain right now the reduction in pain intensity score was not statistically significant ($P = 0.12$) and $P=0.06$ respectively (Table 6.3).

To improve clinical interpretation of the results, patients were classified into groups based on the recommendations of the IMMPACT group on benchmarks for interpreting clinically important changes (Dworkin et al., 2008). As per the recommendations of the IMMPACT group, a 10-20% decrease in pain intensity was considered minimally important, $\geq 30\%$ decrease was considered moderately important and a reduction of $\geq 50\%$ was considered substantially important (Dworkin et al., 2008). Additionally, patients achieving a reduction in “average pain” intensity score of less than 10% were grouped under

“no meaningful change” and patients for whom “average pain” intensity scores were more than the baseline scores were grouped under “deterioration in pain score”. Thirteen (37.1%) patients achieved a minimum clinically important difference while two (5.7%) each achieved moderately and substantially important differences (Figure 6.5). For 3-month follow-up, pain intensity scores were available for 9 patients only. The median (IQR) values for worst pain, least pain, average pain, and pain right now were 7 (5.50;8), 4 (3;6), 5 (4;6.5), 5 (2;7). The results of 3-month follow-up were not statistically compared with the baseline as the number of patients for 3-month follow-up was too small to make any meaningful comparison.

Table 6.3. Comparison of pain intensity scores at the baseline and discharge

	N	N*	Median (IQR)	Z	**P value
Worst Pain					
Baseline	79	35	8.00 (7.00;9.00)	- 2.41	0.02
Discharge	35		7.50 (5.00; 8.00)		
Least Pain					
Baseline	79	35	5.00 (3.00; 7.00)	-1.56	0.12
Discharge	35		4.00 (2.00; 6.00)		
Average pain					
Baseline	79	35	7.00 (5.00; 8.00)	-2.32	0.02
Discharge	35		6.00 (4.00;7.00)		
Pain right now					
Baseline	79	35	7.00 (5.00; 8.00)	-1.82	0.06
Discharge	35		6.00 (2.00; 7.00)		

* Number of patients for whom pain scores were available both at the baseline and discharge. **Calculated from Wilcoxon-Signed rank test.

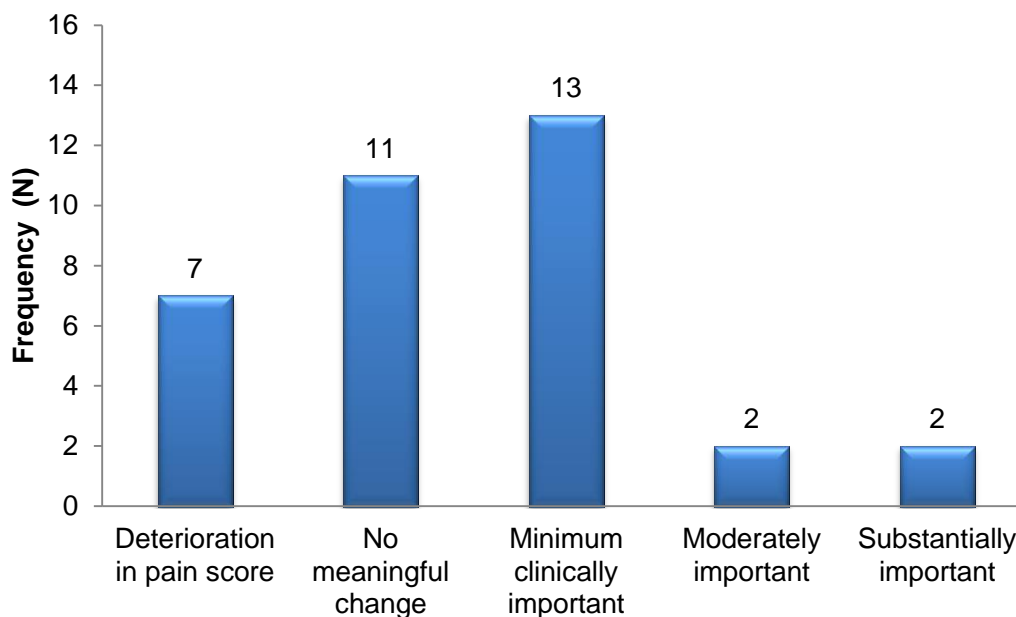


Figure 6.5. Stratification of patients based on clinically important changes in average pain intensity

6.3.2 Physical functioning

Physical functioning was assessed using the seven interference items of the Brief Pain Inventory (BPI). These included: general activity, mood, walking ability, normal work, relationship with other people, sleep and over all enjoyment of life. In addition, an overall interference score was also calculated based on the method described earlier in chapter 5 (section 5.3.4.3). Baseline scores across each domain were calculated for all 79 patients. Discharge results were available for 35 patients except for sleep, enjoyment of life and over all interference, which were available for 36 patients.

There were significant reductions in two pain interference domains, sleep ($P = 0.04$) and enjoyment of life ($P = 0.01$) upon discharge. Overall interference of pain with physical activity was also significantly reduced ($P = 0.02$). There

was also a trend of reduced interference in the remaining five domains but this did not reach statistical significance (Table 6.4).

BPI scores were available for only nine patients for the 3-month follow-up. Statistical analyses were not performed as the numbers were too small to make any meaningful comparison between the baseline and 3-month follow-up results.

Like pain intensity, patients were classified into groups as per the recommendations of IMMPACT group on benchmarks for interpreting clinically important changes for physical functioning (Dworkin et al., 2008). A reduction of one point in the overall interference of pain is considered minimum clinically important. But unlike pain intensity, criteria for defining a moderate and substantial change have not been described by the IMMPACT group (Dworkin et al., 2008). Patients not meeting criteria for the minimum clinically important difference were either classified into “no clinically important reduction” if there was a reduction in the overall interference score upon discharge, or into “deterioration of physical activity” if the overall interference score was higher at the discharge compared to the baseline (Figure 6.6). Fourteen (40%) patients achieved minimum clinically important difference.

Table 6.4. Comparison of pain interference with physical functioning at baseline and discharge

Item	N	N*	Median (IQR)	Z	**P
General Activity					
Baseline	79	35	7.00 (6.00;9.00)	-1.58	0.11
Discharge	35		7.00 (3.00; 9.00)		
Mood					
Baseline	79	35	7.00 (5.00;9.00)	-1.25	0.21
Discharge	35		5.00 (2.00; 8.00)		
Walking ability					
Baseline	79	35	8.00 (4.00;10.00)	-1.43	0.15
Discharge	35		7.00 (3.00;10.00)		
Normal work					
Baseline	79	35	8.00 (5.00;10.00)	-1.93	0.05
Discharge	35		7.00 (4.00;9.00)		
Relationship with other people					
Baseline	79	35	6.00 (2.00;8.00)	-0.21	0.84
Discharge	35		5.00 (1.00;8.00)		
Sleep					
Baseline	79	35	8.00 (6.00;10.00)	-1.98	0.04
Discharge	36		7.00 (4.00;10.00)		
Enjoyment of Life					
Baseline	79	35	7.00 (5.00;9.00)	-2.60	0.01
Discharge	36		6.00 (2.00;9.00)		
Over all Interference					
Baseline	79	35	7.14 (5.71;8.28)	-2.31	0.02
Discharge	36		6.14 (4.00; 8.71)		

*Number of patients for whom both baseline and discharge scores were available. ** Calculated from Wilcoxon-Signed rank test.

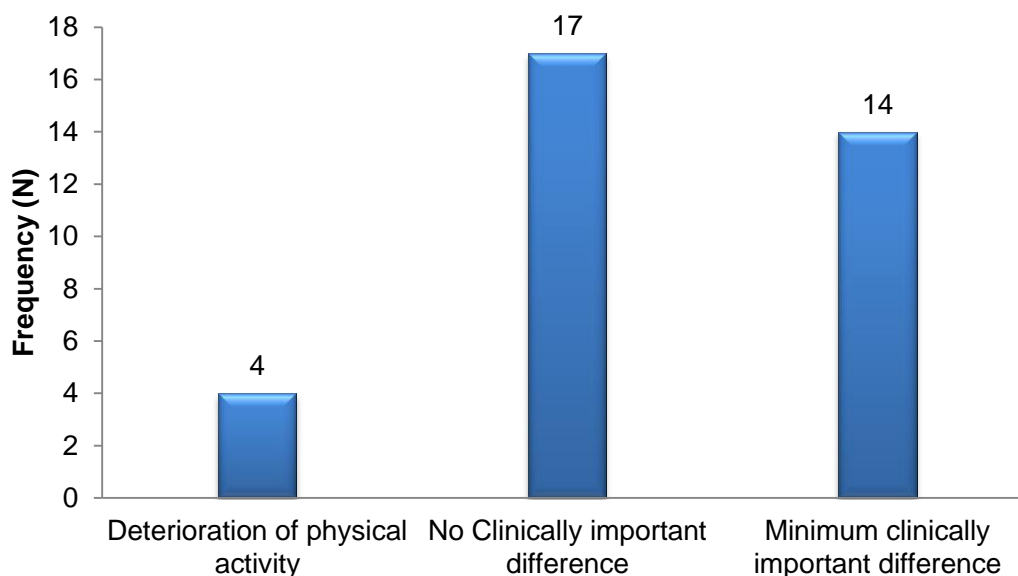


Figure 6.6. Stratification of patients based on clinically important changes in overall pain interference with daily activities

6.3.3 Anxiety and Depression

Anxiety and depression were assessed by using the respective subscales of the Hospital Anxiety and Depression Scale (HADS). Both HADS-A and HADS-D were divided into four ranges: normal (0-7); mild (8-10); moderate (11-15); and severe (16-21). The median HADS-A score at baseline was 10 (7; 14), calculated for 76 patients (missing data for 3 patients). Almost two-thirds of the patients (67.1%) had HADS-A scores more than 7, i.e. were likely to have an anxiety disorder. Twenty-four (31.6%) patients had moderate anxiety (Table 6.5). The median HADS-A score upon discharge was 8.5 (5.75; 12.25), calculated for 34 patients. However, the reduction in the median HADS-A score was not statistically significant ($P = 0.21$). However, for 13 (38.2%) patients there was a reduction in the severity of anxiety by at least one category (e.g. moderate to mild or severe to moderate etc.).

Table 6.5. Categorisation of patients based on HADS-A scores at the baseline and discharge

HADS-A	Baseline	Discharge	Change in category	N (%)
	N (%)	N (%)		N = 34
	N = 76	N = 34		
Normal	25 (32.9)	14 (41.2)	≤ -1	13 (38.2)
Mild	14 (18.4)	10 (29.4)	0	13 (38.2)
Moderate	24 (31.6)	7 (20.6)	≥ 1	8 (23.5)
Severe	13 (17.1)	3 (8.8)		

The depression scores (HADS-D) at baseline were calculated for 76 patients with a median score of 10.00 (5.00; 13.00). The majority of the patients (46 [60.5%]) had HADS-D scores more than 7, likely to suffer from depression. Twenty-seven (35.5%) patients had moderate depression and eight (10.5%) had severe depression (Table 6.6). The HADS-D scores upon discharge were available for 34 patients with a median score of 8.00 (3.75; 12.25). Like anxiety, the reduction in the HADS-D score was not statistically significant ($P = 0.22$). However, a reduction in severity of depression by at least one category was noticed in 7 (20.6%) patients (Table 6.6).

For the 3-month follow-up HADS-A and HADS-D scores were available for nine patients. Of these nine patients, the majority of them ($n=6$) had their HADS-A scores less than 7, likely not to suffer from any anxiety disorder. The remaining three patients had mild ($n=1$), moderate ($n=1$) and severe ($n=1$) anxiety. Compared to the baseline, at the 3-month follow-up, there was reduction in the severity of anxiety by at least one category for three patients (33.3%). While, no change (improvement or worsening) was found for five

patients (55.6%) and increase in the severity of anxiety by at least one category was found in one patient (11.11%).

Similar to the HADS-A score, six patients had their HADS-D scores less than 7, likely not to suffer from any depression disorder. One each had mild, moderate and severe depression. Compared to the baseline, there was reduction in the severity of depression by at least one category for two patients (22.2%); no change in severity class for five patients (55.6%); and increase in severity by at least one category for 2 patients (22.2%) at the 3-month follow-up.

Table 6.6. Categorisation of patients based on HADS-D scores at the baseline and discharge

HADS-D	Baseline	Discharge	Change in	N (%)
	N = 76	N = 34	category	N = 34
	N (%)	N (%)		
Normal	30 (39.5)	16 (47.1)	≤ -1	7 (20.6)
Mild	11(14.4)	5 (14.7)	0	21 (61.8)
Moderate	27 (35.5)	10 (29.4)	≥ 1	6 (17.6)
Severe	8 (10.5)	3 (8.8)		

6.3.4 Chronic pain grade

As mentioned in the previous chapter, the CPG questionnaire was scored using the method suggested by Von Korff et. al. (1992). Patients were classified into one of the four hierarchical categories according to pain severity:

- Grade I, low disability-low intensity.
- Grade II, low disability-high intensity.
- Grade III, high disability-moderately limiting.
- Grade IV high disability-severely limiting.

At baseline, CPG scores were calculated for 76 patients. The median for pain intensity score was 76.66 (66.67; 83.33) and the median for disability score was 70 (60.00; 90.00) at baseline. Compared to the baseline, there was a statistically significant reduction in pain intensity (Median 73.33; IQR 55.00; 83.33) at discharge ($P = 0.02$). However, no statistically significant improvement in disability score was found ($P = 0.89$) at the discharge (Median 73.33; IQR 51.66; 91.67).

At the baseline, a majority of the patients (50 [65.8%]) were categorised in grade IV. CPG scores at discharge were available for 34 patients. In terms of change in chronic pain grade, 7 (20.6%) patients reported improvement in chronic pain grade by at least one grade. However, the majority of the patients, 21 (61.7%) did not report any improvement (Table 6.7).

Table 6.7 Comparison of chronic pain grade at the baseline and discharge

Chronic Pain Grade	Baseline N (%) N=76	Discharge N (%) N=34	Change in Grade (Outcome)	N (%) N=34
I	2 (2.6)	4 (11.8)	≤ - 1	7 (20.6)
II	13 (17.1)	2 (5.9)	0	21 (61.7)
III	11 (14.5)	7 (20.6)	≥ 1	6 (17.6)
IV	50 (65.8)	21 (61.8)		

6.3.5 Quality of life

As discussed in the methods chapter (section 5.3.4.5), quality of life was assessed using SF-36. It should be noted here that higher scores represent a better quality of life. Both the individual domain scores and summary scores (Physical and Mental) have been presented in Table 6.8. The comparison of QoL scores between baseline and discharge is shown in Figure 6.7. For individual domain scores, compared to the baseline score statistically significant improvements were found in physical role (RP) (P= 0.01), bodily pain (BP) (P=0.01) and social functioning (SF) (P=0.03) at discharge. However, there were no statistically significant differences in physical component summary (PCS) scores (P=0.15) and mental component summary (MCS) scores (P=0.08).

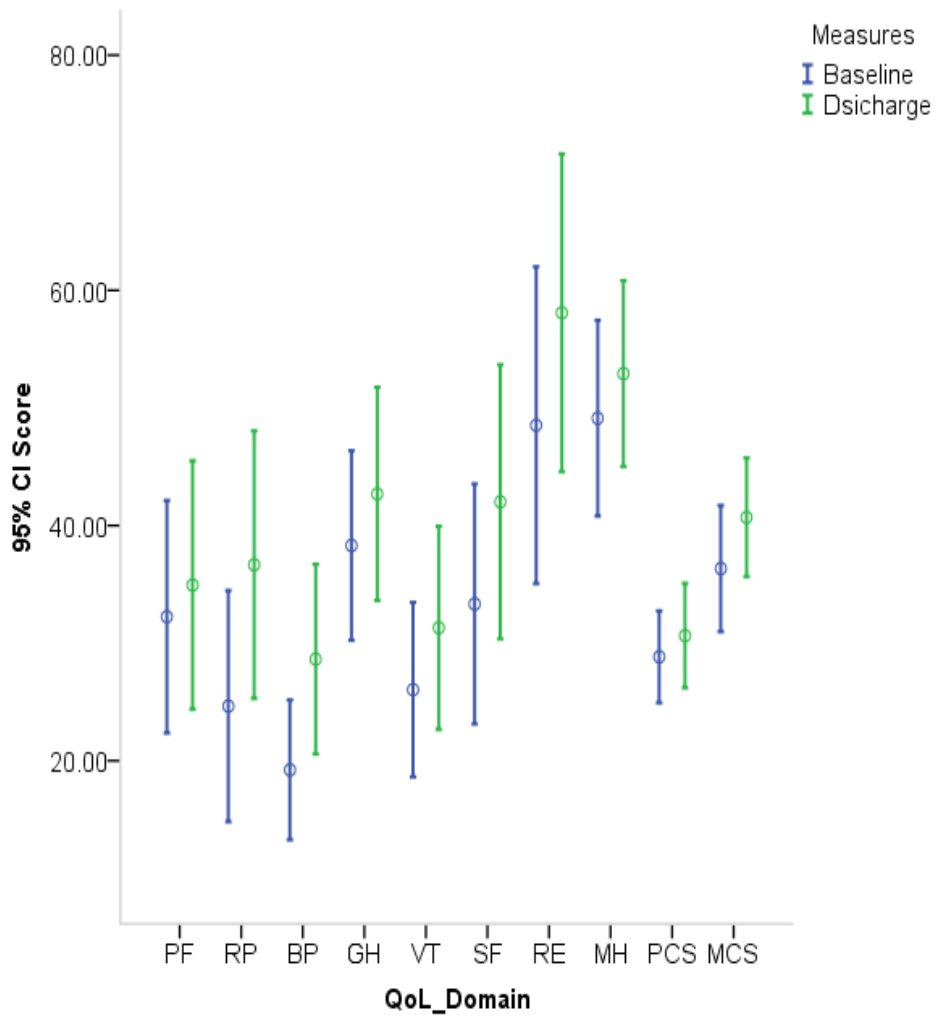


Figure 6.8. Comparison of QoL at the baseline and discharge.

PF=Physical Functioning; RP= Physical Role; BP=Bodily Pain; GH=General health; VT=Vitality; SF=Social Functioning; RE=Emotional Role; MH=Mental Health; PCS= Physical Component Summary; MCS=Mental Component Summary

Table 6.8. Comparison of quality of life at baseline and discharge

Domain	N	N*	Mean (SD)	T	**P
PF					
Baseline	78	36	28.84 (11.03)	1.11	0.27
Discharge	36		30.82 (12.92)		
RP					
Baseline	78	35	24.64 (28.63)	2.89	0.01
Discharge	36		36.66 (33.12)		
BP					
Baseline	78	36	14.22 (17.56)	3.28	0.01
Discharge	36		28.63 (23.84)		
GH					
Baseline	77	35	38.97 (23.83)	1.26	0.21
Discharge	35		42.68 (26.41)		
VT					
Baseline	79	36	26.04 (21.93)	1.73	0.09
Discharge	36		31.30 (25.57)		
SF					
Baseline	78	36	33.33 (30.17)	2.16	0.03
Discharge	36		42.01 (34.47)		
RE					
Baseline	77	34	Median 50.00	Z= -	***0.098
			IQR (20.83;83.33)	1.654	
Discharge	36		Median 54.16		
			IQR (25.00; 100.00)		

MH					
Baseline	79	36	49.13 (24.63)	0.98	0.33
Discharge	36		52.91 (23.34)		
PCS					
Baseline	74	33	28.84 (11.03)	1.49	0.15
Discharge	35		30.82 (12.92)		
MCS					
Baseline	74	33	36.34 (15.17)	1.83	0.08
Discharge	35		41.20 (14.63)		

*Based on the number of patients for whom both scores were available.

Calculated from paired t-test.*Calculated from Wilcoxon signed rank test.

PF=Physical Functioning; RP=Role-Physical; BP=Bodily Pain; GH=General health; VT=Vitality; SF=Social Functioning; RE=Emotional Role; MH=Mental Health; PCS= Physical Component Summary; MCS=Mental Component Summary

6.4 Nature of intervention

Data on the nature of the intervention were available for 35 patients. The mean number of visits made by each patient to the pain clinic was 3.05 (S.D.=0.97) (Range 2 to 6). Fourteen (40%) of the patients were discharged after 3 visits (Table 6.9). Recommendations were made to the GP for 34 (97.1%) patients. In total, 101 medicine-related recommendations were made to the GP with a mean of 2.9 (range 1 to 6) recommendations per patient. For most of the patients [22 (62.8%)] 3 to 5 medicine-related recommendations were made to their GPs. In addition, 34 non-pharmacological recommendations were made in total with a mean of 1.3 (range 1 to 3) per patient. The different types of medicine-related interventions made at the clinic are shown in Figure 6.7. Adding a new drug (n = 30) followed by titrating the dose (n = 29) were the most commonly made recommendations. Among non-pharmacological recommendations, pacing activities (n = 18) were the most common. Other non-pharmacological interventions included referrals to: physiotherapy (n = 3); psychological therapy (n = 3); and a local pain support group (n = 6). Six (17.1%) patients were also referred for spinal injection.

Table 6.9. Care process at the pain clinic

Item	N (%)
Number of visits	
2	11 (31.4)
3	14 (40.0)
4	8 (22.9)
5	1 (2.9)
6	1 (2.9)
Recommendation made to the GP	
Yes	34 (97.1)
No	1 (2.9)
Number of pharmacotherapeutic recommendations	
No recommendation	1 (2.9)
Less than 3	9 (25.7)
3-5	22 (62.8)
More than 5	3 (8.5)
Referrals	
Physiotherapy	3 (8.5)
Spinal injection	6 (17.1)
Psychological therapy	3 (8.5)
Support group	6 (17.1)

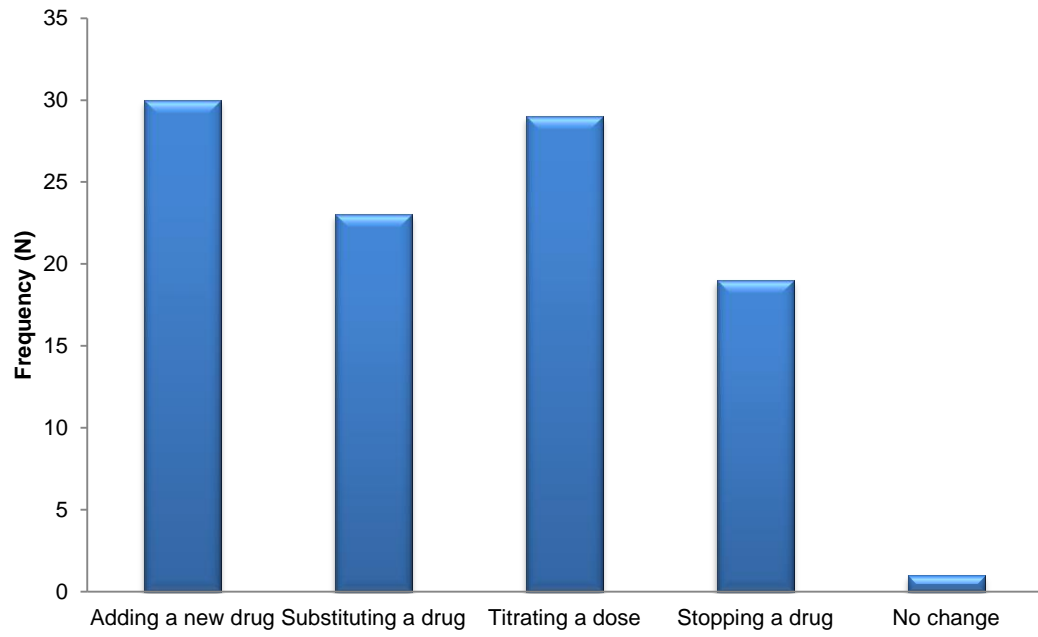


Figure 6.9. Number of pharmacological recommendations made at the pain clinic

6.5 Summary of key findings

- Seventy-nine patients were enrolled in the study. Data collection upon discharge was stopped as the service was decommissioned by the Leeds Primary Care Trust and was available for 36 patients. 30 patients were sent the 3-month follow-up questionnaires, only nine patients returned the questionnaires (BPI and HADS).
- Almost half of the patients were between 36 to 50 years of age (range 22-86). Approximately two thirds of the patients were female.
- Slightly more than a quarter (25.3%) of patients was unemployed due to pain.
- More than half (56.6%) of the patients had chronic pain for more than 3 years and 56 (70.9%) patients had never been referred to a pain clinic/consultant in the past.
- For pain intensity, statistically significant reduction was noted for worst pain ($P = 0.02$) and average pain ($P = 0.02$) but not for ($P = 0.12$) least pain and pain right now ($P=0.06$). Thirteen (37.1%) patients achieved a minimum clinically important difference while two (5.7%) each achieved moderately and substantially important differences.

- For physical functioning, overall interference of pain with physical activity was significantly reduced ($P=0.02$) at the discharge. Fourteen (40%) patients achieved minimum clinically important difference.
- For anxiety and depression, no significant differences were found between baseline and discharge scores for HADS-A and HADS-D. However, a reduction in severity of anxiety and depression by at least one category was noticed in 13 (38.2%) and 7 (20.6%) patients respectively.
- For chronic pain grade, 7 (20.6%) patients reported improvement in chronic pain grade by at least one grade. However, the majority of the patients, 21 (61.7%) did not report any improvement.
- For quality of life (SF-36), among individual domains, there were significant improvements in physical role (RP) ($P=0.01$), bodily pain (BP) ($P=0.01$) and social functioning (SF) ($P=0.03$). However, for summary scores, there were no significant improvements in either physical component summary (PCS) ($P=0.15$) or mental component summary (MCS) ($P=0.08$).
- For 35 patients, 101 medicine-related (2.9 per patient) and 34 non-pharmacological (1.3 per patient) recommendations were made. Adding a new drug and titration of the dose were the most frequently made medicine-related recommendations.

CHAPTER 7

FINDINGS OF THE QUALITATIVE PHASE

CHAPTER 7

FINDINGS OF THE QUALITATIVE PHASE

7.1 Introduction

This is the second of the two results chapters of this thesis. In the previous chapter the results of the quasi-experimental study, quantitative phase, have been presented. In this chapter findings of the descriptive qualitative study are presented. As mentioned earlier, the main objective of the qualitative study was to explore patients' views about their satisfaction with the care received from the pain clinic. In addition, patients' experiences of living with chronic pain and using other chronic pain services were also explored. The rationale and methods for the descriptive qualitative study have been presented earlier in chapters 4 and 5.

The chapter begins with a description of the sociodemographic characteristics of the participants. Following that the key themes and subthemes which emerged from the data analysis are outlined. Anonymized quotes from the participants' interviews have also been provided within each theme and subtheme, a measure to ensure the trustworthiness of the findings. A theme summary is also presented at the end of the each theme.

7.2 Sociodemographic characteristics of participants

In total, 19 participants including eight males and eleven females were interviewed. The age of the participants ranged from 27 to 74 years. Ten interviews were conducted at patients' homes, eight at the pain clinic and one at the patient's office (during lunch break). Interviews lasted between 25 and 45 minutes. The sociodemographic characteristics of the participants are given in Table 7.1.

Table 7.1. Sociodemographic characteristics of participants

ID	Age in Years	Gender	Employment status	Marital status	Chronic pain duratio n in Years	Pain intensity (baseline)
Pt.1	36	Female	Full-time	Married	5-10	5
Pt. 2	49	Male	Full-time	Married	5-10	5
Pt. 3	63	Male	Retired	Married	5-10	5
Pt. 4	30	Male	Full-time	Married	5-10	6
Pt. 5	74	Female	Retired	Undisclosed	< 1	0
Pt. 6	58	Female	Unemployed	Divorced	> 10	7
Pt. 7	39	Male	Unemployed	Single	1- 3	7
Pt. 8	40	Female	Part-time	Married	< 1	7
Pt. 9	51	Male	Part-time	Married	3-5	10
Pt. 10	54	Female	Undisclosed	Divorced	3-5	7
Pt. 11	44	Female	Part-time	Single	1-3	5
Pt. 12	39	Female	Full-time	Married	> 1	8

Pt. 13	54	Male	Unemployed	Widowed	5-10	10
Pt. 14	64	Female	Retired	Married	> 10	5
Pt. 15	55	Male	Full time	Married	3-5	9
Pt. 16	54	Female	Part time	Married	1-3	6
Pt. 17	48	Female	Unemployed	Married	>10	4
Pt. 18	27	Female	Unemployed	Married	1-3	5
Pt. 19	47	Male	Full time	Single	>10	7

7.3 Key themes

Three major themes emerged from the data: impact on life; barriers to effective pain care; and satisfaction with the service provided at the pain clinic. The detailed description of each theme and its sub-themes is presented below.

7.3.1 Impact on life

The patients reflected on the multidimensional negative impact of chronic pain on their lives. From not being able to enjoy a television programme through to the inability to work full-time, chronic pain turned the lives of the patients upside down. The patients were unable to enjoy their lives, as chronic pain interfered with their sleep, mood, and physical functioning. Chronic pain even affected their relationships with their partners and/or children.

“It’s hard to explain to people how you actually feel. It’s like, walk in my shoes for a week and you will see exactly what my life is, you know.” [Pt. 6, 58 years old female]

"I can't kneel down, I can't squat, I can't put my own socks on, he has to put my socks on for me. So that shows how much the pain affects your life." [Pt. 14, 64 years old female]

Major sub-themes in the "impact on life" theme are outlined in Figure 7.1. The detailed description of each sub-theme is given below.

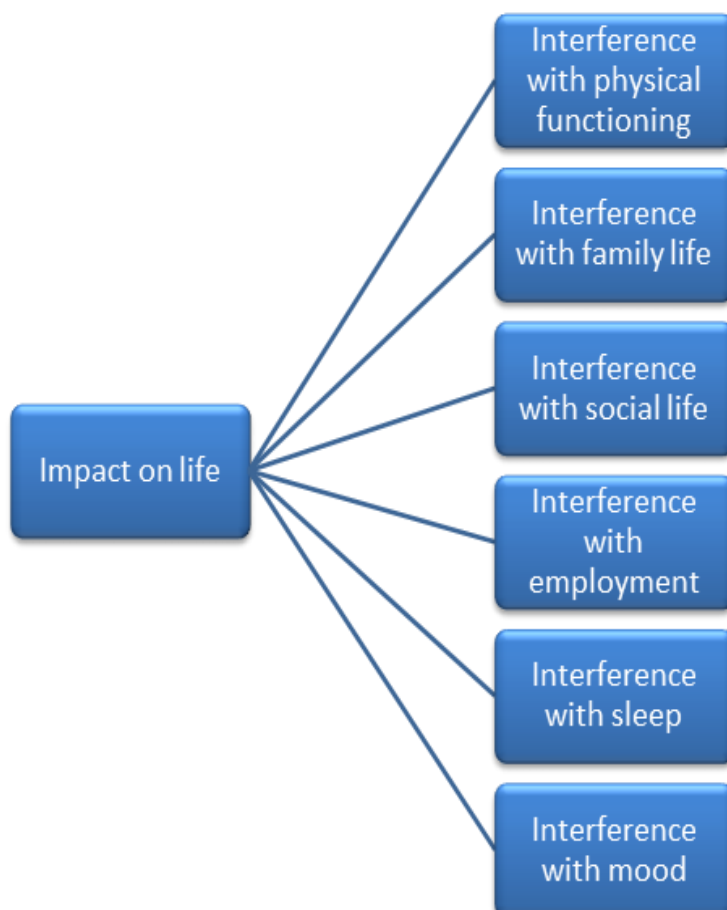


Figure 7.1. Sub-themes within the impact on life theme

7.3.1.1 Interference with physical functioning

The interference of chronic pain with their physical functioning was seen as the root cause of all the other problems in the lives of chronic pain patients. It restricted patients' physical activity to an extent that they struggled to perform simple daily routine tasks like cooking, washing and hoovering.

"I can't do things that I want to do physically, it just restricts me and it's getting worse and worse and worse." [Pt 4, 30 years old male]

"Even things like bending down to the washing machine, maybe I can get down but then I can't get back up again, [laughs] so I've got to physically drag myself up from the thing." [Pt. 8, 40 years old female].

In addition to the increase in pain severity, another factor which contributed to patients' restricted physical activity was their lack of energy. A few patients described chronic pain as an "energy drain"- depriving them of their energy, meaning that they had to adjust their lives accordingly.

"I think it's like a niggling injury or a niggling pain, it's just there all the time and it's just draining, a drain on your life." [Pt. 1, 36 years old female]

"Well basically it was like somebody had taken... zapped me of all my energy for one, and my life had to change because I couldn't do things like I did before." [Pt. 6, 58 years old female]

7.3.1.2 Interference with employment

The majority of the participants also described negative impacts on their professional life. The impact on employment was directly associated with the patients' inability to be physically active. Since chronic pain restricted their physical activity, some patients had to stop working, switch jobs or work only on a part-time basis. Subsequently, the patients had to face financial problems as they were not able to work full-time.

"It's ruined it. It's totally ruined it, you know. I can't work in my job I've done for 22 years, suddenly that's it, it's gone." [Pt. 9, 51 years old male]

“When I started with this back pain and I went off sick that was it. They waited the statutory two years and got rid of me. So that was very difficult.” [Pt 15, 55 years old male]

“I was earning 1,000 pound and now that’s cut our income down by half.” [Pt. 10, 54 years old female]

However, the impact of chronic pain was not significant for all patients and a couple of patients continued to work as before despite suffering from chronic pain.

“I’m the kind of person that regardless of what I’m... if I’m ill or I’m in pain I still work. I’ve been like that all through my life and I think the past 6-7 years I’ve had two days off ill.” [Pt. 4, 30 years old male]

“Well it’s not massively affected me. I mean... I can... I still do anything that I used to do it’s just that I put up with the pain.” [Pt 2, 49 years old male]

7.3.1.3 Interference with family life

A number of the patients described the negative impact on their relationships primarily due to their inability to fulfill their partner’s expectations. The patients felt that they had become a burden on their partners/spouses as they were not able to perform their own daily routine tasks due to the pain.

“Well it puts pressure on it because I can’t stand and iron, I can’t Hoover or anything for too long because then the pain starts coming on. If the pain’s bad we won’t go out anywhere because I just can’t drive. So yes it does affect that, it puts a strain on it.” [Pt. 4, 30 years old male]

“Well, our marriage has more or less broken down and I think that a lot of it is to do with me becoming less and less able to cope with life in

general, which seems a bit harsh but there you go. But yes, it's heart breaking knowing what I used to be able to do." [Pt 10, 54 years old female]

However, patients also recognised the importance of support from family and friends in helping them overcome chronic pain. Family and friends provided patients with both physical and emotional support, enabling them to cope well with their difficulties. Family and friends were seen as giving patients a purpose to continue living and fighting their chronic pain.

"Easily, I would have taken my life a long time ago if it weren't for my children and my husband, I wouldn't be here now, no way." [Pt. 12, 39 years old female]

"If I get pain that bad I end up taking my frustrations out on my son and my daughter, which is wrong, which I shouldn't do, but they're the only people there that I can bounce off. Yes, yes, if it wasn't for my son and my daughter I'd either be locked up or dead, one of the two." [Pt. 13, 54 years old male]

"I've got my husband and he helps, well we work together you know." [Pt. 14, 64 years old female]

Chronic pain did not only negatively affect patients' relationships with their partners but also relationships with their children/grandchildren. Quite a number reflected on their inability to actively engage in activities with their children. The patients were annoyed and displeased because they were not able to play with their children like other parents due to persistent pain.

"I couldn't take my daughter places where I'd do things, you know, like running round the park as other parents do, I couldn't do any of that." [Pt. 15, 55 years old male]

“He’s quite an active little boy so I can find it difficult to kind of keep up with him.” [Pt. 18, 27 years old female]

“There’s nothing wrong with me, you know, it’s not chopped off, it’s not broken it just annoys me because you can’t do stuff with the kids, you know what I mean.” [Pt 7, 39 years old male]

This did not only affected the patients but also their children as they were no longer able to play or go out with their parents.

“They’re suffering as in we don’t go out on weekends anymore. We used to go walking everywhere and now they’re got getting out.” [Pt. 8, 40 years old female]

7.3.1.4 Interference with social life

As with other aspects of life, the social life of the patients suffered as well. The patients had to give up their social lives and became socially isolated either because of the restricted physical activity associated with chronic pain or due to depression resulting from the pain. They became confined to their homes and were not able to go out and enjoy their lives like their peers.

“It’s completely screwed my life up. I can’t go back to work, I can’t work, I can’t go out. I can’t remember the last time I was in a pub, and I’m stuck in four walls, I’m stuck in my house.” [Pt. 13, 54 years old male]

“I just cut back on doing things socially and that changes you as a person really when you’re not sort of like getting the most out of things.” [Pt. 19, 47 years old male]

Patients avoided engagement in social activities when in pain as a coping strategy. This reflects that, perhaps depression associated with chronic pain

may be a key contributing factor towards chronic pain's interference with social activity.

"I am a sociable person but when you're in pain I go quiet and I don't want to be talking because I'm concentrating on getting rid of this pain." [Pt. 6, 58 years old female]

Since the patients were not able to socially engage in activities outside their homes, they lost interest in getting dressed and looking good, another indication of depression being a contributing factor.

"No I don't bother getting dressed, I just think, well I'm not going out so what's the point. It's affected my appearance, I can't be bothered, I can't drink anymore so we haven't been out to the pub for over a year." [Pt. 8, 40 years old female]

Similarly, patients were unable to continue to play sports due to fitness problems, lack of energy and motivation, common consequences of chronic pain.

"I used to play football and I can't play football or golf. I can't play a full round of golf anymore." [Pt 4. 30 years old male]

"I was always very active, I couldn't do the sport that I used to do, I was still only in my early 30s then, I was still playing football then. I had to stop all that." [Pt. 15, 55 years old male]

7.3.1.5 Interference with sleep

Sleep deprivation was also reported by a number of patients. In addition to the problem with falling asleep, repeatedly waking up during the night because of pain was also seen as a major issue which prevented them enjoying a good night's sleep. As a result, the patients were not able to perform their daily activities/work efficiently and felt tired all the time.

"I think the biggest problem for me is sleep deprivation when I wake up in the night I find it very difficult to get back to sleep and I think when you're tired everything is worse, the whole world is worse". [Pt. 1 36 years old female]

"I'm always tired because yes you move about 10-15 times in a night but when you're in pain you wake up and it's hard to get back to sleep." [Pt. 7, 39 years old male]

Patients believed that their poor sleep affected their ability to cope well with chronic pain.

"It keeps you awake; you've no energy to face the day. If you get a good night's sleep it's not so bad, you can cope during the day but during the night when you're kept awake that is bad." [Pt. 14, 64 years old female]

7.3.1.6 Interference with mood

Chronic pain not only affected patients physically but also mentally. A majority of the patients described negative impact of chronic pain on mental functioning. The impact of pain on mood was often very apparent.

"It affected my mood, of course it did, yes it does affect your mood, pain does. You try and ignore it but you can't sometimes." [Pt. 16, 54 years old female]

Two important associations came up during the analysis. Firstly, the patients linked their anger and frustration with their inability to perform daily activities. As described above, the patients were unable to perform routine daily activities as their physical activity was limited by their pain.

"You can't do things that you want to do or if you do them it's painful, it's very frustrating and that can make you very sort of, not anxious but very kind of het up about things and very frustrated." [Pt. 1, 36 years old female]

"I couldn't do things like I did before, like taking the curtains down and putting them up, like moving objects too heavy, so it was very frustrating and I was so annoyed, really angry that I couldn't do these things." [Pt. 6, 58 years old female]

Secondly, patients described a two-way association between pain and depression. Patients felt depressed due to pain and experienced more intense pain when depressed.

"You know, if you're a bit depressed it [pain] seems to be worse than it is." [Pt. 3, 63 years old male]

"It's a bad combination, it's a really, really bad combination. It just... because when you get down you think about your pain more." [Pt. 12, 39 years old female]

Patients experienced low mood because of their pain but recognised the importance of keeping a positive attitude to avoid escalating the negative impact of chronic pain on their mood.

“But I also feel it’s a vicious circle because the more depressed I get or the more down I feel then I believe that my body responds to the emotional thing as well. And I believe that stuff gets worse if you can’t keep a positive attitude.” [Pt. 10, 54 years old female]

Foreseeing little to no chance of improvement in their pain and fearing continuous suffering associated with pain for the rest of their lives also contributed to patients’ low mood.

“...mentally I just thought, I don’t want to live like this, you know. And that’s when you think that it’s never going to go away.” [Pt. 5, 74 years old female]

“When the pain was really bad I’d often kind of feel quite low and feel like it was never going to improve.” [Pt. 18, 27 years old female]

7.3.1.7 Theme summary

Within this theme, the impact of chronic pain on various aspects of patients’ lives was explored. Chronic pain changed patients’ lives to a great extent, with limited physical activity being the root cause of the majority of the other problems. It restricted their physical activity, compromising their ability to work, play with their children, enjoy a good relationship with their spouses, perform routine tasks and enjoy a good night’s sleep. This led to anger, frustration and depression. When depressed, the patients felt more pain and lacked motivation to engage in any physical activity. This became a vicious circle which it was often difficult to break and come out from.

7.3.2 Barriers to effective pain care

In general, the patients had predominantly negative experiences with healthcare professionals, and described dissatisfaction and displeasure with the service that they received in the past from various healthcare professionals especially from the GPs. During the interviews the patients highlighted a number of barriers which affected the quality of care that they received. These barriers have been classified into two categories: healthcare professional-related and healthcare system-related (Figure 7.2).

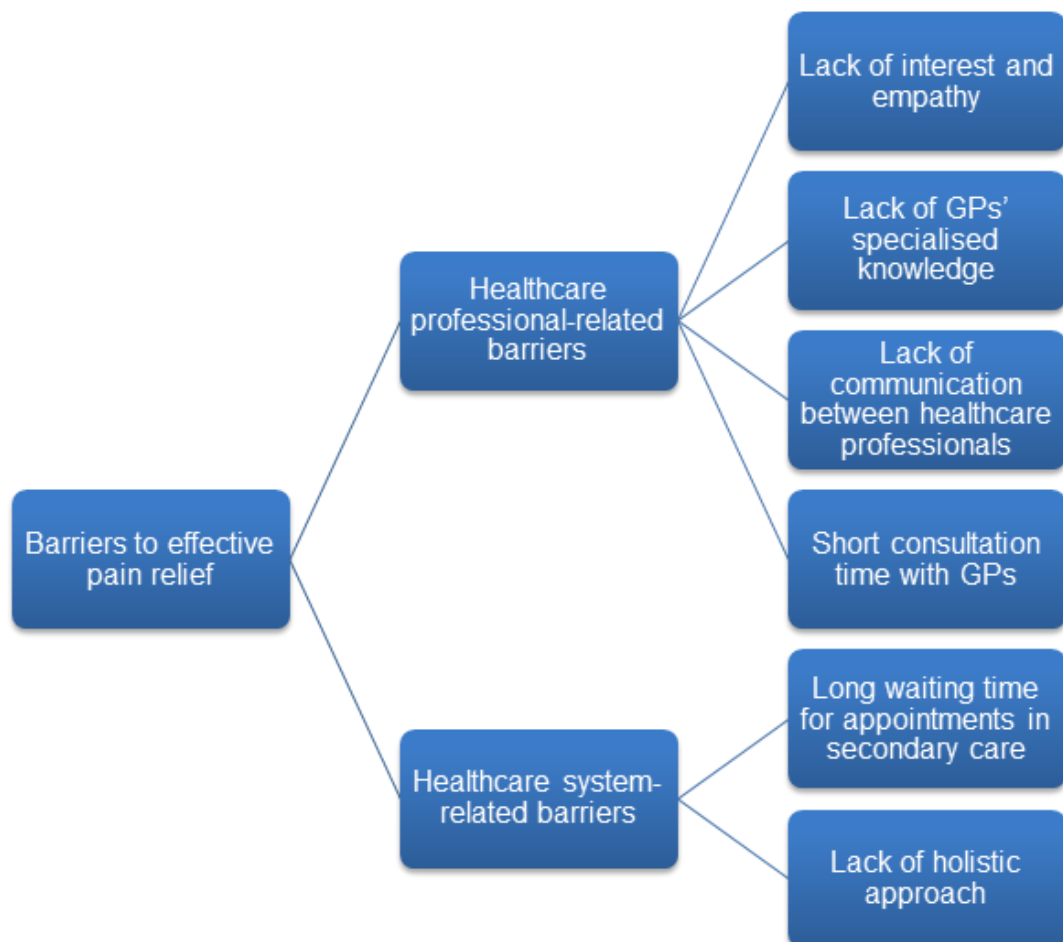


Figure 7.2. Sub-themes within barriers to effective pain care theme

7.3.2.1 Healthcare professional-related barriers

Healthcare professional-related barriers included: lack of interest and empathy; lack of GP's specialised knowledge; short consultation time with GPs; and lack of communication between healthcare professionals. Since chronic pain is predominantly managed in primary care, a number of the barriers in this category were related to the GPs' ability to assess and manage chronic pain. However, some of the issues identified by the patients were not only limited to GPs but also applied other healthcare professionals. These barriers have not been listed in any order of priority.

a. Lack of interest and empathy

A number of patients expressed concerns over the lack of interest shown by healthcare professionals in listening to their problems and managing their pain. The patients felt that, perhaps chronic pain was not a life-threatening disease (like, for example, cancer), healthcare professionals were not interested in identifying the cause of the pain.

"I went to my GP and was just told it's wear and tear, age, nothing we can do about it, left it at that." [Pt. 9, 51 years old male]

The patients were disappointed and felt that they were wasting their time in explaining their problem as no one was interested in listening to their problems.

"I'm not getting anywhere and I thought, oh don't bother saying anything, it's a waste of time, nobody's listening – that's what I'm trying to say." [Pt. 6, 58 years old female]

The patients felt that the GPs did not understand pain well enough to appreciate its negative impact on their daily lives, and this lack of understanding was very frustrating for them (patients).

“They [GPs] don’t understand what the pain is. They just look at you and think, well how you can have pain, you know, they don’t realise what pain is and what it does to you. I mean at times it drives me mad.”
[Pt. 13, 54 years old male]

A few of the patients considered that rheumatologists on the other hand were only interested in listening to their initial problems, but not to their other ongoing problems, which sometimes might have been of more importance to the patients.

“And then from rheumatology they don’t listen to you, they don’t... they listen to the initial problem and then they just do what they want to do and they don’t listen to the ongoing problems from thereon.” [Pt. 4, 30 years old male]

The patients found that physiotherapists were not different from the GPs and rheumatologists in terms of listening and understanding their medical problems. A few were told that there was nothing wrong with them and they were not suffering from chronic pain.

“My last visit to physiotherapy at the hospital rheumatology, she just didn’t want to listen, she didn’t think that there was much wrong with me and pushed me straight out the door effectively.” [Pt. 4, 30 years old male]

A number of the patients felt that they were disbelieved and judged by the healthcare professionals. They were annoyed by these attitudes and this led them to stop seeking any further treatment from that particular healthcare professional.

“The second physiotherapist I saw basically told me that the pain was in my imagination. So I had one appointment with him and he said

that I was imagining it, it wasn't real and I didn't go back because it is real to me. I'm in enough pain not to be able to tolerate people who are telling me it's not real, you know, because it is real. [Pt. 10, 54 years old female]

However, the patients also praised some GPs who listened to them and showed a duty of care towards them.

"... I don't feel as they've just been giving me anything just to get rid of me, no they've been good." [Pt. 16, 54 years old female]

"My GP is superb. He will say, what's wrong with you, like blah-blah-blah, right what do you want me to do." [Pt. 7, 39 years old male]

b. Lack of GPs' specialised knowledge

The main reason, highlighted by the patients, for GPs' inability to effectively manage chronic pain was the lack of specialised knowledge in chronic pain management. Patients expressed concerns over the competency of GPs to effectively deal with and manage chronic pain, and frequently did not find they received much help from them.

"My GP she was absolutely useless and I kept telling her it's not helping, it's not doing me any good, it's not..." [Pt. 12, 39 years old female]

"I'm not saying my GP isn't qualified but he is a general practitioner, he's not a consultant and he's not specified in that area." [Pt. 6, 58 years old female]

Since the GPs had no specialised chronic pain management knowledge, they had to rely on other services (e.g. pain clinics) to get the right information to develop an appropriate management plan.

"I think the issue had been that because there's been a diagnosis of fibromyalgia the doctor really didn't know enough about fibromyalgia so she's relied on this service... To help give her the knowledge.." [Pt.8, 40 years old female]

A few of the patients also felt that this lack of specialised knowledge was used as an excuse by the GPs to refer to the physiotherapist without establishing whether the patients actually needed physiotherapy or not.

"I think the your GP finds it an easy... she doesn't know...he or she doesn't know what the problem is they just not specialised in anything, it's the easy answer to shove you to the physio and let them have a look at you and then see what bounces back out of that. That seems to be the way and a lot of people end up with that, oh I'll send you to physio.." [Pt.4, 30 years old male]

Patients saw GPs as having limited therapeutic options, with their approach towards pain management being confined to prescribing a range of painkillers, irrespective of whether the patients were gaining any benefit or not.

"The GP's have been useless basically. According to them all they could do was give me paracetamol, and the best was co-codamol." [Pt.9, 51 years old male]

"He'll just keep giving me tablets. He doesn't feel there's anywhere else to go as regards trying to find out what it is." [Pt.3, 63 years old male]

c. Short consultation time with GPs

Another problem frequently pointed out by the patients was the short consultation time with the GP. This meant that the GPs could not listen to the patient's full story and therefore could not design an individualised therapeutic plan to meet their needs.

"It's the running of the GPs basically, we're not getting heard, patients aren't getting heard and listened to. There's not enough time [Pt.6, 58 years old female]"

The short consultation time was seen as insufficient, by the patients, to obtain full medical and medication history, perform any physical examination and to develop an appropriate therapeutic plan accordingly. The patients felt that the combination of the lack of sufficient consultation time and GPs' lack of specialised knowledge often hindered the development of individualised therapeutic plans.

"No sadly I don't think the GPs have enough time to look at each individual and to go through their medical history to see if they can tweak it here and there to help that patient. Sadly they haven't" [Pt.6, 58 years old female]"

"The GP...again it goes back down to the amount of time that he has to work with an individual patient. I mean he's working on an average of about 13 minutes with a patient. There's not much he can do, you know, on a really, really personal level. [Pt.10, 54 years old female]"

In some cases, the patients felt that due to the limited consultation time, GPs just prescribed medicines as requested by them without obtaining a full history, putting them at high risk of experiencing an adverse or even life threatening

event. The patients felt that a careful review of medical and medication history was essential as it would enable GPs to recognise an ongoing and/or a potential drug-related problem (DRP), and to take appropriate measures to prevent any negative consequences.

“I went to the doctors and asked if I could have a stronger painkiller.... she just prescribed it, she didn't ask me any questions apart from how long had I had the pain, and she just prescribed me co-codamol.” [Pt. 17, 48 years old female]

“The GP was worried about the high blood pressure but didn't take time to look at the medication she'd actually put me on, whereas the pharmacist pointed it out to her. Potentially according to the pharmacist, for three months, I was at high risk of having a stroke because of the GP.” [Pt. 9, 51 years old male]

d. Lack of communication between healthcare professionals

Since the patients were referred to various specialists, the patients were concerned about the lack of communication between the different healthcare professionals, which led to inconsistency in terms of the approach towards pain management.

“I think you tend to see everybody in isolation so the physio will refer and they will write a little letter and they will refer to a podiatrist. But then the podiatrist kind of sees the problem from such a different light that they're not really communicating with each other, so the podiatrist when I go tends to focus on my ankle because I still limp, rather than my back.....”.[Pt. 1, 36 years old female]

The patients felt that a number of unnecessary referrals were made due to the lack of effective communication between healthcare professionals, and considered that better communication would have ensured referral to the correct healthcare professional, saving both time and money.

“I went to the doctors, it’s nothing. Tennis elbow, then it was arthritis, then it wasn’t arthritis, then it was because of a previous injury. He sent me for an x-ray then referred me to physiotherapists here. I came here, the physiotherapist looked at the x-ray and couldn’t understand why I’d been referred here, he said it’s arthritis, there’s nothing you can do with it and referred me back to the GP.” [Pt. 9, 51 years old male]

In some instances the lack of communication led to clash of opinions between the healthcare professionals and left the patient confused about their diagnosis.

“I was caught up in a bit of a battle between them two because the rheumatologist was saying no it’s not a rheumatology problem and the orthopaedic guy was saying, well we believe it is.” [Pt. 15, 55 years old male]

7.3.2.2 Healthcare system related barriers

In addition to a number of healthcare professional related barriers, described above, a number of healthcare system related barriers were also identified. These barriers included long waiting time for appointments in secondary care and the lack of a holistic approach. In general, the patients were not satisfied with the quality of the care provided by the NHS and were willing to seek treatment from the private sector.

a. Long waiting time for appointments in secondary care

The patients were concerned over the long waiting times not only for appointments with the consultants but also for scans, x-rays and other tests. The long waiting time delayed the whole care process. The patients considered that there were many unnecessary steps in the referral chain, and consequently expressed dissatisfaction with the service that they received from the NHS.

“You’re going round the houses to get back to where you want to be. It takes a long time, it does take a long time. And like even from being referred to having a scan can take time.” [Pt. 3, 63 years old male]

“I felt like I’d just had to jump through hoops really, and they’re just unnecessary steps in the chain.” [Pt. 19, 47 years old male]

“I was brought up to think that the Health Service would provide everything, but it doesn’t, not quickly enough.” [Pt. 5, 74 years old female]

In some instances, patients spent a long time under the care of the GP, without making any significant progress before being referred to the specialist, which also contributed to the overall waiting time.

“I had to wait... I mean my doctor she took ages. I think I had 7 months because she referred me; 7 months I had to wait and she could see that nothing she was giving me was working at all.” [Pt. 12, 39 years old female]

As described above, the patients felt that healthcare professionals, especially GPs, were not interested in listening to and understanding their problems, which in some instances led to referral to the wrong healthcare professionals, causing

delay in receiving correct treatment. Timely referral to the right healthcare professional was viewed as very important for effective pain management.

“My GP sent me to [hospital] and they put it down as sciatica which I said to my GP, it doesn’t start in my spine, I said it starts at the bottom of my hips and it works its way round. They said it’s sciatica. So they sent me back to the [hospital] under the doctor, I can’t remember his name, he was a back specialist. They scanned me and I went back to see him just before Christmas and he said, there’s nothing wrong with your spine. I said well I’ve said that to my GP, I said, what about my hips. He said that’s not my department, it’s a different department. So I went back to my GP and told her what I thought. I said I told you it wasn’t sciatica, I haven’t got sciatica, I said it’s my hips [13]

Another patient had a similar experience.

“I went for an x-ray and, it turned out it was osteoarthritis. He was a rheumatoid arthritis specialist so he shouldn’t have been seeing me, although he’d been seeing me for 18 months. He then referred me on to see another consultant.”[Pt. 9, 51 years old male]

Since the patients were not happy with the long waiting time for the appointments in secondary care, they expressed their desire to go for private treatment, provided that they had the funds to meet the cost.

“.....if I could afford it I’d go private, put it that way.” [Pt. 4, 30 years old male]

Patients who were able to afford it went on to seek care from the private sector and felt that the service provided there was much better than the NHS.

“I find the private sector, you know, service is much better. I do, I’ve found the NHS physio not very... [Pauses], if you are paying for treatment it is better, let’s face it.” [Pt. 11, 44 years old female]

Since the patients, being tax payers, had already paid into the NHS, they expected a good service from it. They were annoyed by the fact that the treatment was in fact better in the private sector and they had to pay again to obtain this good service.

“You wait so long in the Health Service. But I had no alternative really except pay to see somebody, and that really rankles me, I don’t want to do that. Because I’ve paid into it haven’t I, my husband all these years.” [Pt. 5, 74 years old female]

b. Lack of holistic approach

Since chronic pain has a multidimensional impact on patients’ lives, a uni-dimensional approach towards its management based on the bio-medical model may not achieve optimum pain relief. The set-up and the working of chronic pain management services in the NHS was seen as a hindrance in delivering integrated holistic care to patients.

“Within the NHS, every individual is great and they work really hard and they’re really supportive, but they seem to be very caught in their little boxes and can’t or aren’t allowed to step outside them to maybe provide a more effective solution sometimes.” [Pt. 1, 36 years old female]

In addition to the lack of a holistic approach in terms of the working and integration of chronic pain services, there was also a lack of holistic approach in terms of management of chronic pain patients. The specialists tended to focus

on the initial problem only, but not on the ongoing problems. The patients felt that they were not managed as a whole, but that healthcare professionals instead focused on only one of the affected area or joint.

“He was not interested in any other joints, just the left elbow and I wanted them to look at all.” [Pt. 9, 51 years old male]

Patients felt that they were treated impersonally, being thrown from one healthcare professional to another.

“Well certainly NHS, I believe that it does need a big shape up because there’s... the way that they treat you is absolutely disgusting from point to point, there’s no... you’re treated as a number, you’re not treated as a person.” [Pt. 4, 30 years old male]

Since chronic pain interfered with both physical and mental functioning, patients believed that a holistic, interdisciplinary approach was required to effectively manage their pain.

“Well the pain management, my doctor looks after really, and the physio did the exercise part of it and I think both of it together was needed, you know.” [Pt. 5, 74 years old female]

“Especially for people who are dealing with kind of long term and chronic pain because it can kind of cause people, you know, as well as the physical pain it can cause emotional problems and I think it’s important to have a service where kind of all of that can be addressed together.” [Pt. 18, 27 years old female]

The patients stressed the need for a collaborative holistic approach and were frustrated with the current situation feeling that perhaps the NHS was not willing to make necessary reforms in order to improve chronic pain management.

“I don't know whether that's a cost thing, whether arthritis is not a sexy disease like cancer or other things that the NHS want to throw money at.” [Pt. 9, 51 years old male]

The patients believed that structural reforms were needed within the NHS so that it could better serve the needs of chronic pain patient population.

“I find that very frustrating because I think, you know, maybe if the NHS was set up in a slightly different way so that people worked together better, that maybe we could resolve the problem” [Pt.1, 36 years old female]

7.3.2.3 Theme summary

In this theme, various healthcare professional and health system-related barriers, hindering an effective delivery of quality pain management services, were explored. In general, patients expressed their dissatisfaction with the quality of care provided by the NHS. A common perception existed among patients that GPs lacked interest and did not have specialised knowledge in managing chronic pain. The patients also felt that the lack of communication between the healthcare professions led to unnecessary referrals, adding to patients' frustration. This also partly contributed to the long waiting time for appointments in secondary care. Another key issue highlighted by the patients was the lack of interdisciplinary chronic pain services within the NHS. A need to reform chronic pain services within the NHS was also emphasised in order to facilitate the effective delivery of quality services.

7.3.3 Experiences at the nurse-pharmacist managed pain clinic

In general, the patients had good experiences of the services received at the nurse pharmacist managed pain clinic. Expectations of a particular service are major drivers of patient satisfaction and overall experience. Early recognition of these expectations can help healthcare professionals to tailor their approach accordingly. As reported in the previous chapter, patients of different sociodemographic and clinical characteristics were referred to the pain clinic. Therefore, their expectations from the nurse-pharmacist managed pain service varied and were influenced by the duration of their pain, past experiences of other pain services and information from their peers. Their expectations ranged from a probably unrealistic hope of cure from chronic pain to simply knowing what was wrong with them.

“Miracles [laughs]; I was expecting miracles. No, in reality I was hoping to reduce the medications because I’m on such a lot.” [Pt.10, 54 years old female]

“My expectations... well my hopes were to end up painless [laughs].” [Pt. 2, 49 years old male]

“I wanted to find out what was wrong with me.” [Pt.7, 39 years old male]

Some patients had no clue about the service and had no clear expectations from it

“I wasn’t entirely sure what it was about, no one explained that, you know, this was what was going to happen. It was, this is chronic pain services, they’ll talk to you about your pain and that’s it, so I wasn’t sure if it was going to be, I don’t know, some kind of psychiatrist kind of

thing or if it was physiotherapy again or anything to be honest.” [Pt. 4, 30 years old male]

Some of the patients expected a negative attitude from the service, but were surprised to receive a listening and caring attitude from both the nurse and the pharmacist.

“I thought I’d come here and they’d palm me off with something, you know, go for physiotherapy, like the GPs.” [Pt. 9, 51 years old male]

The sub-themes identified are outlined below in Figure 7.3.

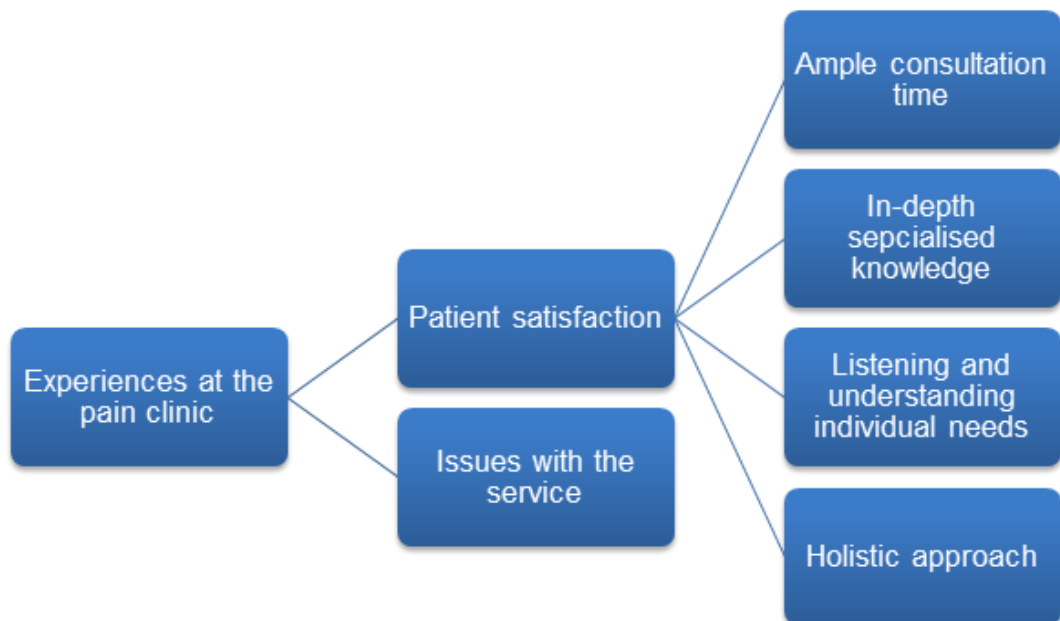


Figure 7.3. Sub-themes within experiences at the pain clinic theme

7.3.3.1 Satisfaction with the service

Overall, the patients were satisfied with the quality of care that they received at the pain clinic. Four factors were identified during the data analysis which contributed towards positive patient experience with the service: ample consultation time, in-depth specialised knowledge, listening and understanding individual patients' needs, and a holistic approach. The patients recognised and appreciated the role of both the clinical nurse specialist and the pharmacist at the pain clinic.

"I think it's a good little service that they've got going on there; I really, really do." [Pt. 12, 39 years old female]

In the following sections, these factors are described in detail.

a. Ample consultation time

The patients felt that they were given full freedom and time to express their views. In contrast to the ten minute consultation slot with the GP, the patients had one hour for the initial consultation and 30 to 45 minutes for the follow-up appointments which allowed them to discuss their problems more openly and freely.

"You're very conscious of the amount of time you have with your GP and it was knowing that I was going to see somebody who actually is a pain specialist, you just feel more confident and that because you feel they will take time with you and listen to you and understand..." [Pt. 16, 54 years old female]

"When you come here you don't feel that pressure, so you can be a bit more open and a bit more frank and you can be a bit more descriptive." [Pt. 8, 40 years old female]

“I mean [the clinical nurse specialist] sits and listens and then she writes them [GP] letters and it helps me when I go down to see them [GP].”
[Pt. 13, 54 years old male]

b. In-depth specialised knowledge

The in-depth specialised knowledge of both the nurse and pharmacist in terms of chronic pain management was quickly recognised by the patients. Patients had the impact of pain on their lives, pacing activities, the impact of being active on pain, and the usefulness of light exercise explained by the clinical nurse specialist.

“I think there’s also that knowledge base here. They’re obviously treating or speaking with people that have got similar symptoms and therefore know what kind of route to take when it comes to pain management and so on.” [Pt. 8, 40 years old female]

“I learnt quite a lot from them about pacing myself and timing [activities].” [Pt. 10, 54 years old female]

“[The clinical nurse specialist] explained what’s going off, how it affects me, and then [Pharmacist] we’ve been sat down and we’ve been balancing all my medications out, how much there is to take and how much... and what to take and what not to take, you know. So it’s been a real...to me it has, it’s been a really good thing to have been coming up here to the pain clinic.” [Pt. 13, 54 years old male]

The pharmacist focused on optimising the use of analgesics and other medicines involved in pain management. The patients were informed about the side effects and negative impact of over/under dosing. She also encouraged the patients to adhere to the therapeutic regimen.

“We [pharmacist and I] talk and they sort my medication out more than what... my GP hasn’t got a clue, you know, they haven’t got a clue what I’m doing. I mean I could go and ask them for anything and I think they’d just give me it, you know. I was taking too much and they said, well you won’t get any benefits from taking extra MST [Morphine], so I cut it down, I stopped taking as much.” [Pt.13, 54 years old male]

As a routine practice, the pharmacist reviewed patients’ medication history. In cases where the dosage was not right, the pharmacist recommended the right dose and medication was stopped if the medication was not required by the patient.

“She [GP] was overdosing me as well on there and the pharmacist was absolutely mortified when she found out how much I was taking. And I didn’t know, I’m no doctor, you know, I’ve just gone by my GP.” [Pt.12, 39 years old female]

“I felt she was very professional and she knew what she was doing, which is comforting. I’ve seen the pharmacist on Tuesday and the way she sort of looked at my medication and she knows what everything’s doing, she knows what it should be doing, and she probably knows what I can do without, hence the tramadol [was taken off].” [Pt. 10, 54 years old female]

c. Listening and understanding individual patients needs

The patients found that both the nurse and the pharmacist expressed their interest in listening to patients’ views, in contrast to the GPs who the patients perceived as not being interested in obtaining a full medical and medication history. Based on thorough face-to-face interviews and careful consideration of individual patient’s needs, the nurse and pharmacist developed a therapeutic

plan in consultation with the patients. The patients felt that finally there was someone who was listening to their needs.

“She [the clinical nurse specialist] was very good at listening. She was, very good. It was lovely having somebody to talk to who understood what pain does to people and you could talk to her, she were a person that you could talk to, some you can’t can you, you know? Some people, they just give off that aura, they don’t really care, you know. But she were very good, she was yes.” [Pt. 14, 64 years old female]

“I think it’s because there’s a sympathetic ear and people will listen. And there seems as if this understanding and they’re offering advice that we’ll take on board, whereas we’ve not really had that... we’ve not felt that comfortable with the GP because she openly admitted that she didn’t really know anything about fibromyalgia and therefore she didn’t really know how to treat it.” [Pt. 8, 40 years old female]

After each consultation, as per the routine clinical practice, a letter was sent to both the patient and his/her GP explaining the nature of and history of the present complaint with recommendations for a future therapeutic plan.

“I can tell maybe because they sent me a copy of the letters that they send to the GP and everything I’ve said to them they’ve taken notice of and they’ve pointed out to the GP, you know.” [Pt. 9, 51 years old male]

d. Holistic approach

The clinic offered a more holistic approach towards pain management compared to the GP. The patients were given adequate time to explain their problem and both the clinical nurse specialist and the pharmacist listened to their problems, allowing carefully individualised therapeutic plans to be

designed. Both pharmacological and non-pharmacological therapeutic options were explored for each patient.

“Well really I suppose here they go through absolutely everything you know so it’s a lot more in-depth and looking at the whole picture rather than simply trying to give you medication for a problem like the GP does and then refer you to physio etc. It’s.....[Pauses]. Here it’s a much more holistic approach really and they try and cover absolutely everything for you and see what other services they may be able to refer you to or ask your GP to refer you to. So I think really it’s a complete programme so it’s good in that way.” [Pt. 11, 44 years old female]

“Go to pilates, I did and that’s helped, yes, yes [Pt. 5, 74 years old female]

The emotional needs of the patients were also assessed and appropriate referrals were made in order to help them in this respect..

“They have taken steps to help the emotional side, which that’s, you know, sort of getting out and meeting people. And [the CNS] picked up on that very quickly, very, very quickly.”[Pt. 10, 54 years old female]

After assessing individual patient’s needs, the patients were also referred to other services such as the expert patient groups, musculoskeletal services, and psychological services if required. The patients also found these referrals beneficial, contributing to an overall satisfaction with the service.

“They [pain clinic] referred me to a physiotherapist who specialised in chronic pain. And so through seeing that physiotherapist I’ve learnt different ways of managing the pain which I found to be more effective than the medication I was on.” [Pt. 18, 27 years old female]

“Because I’ve ended up if I hadn’t have come here I wouldn’t have had the injection, because that injection I don’t think would have been offered to me by my doctor.” [Pt. 2, 49 years old male]

7.3.3.2 Issues with the pain clinic

The patients also highlighted some negative issues with this service. They were not pleased by the fact that the pain clinic did not prescribe medicines to them and they had to go to their GPs to get the medicines. Patients felt that this caused unnecessary delay and had expected to get their medicines at the pain clinic.

“When I found that I was going to have to go back to him for the prescription I was a bit in shock really. I’m thinking what? He’s referred me to you for you to... saying that you’ll be able to look at these things and I’ve come here hopefully to get these things and then you’re saying I’ve got to wait another two weeks while you send a letter to my doctor and then he’ll just write a prescription....[Pt. 19, 47 years old male]

“I think the one thing we weren’t expecting is that there was going to be referrals from the pain management to the doctor. We were thinking they were kind of independent bodies.” [Pt. 8, 40 years old female]

Some of the patients also felt that they were not appropriate for this service and should not have been referred here. They considered that they had pain for quite a long time and knew about the various self-management strategies discussed at the pain clinic including being active, exercise and pacing activities.

“I think was more aimed at getting people re-motivated past their pain, so we did talk a little bit about painkillers and modified those a bit, but the main part of pain clinic to me seemed to be about getting people to get up and go and take additional steps that maybe they weren’t already doing, which really wasn’t kind of suitable for me I don’t think. I don’t ever sit down; I don’t have time, so I think maybe I wasn’t really their target audience.” [Pt. 1, 36 years old female]

“Well I just went through everything that I’d been through, you know discussing everything, going through every remedy and possible thing that may help but I’d heard it all and done it all, you know, it wasn’t anything new really.” [Pt. 11, 44 years old female]

Although the patients appreciated the quality of care delivered at the nurse-pharmacist managed pain clinic, not all the patients were able to achieve the desired pain relief.

“I was expecting they might be able to do something different, but I’m quite happy with how it was conducted. But I don’t feel as though I’ve made any progress.” [Pt. 3, 63 years old male]

“I’m still in pain and what they’ve suggested so far it’s not helped the pain.” [Pt. 4, 30 years old male]

7.3.3.3 Theme summary

In this theme, the factors contributing towards patients’ good experiences and satisfaction have been explored. In addition, patients’ concerns about the service have been presented. The patients were generally satisfied with the service. The long consultation time and specialised pain management knowledge at the pain clinic enabled patients’ pharmacological and non-

pharmacological needs to be explored and addressed. Individualised pain management plans were devised for patients after a careful review of their medical and medication history. In addition, the patients benefited from referrals to other services, where required. However, some of the patients were disappointed by the fact that they had to visit their GPs to get the prescribed medications.

CHAPTER 8

DISCUSSION

CHAPTER 8

DISCUSSION

8.1 Introduction

In this final chapter of the thesis, the results/findings of both the quantitative and qualitative phases are discussed in the context of the wider literature. In addition to studying the sociodemographic and clinical characteristics of the patients referred to the pain clinic, the aim of the quantitative phase was to evaluate the impact of nurse-pharmacist managed pain clinic on pain intensity, physical functioning, emotional functioning, quality of life and chronic pain grade. The aim of the qualitative phase was to explore patients' views about their experiences at the pain clinic. The findings are discussed in the light of these objectives. Where possible, the findings of both the quantitative and qualitative phases are integrated to facilitate a better understanding of the results. Since the findings of the systematic review have already been discussed in detail in chapter 3, they are not discussed in detail here. However, reference to the findings of the systematic review is made where appropriate.

The chapter begins with a general discussion on the use of the mixed-methods methodology for this study and then the sociodemographic and clinical characteristics of the patients referred to the pain clinic are discussed. This is followed by the discussion on the effectiveness of the pain clinic. The limitations of the current study are then highlighted and recommendations for future research and policy are suggested. Finally, the dissemination plan for the research findings is outlined.

8.2 Discussion

8.2.1. Learning experience during PhD: A reflective account

In my understanding, the overall aim of a PhD training is to facilitate transformation of the student into an independent researcher by equipping him with the necessary knowledge and skills required to undertake research. With the growing use of qualitative and mixed-methods research methodologies within practice disciplines, it has become increasingly important for practice researchers to understand the strengths and weaknesses of these methods as well.

My PhD project which consisted of a systematic review and meta-analysis, and a mixed-methods study provided me with an excellent opportunity to learn and apply different research skills. As I highlighted earlier (section 1.1), I had only a limited research training in the past, which was predominantly quantitative. During my PhD, I gained valuable knowledge and skills of designing and conducting systematic reviews, qualitative, quantitative and mixed-methods research. In addition, I learnt a lot about the art and science of publishing in a peer-reviewed journal, an important skill for an academic researcher. However, I do not consider myself as an expert qualitative and/or quantitative researcher but the PhD training has enabled me to become independent – I can find my way. I believe, because the research methods and issues keeps evolving, it is a life long journey which has just formally begun.

8.2.2 A word on methodology

This study used a mixed-methods methodology to evaluate the effectiveness of a community based nurse-pharmacist managed pain clinic. Over the past few years, there has been growing interest in the use of mixed-methods approaches

in health services evaluation (O'Cathain et al., 2008) as they allow the use of multiple methods to comprehensively answer different research questions in a single study (Creswell and Plano Clark, 2011). The rationale for using a mixed-methods approach has been described in detail in the methodology chapter. Briefly, the use of mixed-methods methodology generated both effectiveness and satisfaction data within a single study, thus providing a holistic evaluation. Furthermore, the findings of the qualitative study not only identified the factors contributing to patients' satisfaction but also enabled the author to overcome some of the threats to the internal validity of the quasi-experimental study (described in detail later in the limitations section).

In the following sections the key findings of both quantitative and qualitative studies are discussed.

8.2.3 Sociodemographic and clinical characteristics of the patients

In general, the sociodemographic profile of the patients referred to the nurse-pharmacist managed pain clinic was similar to the profile of patients visiting outpatient pain clinics in Hong Kong and Toronto. In the present study, the mean age was 46.5 (SD 14.5) with almost half (46.8%) of the patients being middle aged (36-50 years). Similarly, the mean age of patients attending an outpatient pain clinic in Hong Kong (Chen et al., 2004) and a university hospital affiliated pain clinic in Toronto (Canada) (Mailis-Gagnon et al., 2007) were 48.7 years (SD 15) and 48.5 years (SD 14.2) respectively, with the majority of the patients being middle aged (35-49 years age range) in both studies. The majority of the patients were female (67.1%). Chronic pain is more prevalent among women and they have been reported to use more healthcare resources compared to the men. The National Health Survey (Bridges, 2012) also reported a higher prevalence of chronic pain among females (37% females compared to

31% males). The high prevalence of chronic pain and higher utilisation of healthcare resources may explain the high number of female patients in the sample. More than a half (56.5%) of the patients had chronic pain for more than 3 years and, more importantly, for 70% of the patients this was the first visit to a specialised pain service/clinic.

The interplay of a number of factors including patients' medical help seeking behavior, GPs' lack of willingness to refer patients to a specialised pain service and, lack of awareness among the GPs and patients about the existence of such clinics may partly explain the delay in referral to a specialised pain service. In the present study, most of the patients were referred by the GP (72.2%), which suggests that the GPs were willing to refer the patients. However, how long the GPs kept the patients under their care before referring on to the clinic could not be established. Furthermore, during the qualitative interviews a few patients highlighted that they had to repeatedly ask their GPs for referral before they were referred. It will be interesting for future researchers to further explore this issue and its implications for the treatment outcomes.

In the present study, 67.1 % of patients had HADS-A score of 8 (likely to suffer from anxiety) or above and 60.5% HADS-D score of 8 (likely to suffer from depression) or above. Anxiety and depression are common among chronic pain patients. The prevalence of depression, depending on the method of assessment, has been reported to vary from 1.5% to 87% (Worz, 2003). Chronic pain can cause and/or worsen symptoms of depression; on the other hand, depression is associated with increased pain intensity, reduced physical, social and occupational activity and a higher use of health services (Geisser et al., 1997, Worz, 2003). Patients in the qualitative interviews also highlighted significant impact of chronic pain on their mental functioning and described a 2-

way relationship between pain and depression. The patients felt depressed during the times when pain intensity was high and also felt that depression was contributing towards increased pain intensity. The National Health Survey (Bridges, 2012) also reported that participants in chronic pain grade IV (high disability-severely limiting) were more likely to be anxious and depressed than the participants with grade I (low disability-low intensity) and II (low disability-high intensity) (Bridges, 2012). In the present study, more than 60% of the patients fell under Grade IV (high disability-severely limiting), explaining a high incidence of anxiety and depression among patients referred to the clinic. The high prevalence of anxiety and depression calls for integrating psychological services with chronic pain services to improve overall patient experience.

In the present study, almost half of the patients (43%) were unemployed, of whom more than a quarter (25.3%) were unemployed due to pain. The negative impact of chronic pain on employment status was discussed frequently by the patients indicating its significance in their lives. The patients had to either stop working or switch jobs from full time to part time because of the pain. The negative impact of chronic pain on employment status, sickness absences, and loss of productivity is well documented in the literature (Steenstra et al., 2005). Studies have also documented an association between employment status and chronic pain intensity after adjusting for confounders. A systematic review by Patel et al. (2012), found that interference of chronic pain with employment affected 26% (Breivik et al., 2006) to 88% (Friessem et al., 2009) of patients with the loss of employment due to chronic pain reported to range from 18% to 23% (Patel et al., 2012).

The information on sociodemographic and clinical characteristics of the patients is valuable in a number of ways. Firstly, the clinical characteristics of

the sample represent a typical chronic pain population; therefore the findings of this study are potentially generalizable to the chronic pain population, keeping in view the limitation of inadequate sample size (issue further discussed in section 8.5). Secondly, this information is important for identifying a suitable control group for future RCTs evaluating community-based pain clinics. Thirdly, for service commissioners, the high prevalence of psychiatric comorbidity among chronic pain patients calls for the integration of psychological services with chronic pain services as anxiety and depression can interfere with chronic pain management.

8.2.4 Outcomes assessment

The rationale for selecting the outcome measures and respective scales has been discussed in detail in chapter 5 (section 5.3.4). The recommendations made by the IMMPACT group guided the selection of outcome measures (Dworkin et al., 2005). In terms of pain relief, statistically significant reductions in the “worst pain” and “average pain” were observed upon discharge. However, no significant differences were found for the “least pain” and “pain right now”. Due to the small sample size statistical analysis were not performed for 3-month follow-up. For physical functioning, there was a significant reduction in the overall interference of chronic pain with physical functioning ($P=0.02$). As highlighted earlier (Chapter 3, section 3.5.1), it has been suggested that the population distribution of pain scores are usually not normally distributed and are ‘U-shaped’; therefore, reporting merely changes in the means/medians for continuous data (e.g. pain intensity) can be misleading (McQuay et al., 1996) as patients tend to have either very good or very poor pain relief. To avoid this limitation and to improve clinical interpretation of the results, percentages of patients responding to treatment have been reported as well, in addition to reporting medians/means, for two of the outcome measures: pain intensity and

physical functioning (IMMPACT group recommendations were available for these two outcomes measures only). For pain intensity, 17 out of 35 patients (48.6%) discharged from the clinic had achieved at least a minimum clinically important difference (10% of the baseline score) at the time of discharge. However, since the data were not available for all the patients, this figure (48.6%) may not be an accurate representation of the effectiveness of the clinic. For physical functioning, fourteen out of 35 (40%) patients had achieved minimum clinically important difference at the time of discharge from clinic. Again, the 40% could be an under or over representation of the effectiveness of the clinic. The findings of the systematic review reported in chapter 3 also found a significant reduction in pain intensity and a significant improvement in physical functioning among patients who had the intervention (i.e. pharmacist-led medication review) compared to the control.

No statistically significant reductions were noted for anxiety ($P=0.21$) and depression scores ($P=0.22$). However, for anxiety, 13 out of 34 patients (38.2%) had improved at least by one category (e.g. from mild to normal or from moderate to mild etc). On the other hand, for depression, only 7 out of 34 patients (20.6%) showed an improvement by at least one category. For quality of life, of the eight domains assessed, statistically significant improvements were noted for bodily pain (BP) and physical role (RP) only. There were no significant improvements in the physical component summary (PCS) score and the mental component summary (MCS) score. The lack of intervention effect in terms of anxiety, depression, and quality of life might be attributed to the small sample size. It is also possible that the intervention was not effective or the outcome measures were not sensitive enough to detect a difference.

For the chronic pain grade questionnaire, compared to the baseline, a significant reduction only in pain intensity subscale was found at discharge. No significant improvement was noted for disability sub-scale. Only seven (20.6%) patients showed improvement in terms of chronic pain grade while the majority of the patients showed neither improvement nor deterioration in their chronic pain grade. An alternative explanation for lack of intervention effect could be the nature of questions within the chronic pain grade questionnaire. All the questions except one (question 1) ask the patients to rank their pain intensity, and associated physical disability, over the past 6 months on a 0 to 10 NRS scale. Therefore, it may not necessarily detect a positive outcome in patients who are discharged less than 6 months of their baseline assessment, thus making it a less useful outcome measure for short to medium term evaluations. However, further research is required to explore this hypothesis.

Patient satisfaction was another outcome, evaluated using face-to-face semi-structured interviews. The issues around patient satisfaction are discussed in the context of barriers to effective pain management, in the following section.

8.2.5 Barriers to effective pain management

In the previous chapter, while reporting the findings of qualitative phase, barriers to effective pain management were also highlighted. Although, the aim of the qualitative interviews was not to explore barriers to effective pain management, however, while exploring patients' satisfaction with the service the patients volunteered a number of issues related to pain management. It is important to understand these issues in order to thoroughly appreciate the reasons for patient satisfaction.

Both healthcare professionals and system-related barriers to effective pain management were identified during the qualitative interviews. The

healthcare professional-related barriers included: lack of interest and empathy, lack of GP's specialised knowledge, short consultation time with the GPs, and lack of communication between healthcare professionals. The lack of interest among healthcare professionals in managing pain has been well documented in the literature (Walker et al., 1999, Harding et al., 2005, Osborn and Smith, 2008, de Vries et al., 2011). The lack of seriousness among the healthcare professionals in managing chronic pain may be partly attributed to their lack of belief in chronic pain patients. In addition to this study, patients in a number of qualitative studies have described a sense of "not being believed" and "being judged" by the healthcare professionals (Walker et al., 1999, Harding et al., 2005, Osborn and Smith, 2008, de Vries et al., 2011). However, a large telephonic survey of primary care physicians (PCP) and chronic pain patients across eight European countries including the UK reported that about 90% (n=1,334) of physicians were interested in improving patients' quality of life and offered all patients some sort of treatment. However, only 12–33% of patients were given written information about their condition (Woolf et al., 2004).

Since chronic pain is predominantly managed within primary care and in the UK, referral to secondary care/pain service is made by the GPs based on their assessment, issues such as lack of specialised chronic pain management knowledge among GPs and short consultation time are of significant importance in the context of chronic pain management. A study from the US reported that, pain was discussed on average for only 2.3 minutes during consultations with primary care physicians (PCPs) (Tai-Sealea et al., 2012). The odds of having pain discussion were significantly associated with the level of pain, physician's supportiveness, and gender concordance (physician and patient are of same gender) (Tai-Sealea et al., 2012). GPs themselves have identified lack of

sufficient knowledge and skills in chronic pain management (Stannard and Johnson, 2003). In a survey more than two thirds (81%) of the GPs expressed an interest in receiving additional education and training in chronic pain management and more than a quarter of GPs surveyed desired more guidelines and local protocols to manage chronic pain (Stannard and Johnson, 2003). The survey further reported that the majority of the GPs (81%) believed that a substantial number of patients received suboptimal treatment for chronic pain. Similarly, 88% of the physicians in the US felt that their training in pain management was poor in medical school (Von Roenn et al., 1993). This suggests that lack of specialised knowledge is not only the patients' perceptions but also GPs/primary care physicians recognize this as a limitation as well. The patients felt that it was due to GPs' lack of interest and specialised knowledge that they were referred from one healthcare professional to another. The interplay of all these factors contributed to patients' dissatisfaction with the quality of care offered to them by various healthcare professionals especially the GPs. There is a need to improve GPs' knowledge and skills in chronic pain management and to develop referral guidelines for chronic pain patients in order to improve chronic pain management in the community. In addition, development of community-based pain clinics or setting up of pain clinics within GP practices managed by clinical specialist nurse and/or pharmacist can also improve chronic pain management in the community

Long waiting times for appointments in secondary care and lack of a holistic approach were among the healthcare-system related barriers identified during the qualitative phase. Waiting time is an important issue in the context of effective pain management as a waiting times of 6-months or more is associated with an increase in pain intensity, depression and poorer quality of

life (Lynch et al., 2008). Unfortunately, no medically acceptable benchmarks for waiting time for chronic pain exist globally (Lynch et al., 2007), suggesting a need to develop evidence based waiting time standards for chronic pain patients. In the UK, no standard waiting-time specifically for chronic pain exist and, therefore the National Pain Audit used a generic 18-week standard waiting time for evaluating chronic pain services in the last audit (Price et al., 2012). However, the National Pain Audit recommended that the Royal College of Anaesthetists and the National Institute of Clinical Excellence (NICE) should develop guidance on waiting times for chronic pain patients (Price et al., 2012). In a survey, the GPs in the UK expressed concern for the long waiting times for appointments in the secondary care (Stannard and Johnson, 2003). On the other hand, primary care physicians in Canada considered long waiting times as a barrier to referral to secondary care (Lakha et al., 2011). Patients were not only concerned about the waiting time for appointments with healthcare professionals in secondary care but also about the long waiting times for medical tests and scans (MRI, CT-scan, X-rays) as the later contributed to overall delay in treatment. In Canada, one third of patients had to wait for more than a year (over all mean 6 months; range 2-14 months) for appointments at publically-funded multidisciplinary clinics (Peng et al., 2007). However, the waiting time for private clinics was less than a month (mean 0.5 months; range 1-4 weeks) (Peng et al., 2007). In the UK, the National Pain Audit reported that 80% of clinics were meeting the 18-week generic waiting time standard (Price et al., 2012). Because of the long waiting time for consultation in secondary care in the NHS, patients during the qualitative interviews expressed an interest to opt for private treatment. However, "affordability" was a barrier. The patients also felt that the healthcare professionals', especially the GPs', approach towards pain management was unidirectional-medicine oriented and lacked holism. The

patients felt that a multidisciplinary approach would have benefited them more in terms of pain relief. Both the clinical effectiveness and cost effectiveness of multidisciplinary pain clinics have been demonstrated (Gatchel and Okifuji, 2006, Scascighini et al., 2008). However, availability of and access to multidisciplinary clinics has been problematic. Only 40% of pain services audited during the National Pain Audit met the minimum criteria of multidisciplinary service (Price et al., 2012). The development of more community-based clinics jointly managed by a nurse and pharmacist can potentially overcome the issues related to availability and access.

8.2.5.1 Patient satisfaction with service

Patient satisfaction was explored using face-to-face qualitative interviews. Patients were generally satisfied with the quality of care provided by the nurse and the pharmacist at the pain clinic. Ample consultation time, in-depth specialized knowledge, listening and understanding individual patient's needs and, a holistic approach were identified as contributing factors toward patients' satisfaction. It should be noted here that these factors are totally opposite to the barriers to effective pain relief discussed earlier which suggests that a community-based pain clinic jointly managed by a nurse and a pharmacist can overcome the barriers to effective pain management. Furthermore, referrals to other services were made, where necessary, after a thorough assessment of individual patient's needs. Non-pharmacological alternatives were suggested in instances where the patient: perceived not to take medicines; issues related to the side effects/tolerance; or non-pharmacological interventions were deemed necessary. The holistic approach was evident from the nature of recommendations made at the clinic. For 35 patients, 101 medicine-related (mean 2.9; range 1 to 6) and 42 non-pharmacological recommendations (mean

1.3; range 1 to 3) were made to the GPs and patients, suggesting that both pharmacological and non-pharmacological needs were assessed and addressed. Patients during the qualitative interviews appreciated the non-pharmacological interventions as well including going to a support group

8.3 Key findings from the three sections of the thesis: Patients' views and outcomes

The key findings from the three sections of the thesis are summarised in table 8.1. Although the aim of this research was not identify barriers to effective pain management but to emphasise the importance of research findings in relation to overcoming those barriers and facilitate a better understanding, the research findings are mapped, where applicable, to the barriers identified during qualitative interviews in Table 8.1.

Table 8.1. Key findings from the three sections of the thesis

Interview and questionnaire data		Systematic review of
Barriers to effective pain relief	Nurse-Pharmacist managed clinic	pharmacist-led medication review
Most of the patients were not pleased with the quality of care received.	Patients were generally satisfied with the clinic.	Patients were generally satisfied with pharmacists' service (small to moderate effect size).
Inadequate pain relief.	On discharge patients reported a significant reduction in worst pain, average pain and an improvement in physical activity.	Pharmacist-led medication review was effective in reducing pain intensity and improving physical functioning.

	Patients wanted their prescription there and then rather than having to return to their GP.	Some weak evidence of reducing adverse drug effects
Inappropriate referrals were made.	Some patients felt it was too late to be attending the clinic and learned nothing new.	
Lack of a holistic approach.	Holistic approach	
Lack of interest and empathy by healthcare professionals (HCPs)	Listening and understanding of individual patients' needs	
Short consultation times with GPs	Ample consultation time	
GP lack of specialised knowledge.	In-depth specialised knowledge.	
Lack of communication between HCPs	Written communication with patients and GPs	
Long waiting times for appointments in secondary care.		

8.4 Conclusion

Community based pain clinics jointly managed by nurses and pharmacists have the potential to improve chronic pain management in the community. In addition to reducing pain intensity and improving physical functioning, such community-based clinics can not only improve access to specialised pain service but also reduce burden on the secondary care. The sufficient consultation time with patients allowed the nurse and the pharmacist to obtain full medication and

medical history and develop an individualised management plan addressing both pharmacological and non-pharmacological needs of the patients. In terms of the patients' perspective, they felt that they were treated with respect and empathy and, were generally satisfied with the quality of service. There is a need to develop evidence-based referral guidelines for such community based clinics to ensure that the patients who are likely to benefit from such services are referred there. GPs should be encouraged to refer patients to such services early during the course of the treatment as GPs' lack of specialised knowledge and short consultation time are barriers to effective pain management.

Unfortunately, the service was decommissioned by the local PCT without taking all the stakeholders on board. This was in spite of the fact that the pilot study had documented positive outcomes and an in-depth evaluation from both clinical and patient perspective was in progress. Even though the patients highly appreciated and valued the role of the pharmacist in solving their medication-related problems and optimizing the use of medicines, the services of the pharmacist were dropped. The findings of the systematic review and meta-analysis, reported in chapter 3, reported a significant impact of pharmacist-led medication review on various patient outcomes including pain intensity, physical functioning and patient satisfaction. This clinic provided a good practical example of public-private partnership in healthcare setting. Given the limited financial resources that the healthcare systems currently have, more avenues of public-private partnerships should be explored and evaluated.

8.5 Limitations

The findings of this mixed-methods study should be carefully considered in context of its limitations. In terms of the design and conduct, there were three main limitations related to the quasi-experimental study. Firstly, in terms of study design, RCTs, not quasi-experimental studies, are considered the gold standard for evaluating the effectiveness of healthcare interventions (Bonnie and Martin, 1998). The reasons for not conducting a RCT for the present study have been discussed in detail in chapter 4 (section 4.4.1). Due to the lack of randomization and control group, several threats to the internal validity of before-and-after quasi-experimental studies have been reported in the literature including history, maturation, Hawthorne, instrumentation, regression-to-the-mean, drop out and testing (Harris et al., 2004). In the context of this study, history, instrumentation and maturation were of significant concern. A “History threat” refers to the occurrence of other influential events, independent of the intervention, which could affect the outcome. Maturation threat to the internal validity refers to a natural processes (e.g. ageing) leading to physical or psychological changes in the participants, thus affecting the outcome measure. The triangulation of the findings of the quasi-experimental (before-and-after) and qualitative descriptive studies enabled the author to address these two threats to internal validity to some extent. The findings of the quasi-experimental study were supported by the findings of the qualitative descriptive study. During the qualitative interviews, the patients reflected on the usefulness of the clinic and attributed pain relief to various pharmacological and/or non-pharmacological recommendations made at the pain clinic. An “instrumentation threat” refers to the change of the scale measuring the outcome between “before” and “after” measurements, which could affect the outcome. As

described in the methods chapter, (Chapter 5) all questionnaires/scales used in this study have well demonstrated validity and reliability. The same questionnaires were used for all outcomes during all assessments (baseline, discharge, 3-month follow-up) minimizing instrumentation threat to the internal validity of this study.

The second major limitation of this study was the inability to achieve the required sample size. The required sample size, after accounting for a 15% dropout rate, to detect a minimum clinically important difference as recommended by the IMMPACT group (Dworkin et al., 2008) for pain intensity was 79. However, discharge data were available for 36 patients only as the service was decommissioned whilst data were being collected. Subsequently, the services of the clinical nurse specialist were absorbed into a musculoskeletal service at the same community health centre and the services of the pharmacist were discontinued. Since there were structural changes in the provision of service, collecting further follow-up data would not have been appropriate. The inability to achieve the required sample size (i.e. underpowered) could lead to Type II error, failure to find a difference in presence of a real difference (Altman, 1991). This could explain a lack of intervention effect on the quality of life, anxiety and depression in the present study. On the other hand, the significant intervention effect on two of the outcome measures, pain intensity and physical functioning, might be due to Type I error, a false positive. Therefore, the results should be interpreted with care. However, as discussed above, patients during the qualitative interviews highlighted positive impact of the clinic on their lives in general.

The third limitation, although linked to the second one, was the low response rate of the postal questionnaire. Traditionally, postal questionnaires

suffer a low response rate and a response rate of 50% or above is considered good {(Babbie, 1973, Kidder, 1981) cited in (Richardson, 2005)}. Sending the questionnaires in the post was the best possible approach for the 3-month follow-up as it would have been unethical to ask the patients to come to the clinic just to complete questionnaires without at least reimbursing their travel expenses. Furthermore, travelling to the pain clinic might have been inconvenient for patients in pain. The decision to drop SF-36 for the 3-month follow-up was made primarily to increase the response rate as shorter questionnaires have been reported to have a better response rate than longer questionnaires (OR 1.86; CI 1.55 to 2.24) (Edwards et al., 2002). In addition, personalized letters were also sent together with the questionnaires in an effort to improve response rates as personalized letters improve response rates as well (OR 1.16; CI 1.06 to 1.28) (Edwards et al., 2002). Monetary incentives have also been reported to improve the response rate (OR 2.02; 95% CI 1.79 to 2.27) (Edwards et al., 2002), but unfortunately, due to lack of funding giving patients monetary reward was not possible.

For the qualitative descriptive study, there were two main limitations as well. Firstly, the patients were interviewed upon discharge from the service; theoretically, patients were discharged once the patients had made desired progress, which may explain their satisfaction from the service. However, as described earlier in chapter 5, a framework for maximum variation sampling was developed and baseline pain-intensity scores rather than discharge scores were considered in developing the framework. Despite that, patients in pain might not have consented for interviews, limiting the pool of potential participants. Secondly, the author/researcher being a pharmacist himself could have introduced researcher bias. However, the author clearly described his position

in the study in the very beginning. In addition, various measures were used such as peer debriefing and providing rich thick description, as described in chapter 5, to ensure transparency, trustworthiness and, to minimize researcher bias. In addition, in-depth description of all the aspects of data collection (sampling, sample size, settings, topic guide) and analysis (data management, method of analysis, methods to ensure rigour) has been provided to ensure transferability of qualitative findings.

8.6 Recommendations for future research

- Further research is required to establish the long-term effectiveness and sustainability of such community-based nurse-pharmacist managed pain clinics. The IMMPACT guidance should be followed in designing and reporting studies evaluating the effectiveness of interventions in chronic pain management.
- The types of patients that are more likely to obtain benefits from such community based services are still not well known. Further research is required to determine the predictors of successful treatment outcomes. This information is crucial and should be used for developing evidence based referral guidelines. Such guidelines could ensure referral to the right healthcare professional at the right time thus minimizing cost to the healthcare system. Additionally, what factors encourage GPs to refer patients to pain clinics/secondary care/physiotherapy should be investigated.
- As described in the literature review chapter, there is only weak evidence to support the cost effectiveness of nurse-led interventions in chronic pain management. However, no cost-effectiveness data are available for such pain clinics jointly managed by the nurse and the pharmacist. Cost

effectiveness data are important to advocate for the wider development of such pain services.

8.7 Recommendations for policy and practice

- The views of all stakeholders, including patients, should be considered especially before decommissioning of service as it may have negative consequences on their health. Service commissioners should rely on best available research evidence for commissioning and/or decommissioning of services. Had the service commissioners waited for this study to be completed, it may have guided them to make a well informed decision.
- Pharmacists working in community pharmacies can play an important role in the management of chronic pain by ensuring the safe and effective use of medicines. Therefore, service commissioners while planning chronic pain services should think of ways of incorporating community pharmacists' services in pain service.
- Employing specialised pain nurses in GP practices can potentially facilitate effective pain management in the community.
- Since anxiety and depression frequently co-exists with chronic pain, there is a need to assess mental functioning of chronic pain patients regularly in primary care. Help from psychological services should be sought when necessary, as anxiety and depression can also interfere with the management of chronic pain.
- Since chronic pain is primarily managed in primary care, there is a need to train GPs in chronic pain management. GPs need to be informed about the existence of such clinics and should be encouraged to refer patients to community-based pain clinics, if available, early during the

course of the disease for a thorough assessment. Further referrals to other services and/or secondary care should only be made based on the recommendations of the pain clinic. This will potentially reduce burden on secondary care.

- Since nurses and pharmacists have the potential to contribute to effective chronic pain management, structured and specialised training programmes in chronic pain management should be developed for them to further improve their knowledge and skills in chronic pain management. The nurses and pharmacists working in such clinics should be encouraged to become independent prescribers as it can improve patients' access to medicines. This will also reduce the number of visits to the GPs to obtain prescription analgesics as well, reducing overall cost and time.

8.8 Dissemination plan

To disseminate the findings of research work is an ethical and professional responsibility. To date, as indicated in the beginning of this thesis, the author has published six peer reviewed papers in addition to two non-peer reviewed papers highlighting various aspects of the work presented in this thesis. The findings have also been presented in various conferences. The future dissemination plan is outlined in Table 8.1.

Table 8.1. Dissemination plan

Proposed title	Potential journal	Submission date
An evaluation of nurse-pharmacist managed pain clinic: A mixed-methods study	The Clinical Journal of Pain/ Health Services Research	June 2014
Patients' experiences of living with chronic pain: a qualitative study	Pain/ The Clinical Journal of Pain	July 2014
Quality of life and clinical characteristics of the patients referred to a nurse-pharmacist managed pain clinic	International Journal of Clinical Pharmacy	July 2014
"No one is listening here"- Chronic pain patients and the NHS: Barriers to effective pain management	The British Medical Journal/ The Journal of Pain	August 2014

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Appendices

Appendix I

Search strategy for Medline

Wolters Kluwer Health | OvidSP

Logged in as Muhammad Hadi at School of healthcare
My Account | Ask the Library | Support & Training | Help | Logoff

Search Journals Books My Workspace Primal Pictures

My Projects | My Searches & Alerts | My eTocs | Install Toolbar

Search History (18 searches) (Click to close) View Saved

<input type="checkbox"/>	# ▲	Searches	Results	Search Type	Actions
<input type="checkbox"/>	1	chronic pain.mp. [mp=title, abstract, original title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]	15648	Advanced	<input type="button" value="Display"/> <input type="button" value="Delete"/> More >>
<input type="checkbox"/>	2	non cancer pain.mp. [mp=title, abstract, original title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]	262	Advanced	<input type="button" value="Display"/> <input type="button" value="Delete"/> More >>
<input type="checkbox"/>	3	non malignant pain.mp.	222	Advanced	<input type="button" value="Display"/> More >>
<input type="checkbox"/>	4	shoulder pain.mp. [mp=title, abstract, original title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]	4255	Advanced	<input type="button" value="Display"/> <input type="button" value="Delete"/> More >>
<input type="checkbox"/>	5	back pain.mp. [mp=title, abstract, original title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]	34202	Advanced	<input type="button" value="Display"/> <input type="button" value="Delete"/> More >>
<input type="checkbox"/>	6	Headache/ or Headache Disorders, Secondary/ or Cluster Headache/ or Headache Disorders, Primary/ or Tension-Type Headache/ or Headache Disorders/	25052	Advanced	<input type="button" value="Display"/> More >>
<input type="checkbox"/>	7	knee pain.mp.	2968	Advanced	<input type="button" value="Display"/> More >>
<input type="checkbox"/>	8	Arthritis, Rheumatoid/ or Arthritis, Infectious/ or Arthritis/ or Arthritis, Gouty/	104555	Advanced	<input type="button" value="Display"/> More >>
<input type="checkbox"/>	9	Osteoarthritis, Hip/ or Osteoarthritis/ or Osteoarthritis, Spine/ or Osteoarthritis, Knee/	37964	Advanced	<input type="button" value="Display"/> More >>
<input type="checkbox"/>	10	medicine* management.mp.	177	Advanced	<input type="button" value="Display"/> More >>
<input type="checkbox"/>	11	(medication adj2 review).mp. [mp=title, abstract, original title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]	481	Advanced	<input type="button" value="Display"/> <input type="button" value="Delete"/> More >>
<input type="checkbox"/>	12	'Drug Utilization Review' / or Community Pharmacy Services/ or Pharmacists/	13248	Advanced	<input type="button" value="Display"/> More >>
<input type="checkbox"/>	13	(drug adj2 review).mp. [mp=title, abstract, original title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]	3657	Advanced	<input type="button" value="Display"/> <input type="button" value="Delete"/> More >>
<input type="checkbox"/>	14	(medicine adj2 review).mp. [mp=title, abstract, original title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]	555	Advanced	<input type="button" value="Display"/> <input type="button" value="Delete"/> More >>
<input type="checkbox"/>	15	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9	212261	Advanced	<input type="button" value="Display"/> More >>
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Remove Selected | Save Selected | Combine selections with: And Or BSS

Appendix II

Risk of bias assessment form for the systematic review

Item	Low/High/ Unclear risk	Justification
Random Allocation		
Allocation Concealment		
Blinding of Participants		
Blinding of Personnel (delivering intervention)		
Blinding of outcome assessor		
Incomplete outcome data		
Selective reporting of outcomes		
Baseline differences		
Use of Invalid questionnaires		
Notes:		

Appendix III**Letter of invitation to participate in the study****UNIVERSITY OF LEEDS**

Dear Sir/Madam,

Invitation to participate in a research study entitled “Evaluation of Nurse-Pharmacist managed pain clinic”

I am a PhD student at the School of Healthcare, University of Leeds. I am conducting research looking at the effectiveness of the nurse-pharmacist led pain clinic. As part of this research we want to find out how well the pain clinic works for the patients in terms of pain management and relief. In particular, we would like your views on the care provided by the clinic. You are receiving this letter because you have been referred to the pain clinic. However, please note that I have not been given access to any personal information about you to maintain confidentiality.

The enclosed information sheet gives further details of the research and will hopefully answer any questions you have. However, please feel free to contact me by phone (0113 3433202) or email (hcmah@leeds.ac.uk), if you would like to know more about the project.

Thank you for taking the time to read this letter.

Yours sincerely,

Muhammad Hadi

Appendix IV**Invitation to take part in a follow-up assessment****UNIVERSITY OF LEEDS**

Dear Sir/Madam,

Thank you very much for taking part in our study of the Nurse-Pharmacist managed pain clinic. You are receiving this letter because it has been three months since you were discharged from the clinic and we would like to know how you are coping with your pain now.

I would be grateful if you could complete the accompanying questionnaires and return by post in the enclosed pre-paid envelope. The questionnaires are the same as the ones you filled in on your first and last visit to the clinic. The “yellow questionnaire” is about pain intensity and the “blue questionnaire” is about mood. If possible, please could you return the questionnaires within one week of receiving them.

Should you have any questions, please feel free to contact me by phone (0113 343 3202) or email (hcmah@leeds.ac.uk). On the behalf of the research team, I would like to sincerely thank you once again for your continued support and participation in our research project.

Yours sincerely,

Muhammad A. Hadi

Appendix V
GP information Sheet



UNIVERSITY OF LEEDS

Dear Dr.

**THE EVALUATION OF A NURSE/PHARMACIST MANAGED PAIN CLINIC: A
MIXED METHODS STUDY**

Your patient, has given their consent to be entered into this study. Your patient would not be given any new medicinal product or treatment as part of this research. The patient will receive usual care from the pain clinic. The aim of the present study is to evaluate the effectiveness of Nurse-Pharmacist managed pain clinic (NPMPC). It is an observational study. Upon discharge, patients will be interviewed about their satisfaction with the service provided by the clinic.

The research study will take place entirely at the pain clinic and should have no ongoing consequences for you. The study is being sponsored and organized by School of Healthcare, Faculty of Medicine and Health, University of Leeds. Should you have any questions, please do not hesitate to contact the undersigned.

Yours sincerely,

Muhammad A. Hadi,
School of Healthcare,
University of Leeds.
Email: hcmah@leeds.ac.uk
Tel: 0113-343-3202

Appendix VI
Patient information sheet



UNIVERSITY OF LEEDS

Evaluation of Nurse-Pharmacist Managed Pain Clinic

We would like to invite you to take part in a research study. Before you decide, you need to understand the purpose of research and what it would involve for you. Please take time to read the following information carefully. If you wish, you can discuss it with your friends and family. Should you need any further information, please feel free to contact us.

1. What is the purpose of the study?

The study will evaluate the effectiveness of nurse-pharmacist led pain clinic. We want to find out how well the pain clinic works for the patients. In particular, we would like your views on the care provided by the clinic. No new treatment will be given specifically as part of this study, but we will collect information from people receiving care at the clinic.

2. Who is doing the study?

The study is funded and organized by School of Healthcare, University of Leeds. The lead researcher is Muhammad Hadi, a PhD student at the School of Healthcare, under the supervision of Dr. Michelle Briggs, Prof. José Closs and Dr. David Alldred.

3. Why have I been invited?

You have been approached because your General practitioner (GP) has referred you to the pain clinic. We aim to include 105 adult patients who have chronic pain and have been referred to the clinic.

4. Do I have to take part?

It is totally up to you to decide. We will provide you with all the necessary information and answer all your questions related to this study. We will then ask you to sign a consent form to show that you have agreed to take part.

You can withdraw from the study at any time without giving a reason. This would not affect the care you receive.

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

You will receive the usual care from the clinic. There are two phases of the study. Participation in both phases is not compulsory and you can choose to participate only in one phase of the study if you wish.

Phase 1: In the first phase, in addition to the routine questionnaires used at the clinic, you will be asked to fill in two questionnaires. One questionnaire is about your quality of life and the other is about severity of chronic pain. These questionnaires will take about 15-20 minutes to complete. You will be asked to fill in these questionnaires three times; 1) during your first visit; 2) upon your discharge from the clinic; 3) three months after discharge. For the first two times you will be asked to fill in the questionnaires at the clinic while waiting for your appointment. For the third time, we will send you the questionnaires by mail together with a pre-paid self addressed envelope. We would like you to return the questionnaires within two weeks. We will also gather information on your age, gender, employment, history of pain, other illnesses, your mood and the intensity and impact of pain on your life, from your clinical record.

Phase 2: The second phase consists of a face to face interview. This will be conducted either at the clinic or your home, whichever you prefer. We would like to interview you within two weeks of your discharge from the clinic. The interview will be about your experience and satisfaction with the care provided by the clinic. We will send you the questions to be asked in the interview in advance, so that you can think about them. There are no right or wrong answers; we just want to hear about your experience of the pain clinic. The interview is expected to last for 20-30 minutes and if you agree, it will be audio taped. You will be asked to sign a separate consent form for the interview. You can choose to stop the interview at any time without giving any reason. We will still include the information you have already given us, unless you ask us not to. Your decision to participate in the interview will not affect the care you receive.

6. Will I be paid to participate in the study?

You will not be paid for taking part in the research.

7. What will I have to do?

You just fill in the additional questionnaires, as explained above.

8. What is the drug, device or procedure that is being tested?

No drug or device is being in particular tested in this research. You will receive usual care from the clinic.

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

There are no risks specifically associated with participation in the study. You don't have to visit the clinic or have any tests. The only possible disadvantage is the time taken to complete the questionnaires and interview (optional).

10. What are the potential benefits of taking part?

We cannot promise the study will help you but the information we get from this study should help improve the care provided by the clinic for other people with chronic pain. It will help us understand the working of the clinic and patient satisfaction with the care provided by the clinic.

11. What happens when the research stops?

You will continue to receive usual care from your GP. You can be referred back to the clinic if desired by your GP.

12. Will my personal data collected during the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. All data obtained will be anonymised and kept in a password protected personal computer. Only the research staff will have access to your data. However, if you tell us something that gives us cause of concern about your health or care, with your permission, we will share this information with relevant healthcare professionals. Your identity will not be revealed in any report and publication. Your GP will be informed about your participation in the research.

13. What will happen to the results of the study?

This project is a key part of the researcher's PhD thesis. We will be happy to share the information about the findings when it is completed in 2013. Findings from the study will be presented at conferences and submitted to relevant journals. Your identity will not be revealed in any publication.

14. What if there is a problem?

If you have any complaints or concerns about the study you can speak to your nurse/researcher who will do their best to answer your questions. Should you have a complaint about the way it is being conducted, please contact his supervisor Dr. Michelle Briggs (Tel: 0113 343 6885; email: m.briggs@leeds.ac.uk) or the Faculty Head of Research Support Ms. Clare Skinner (Tel: 0113 343 4897; email: c.e.skinner@leeds.ac.uk). You can withdraw from the study at any time without giving a reason.

15. Contact for further information

If you require further information, please feel free to ask any questions you wish.

Investigator:

Muhammad A. Hadi
PhD student
School of Healthcare,
Baines Wing, University of Leeds
LS2 9UT Leeds, UK
Tel: 0113 343 3202
Email: hcmah@leeds.ac.uk

Clinical Nurse Specialist:

Kathryn Marczewski
Clinical Nurse Specialist
Leeds Community Healthcare
NHS Trust
Tel: 0113 392 9819
Email: kathryn.marczewski@nhs.net

**Thank you for your time for reading this information
Please keep this copy.**

Appendix VII**Patient information sheet - phase 2****UNIVERSITY OF LEEDS****Evaluation of Nurse-Pharmacist Managed Pain Clinic**

Thank you very much for your participation in Phase 1 of the study. We would like to invite you to take part in the Phase 2 of the study. Before you decide, you need to understand the purpose of research and what it would involve for you. Please take time to read the following information carefully. If you wish, you can discuss it with your friends and family. Should you need any further information, please feel free to contact us. Thank you for taking the time to read this.

1. What is the purpose of the study?

The purpose of phase 2 is to evaluate patient satisfaction with the service provided by the pain clinic.

2. Who is doing the study?

The research team is the same as of Phase 1. The lead researcher is Muhammad Hadi, a PhD student at the School of Healthcare, under the supervision of Dr. Michelle Briggs, Prof. José Closs and Dr. David Alldred.

3. Why have I been invited?

You have been approached because you indicated earlier in your consent form that you were interested in participating in an interview as well. We aim to include 15-25 adult chronic pain patients referred to the clinic.

4. Do I have to take part?

It is totally up to you to decide. We will provide you with all the necessary information and answer any questions you may have about this study. We will then ask you to sign a consent form to show that you have agreed to take part.

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

You will be asked to participate in a face-to-face interview. This will take about 30-40 minutes. The interview can take place at the pain clinic or at your home, whichever you prefer. We would like to interview you within two weeks of your discharge from the clinic and you will be contacted by telephone to arrange a time and venue. You will be interviewed by Mr. Muhammad Hadi (lead researcher, PhD student) who will audio-record the conversation. You will be asked to sign a separate consent form for the interview. Your decision to participate in the interview will neither affect the standard of care nor the participation in the research

6. Will I be paid to participate in the study?

You will not be paid any money for participation in the research.

7. What will I have to do?

You will be asked to participate in the interview as explained above. You will be asked about your expectations of the pain clinic; 2) things that you liked and disliked in the clinic; 3) satisfaction with the service provided; 4) impact (positive or negative) of the clinic on your pain. At the end of the interview, there will be additional time to discuss any other aspects of the clinic, if they have not been covered during the interview.

8. What is the drug, device or procedure that is being tested?

No drug or device is being tested in this research. You will receive usual care from the clinic.

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

There are no risks specifically associated with participation in the study. The only disadvantage is that it will take 30-40 minutes of your time and you may have to travel to the clinic, should you decide to be interviewed there.

10. What are the potential benefits of taking part?

We cannot promise the study will help you, but we hope that the information we get from this study will help improve the service provided by the pain clinic for future patients. It will help us understand the working of the clinic from the patient's point of view.

11. What happens when the research stops?

You will continue to receive usual care from your GP. You can be referred back to the clinic if desired by your GP.

12. Will my personal data collected during the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The interview will be audio recorded and then transcribed onto a computer. All data obtained will be anonymised and kept in a password protected computer. Your response will be treated with full confidentiality and anyone who takes part in the research will be identified only by code numbers. Only the research staff will have access to your data. However, if you tell us something that gives us cause of concern about your health or care, with your permission, we will share this information with relevant healthcare professionals. Your identity will not be revealed in any report or publication. Your GP will be informed about your participation in the research. If the interview upsets you and you feel you would like some additional help after the interview I will be able to advise you who to contact, for example GP, or Community Nurse, You can choose to stop the interview at any time without giving any reason. We will still include the part of the interview you have already completed, unless you ask us not to.

13. What will happen to the results of the study?

This project is a key part of the researcher's PhD thesis, which will be published by the end of 2013. We will be happy to share the information about the findings when it is completed. Findings from the study will be presented at conferences and submitted to relevant journals. Your identity will not be revealed in any materials made public from the study.

14. Who has reviewed this study?

The study has been reviewed and approved by Leeds Research Ethics Committee.

15. What if there is a problem?

If you have any complaints or concerns about the study you can speak to your clinical nurse specialist or the lead researcher who will do their best to answer your questions. Should you have a complaint about the way it is being conducted, please contact his supervisor Dr. Michelle Briggs (Tel: 0113 343 6885; email: m.briggs@leeds.ac.uk) or the Faculty Head of Research Support Ms. Clare Skinner (Tel: 0113 343 4897; email: c.e.skinner@leeds.ac.uk). You can withdraw from the study at any time without giving a reason.

Contact for further information

If you require further information, please feel free to contact the following people.

Lead researcher

Muhammad A. Hadi
PhD student
School of Healthcare,
Baines wing, University of Leeds
LS2 9UT Leeds, UK
Tel: 0113 3433202
Email: hcmah@leeds.ac.uk

Clinical nurse specialist

Kathryn Marczewski
Clinical Nurse Specialist
Leeds community Healthcare
NHS Trust
Tel: 0113 3929819
Email: kathryn.marczewski@nhs.net

**Thank you for your time for reading this information
Please keep this copy.**

Appendix VIII
Patient Consent Form - Phase 1

Project title: Evaluation of Nurse-Pharmacist managed pain clinic

Research Team: Muhammad Hadi, Dr. Michelle Briggs, Prof. Jose Closs,
 Dr. David Alldred, Kathryn Marczewski

Note: Please read each statement carefully and initial each statement in the box provided

1. I confirm that I have read and understood the information sheet.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason. In this case my medical care or legal rights will not be affected in any way.
3. I give permission for my GP to be informed of my participation in the study.
4. I agree to take part in the above study.
5. I give permission to regulatory authorities to access the research data for auditing purposes.
6. I would like to be considered for interview as well.

Name of patient	Date	Signature
Researcher	Date	Signature

Appendix IX
Patient Consent Form - Phase 2



UNIVERSITY OF LEEDS

Project title: Evaluation of Nurse-Pharmacist managed pain clinic

Research Team: Muhammad Hadi, Dr. Michelle Briggs, Prof. Jose Closs,
 Dr. David Alldred, Kathryn Marczewski

Note: Please read each statement carefully and initial each statement in the box provided

- | | |
|---|--|
| 1. I confirm that I have read and understood the information sheet. | <input style="width: 60px; height: 30px;" type="checkbox"/> |
| 2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason. In this case my medical care or legal rights will not be affected in any way. | <input style="width: 60px; height: 30px;" type="checkbox"/>
<input style="width: 60px; height: 30px;" type="checkbox"/> |
| 3. I agree to take part in the interview. | |
| 4. I give permission to use anonymised quotes from my interviews in relevant publications, and I understand that my identity will not be revealed and such information will not be traced back to me. | <input style="width: 60px; height: 30px;" type="checkbox"/>
<input style="width: 60px; height: 30px;" type="checkbox"/> |
| 5. I give permission to regulatory authorities to access the research data for auditing purposes. | <input style="width: 60px; height: 30px;" type="checkbox"/> |
| 6. I give permission to audiotape my interview. | <input style="width: 60px; height: 30px;" type="checkbox"/> |

Name of patient	Date	Signature
-----------------	------	-----------

Researcher	Date	Signature
------------	------	-----------

Appendix X

Patient sociodemographic and clinical questionnaire

Serial no:

Patient Sociodemographic and Clinical questionnaire

1. Age _____ years
2. Gender Male Female
3. Marital status
- Single Married Divorced/Separated Widowed
4. Do you live with your Partner/Spouse and/or Children?
- Yes No
5. Employment status
- Public Private Self Employed Retired Unemployed (pain)
- Unemployed (other reasons) Student
6. Ethnicity
- White (English/ Welsh/ Scottish/ Northern Irish/ British) White (Others)
- Asian/ Asian British Chinese African Caribbean Arab
- Others Please specify: _____
7. Highest Education Level
- GCSE/O-levels A-level/NVQ Diploma Degree Postgraduate
8. Pain Sites
- Head, face, neck Cervical region Upper shoulder and limbs Thoracic region
- Abdominal region Low back Lower limb Pelvic region Anal, perineal, genital
9. Duration of pain
- Less than 1 year 1-3 years 3-5 years 5-10 years More than 10 years
10. Have you attended a pain clinic before?
- Yes No Not sure
- If yes then please specify _____

Appendix XI

Clinical data collection form (Baseline)

Clinical Data Collection Form for Researcher (Baseline)

Patient ID: _____ Date of first appointment: _____

1. Co-morbidities

Diabetes Hypertension HF Ischemic heart diseases CKD

Others: _____

2. Route of Referral

GP Community Pharmacist Hospital Doctor District Nurse

Self Other _____

3. Medication History



Drug	Dose	Comment

Appendix XII
Clinical data collection form (Discharge)

Clinical Data Collection Form for Researcher (Discharge)

Patient ID: _____ Date of first appointment: _____

1. Number of visits to clinic

1 2 3 4 5 6 7

2. Consultation

Nurse only Nurse + Pharmacist

3. Medication reviewed by pharmacist

Yes No

4. Recommendations made to GP about drugs

Yes No

5. Identification of Drug related Problem (DRP)/ Nature of recommendation

Nature	Comment

Appendix XIII

Ethical approval



Health Research Authority

NRES Committee Yorkshire & The Humber - Leeds West

First Floor
Millside
Mill Pond Lane
Leeds
LS6 4RA

Telephone: 0113 3050122
Facsimile: 0113 8556191

19 December 2011

Mr Muhammad Hadi
PhD student
School of Healthcare,
Faculty of Medicine and Health,
University of Leeds
LS2 9UT

Dear Mr Hadi

Study title: THE EVALUATION OF A NURSE/PHARMACIST
MANAGED PAIN CLINIC: A MIXED METHODS STUDY
REC reference: 11/YH/0415
Protocol number: N/A

Thank you for your letter of 16 December 2011, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair and Professor Topping.

Confirmation of ethical opinion

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

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

The consent forms should have the complete section for regulatory authorities, at present it is too brief. Guidance is available from the NRES website, www.nres.npsa.nhs.uk.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Confirmation should also be provided to host organisations together with relevant documentation.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Evidence of insurance or indemnity		28 September 2011
GP/Consultant Information Sheets	1	01 August 2010
Investigator CV		20 October 2011
Letter of invitation to participant	1	19 October 2011
Other: CV for Dr Briggs		20 October 2011
Other: CV for Dr Closs		20 October 2011
Other: CV for Dr Alldred		21 October 2011
Other: Data collection form-patient version	1	01 August 2011
Other: DCF-CI Baseline	1	01 August 2011
Other: DCF-CI Discharge	1	01 August 2011
Participant Consent Form: Phase 1	1.1	23 November 2011
Participant Consent Form: Phase 2	1.1	23 November 2011
Participant Information Sheet: Phase 1	1.1	23 November 2011
Participant Information Sheet: Phase 2	1.1	23 November 2011
Protocol	1	26 September 2011
Questionnaire: Brief Pain Inventory (Short Form)		
Questionnaire: Hospital Anxiety and Depression Scale		
Questionnaire: Chronic Pain Grade		
Questionnaire: SF-36		
REC application		20 October 2011
Response to Request for Further Information		16 December 2011

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "*After ethical review – guidance for researchers*" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

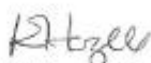
Further information is available at National Research Ethics Service website > After Review

11/YH/0415

Please quote this number on all correspondence

With the Committee's best wishes for the success of this project

Yours sincerely



**Dr Rhona Bratt
Chair**

Email: Elaine.hazell@nhs.net

Enclosures: "After ethical review – guidance for researchers"

Copy to: Mrs Rachel E de Souza, University of Leeds
Linda Dobrzanska, NHS Leeds

APPENDIX XIV

NHS research governance approval



Leeds Community Healthcare **NHS**
NHS Trust

Telephone enquiries, please contact:
Linda Dobrzanska
Phone: 0113 203 3473 / 07958066828
Email: linda.dobrzanska@nhsleeds.nhs.uk

Stockdale House
Headingley Office Park
Victoria Road
Leeds
LS6 1PF

23 December 2011

Mr Muhammad Hadi
PhD student
School of Healthcare
Faculty of Medicine and Health
University of Leeds
Leeds LS2 9UT

Tel: 0113 203 3473
Fax: 0113 203 3400
www.leedscommunityhealthcare.nhs.uk

LCH Ref:NP/0091

Dear Mr. Hadi

Re: The evaluation of a Nurse/Pharmacist managed pain clinic: A mixed methods study

Thank you for your recent submission requesting NHS permission for research to be conducted in Leeds Community Healthcare NHS Trust for the above study.

I am pleased to confirm that NHS permission for the above research has been granted on the basis described in the application form, protocol and supporting documentation.

Conditions of approval

You should be aware that approval is granted subject to the conditions specified below:

- In undertaking this research you must comply with the requirements of the Research Governance Framework for Health and Social Care (2nd edition 2005) which is mandatory for all NHS employees.
- Consent for Leeds Community Healthcare NHS Trust to audit your project, which is implicit in your acceptance of approval.
- Where any amendments, substantial or non substantial are made throughout the course of the study these should be notified to Leeds Community Healthcare NHS Trust.
- A copy of the final study report should be forwarded to Leeds Community Healthcare NHS Trust.
- Should any serious adverse event(s) occur throughout the course of the study these should be notified to Leeds Community Healthcare NHS Trust using the contact details set out above.

Chairman: David Richardson CBE

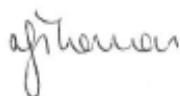
Chief Executive: Rob Webster

- You comply with Leeds Community Healthcare NHS Trust on the handling of data. These policies are available from the research manager.

Should you require any clarification regarding any of the points raised above, or have any further queries in relation to approvals and post approval study management process then please do not hesitate to contact me on 0113 2033473.

Finally, may I take this opportunity to wish you well with your study and look forward to hearing about your progress in due course.

Yours sincerely



Dr. Amanda Thomas
Medical Director

Approved documents

The documents reviewed were:

<i>Document</i>	<i>Version</i>	<i>Date of Document</i>
REC Form	3.3	
SSIF	3.3	
Participant Information Sheet Phase 1 Phase 2	1.1 (both)	23 November 2011 (both)
Research protocol	1.0	26 September 2011
Consent Form Phase 1 Phase 2	1.1 (both)	23 November 2011 (both)
GP Information Letter	1.0	1 August 2011
CV of researcher		reviewed
CV of academic researcher (if applicable)		reviewed
Sponsor identified		University of Leeds

Cc:

(1) Ms Kathryn Marczewski
Clinical nurse specialist pain management
Pain Clinic
St. George's Centre
Middleton
Leeds LS10 4UZ

(2) Rachel De Souza
Faculty of Medicine and Health Research Office
Room 10.110
Level 10
Worsley Building
Clarendon Way
Leeds LS2 9NL

Appendix XV

Letter of access for research



Leeds Community Healthcare 
NHS Trust

Telephone enquiries, please contact: 0113 2033462

Email: andy.smith@nhsleeds.nhs.uk

MR Muhammad Hadi
PhD student
School of Healthcare
Faculty of medicine and Health
University of Leeds
LS2 9UT

Recruitment Department
Headingley Business Park
Stockdale House
Victoria Road
Leeds
LS6 1PF

12th January 2012

Dear Muhammad

Letter of access for research

Research Study: The evaluation of a nurse/pharmacist managed pain clinic

LCH Ref: NP/0091

This letter confirms your right of access to conduct research through Leeds Community Healthcare NHS Trust for the purpose and on the terms and conditions set out below. This right of access commences on 11/1/12 and ends on 3/4/14 unless terminated earlier in accordance with the clauses below.

You have a right of access to conduct such research as confirmed in writing in the letter of permission for research from Leeds Community Healthcare NHS Trust. Please note that you cannot start the research until the Principal Investigator for the research project has received a letter from us giving permission to conduct the project.

The information supplied about your role in research at Leeds Community Healthcare NHS Trust has been reviewed and you do not require an honorary research contract with Leeds Community Healthcare NHS Trust. We are satisfied that such pre-engagement checks as we consider necessary have been carried out.

You are considered to be a legal visitor to Leeds Community Healthcare NHS Trust premises. You are not entitled to any form of payment or access to other benefits provided by Leeds Community Healthcare NHS Trust to employees and this letter does not give rise to any other relationship between you and Leeds Community Healthcare NHS Trust, in particular that of an employee.

While undertaking research through Leeds Community Healthcare NHS Trust, you will remain accountable to your employer University of Leeds but you are required to follow the reasonable instructions of Ms Kathryn Marczewski in Leeds Community Healthcare NHS Trust or those given on her behalf in relation to the terms of this right of access.

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation by Leeds Community Healthcare NHS Trust in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

Chair: David Richardson CBE

Chief Executive: Rob Webster

You must act in accordance with Leeds Community Healthcare NHS Trust policies and procedures, which are available to you upon request, and the Research Governance Framework.

You are required to co-operate with Leeds Community Healthcare NHS Trust in discharging its duties under the Health and Safety at Work etc Act 1974 and other health and safety legislation and to take reasonable care for the health and safety of yourself and others while on Leeds Community Healthcare NHS Trust premises. You must observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of any other contract holder and you must act appropriately, responsibly and professionally at all times.

You are required to ensure that all information regarding patients or staff remains secure and *strictly confidential* at all times. You must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice (<http://www.dh.gov.uk/assetRoot/04/06/92/54/04069254.pdf>) and the Data Protection Act 1998. Furthermore you should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

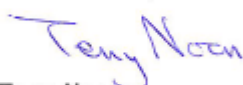
You should ensure that, where you are issued with an identity or security card, a bleep number, email or library account, keys or protective clothing, these are returned upon termination of this arrangement. Please also ensure that while on the premises you wear your ID badge at all times, or are able to prove your identity if challenged. Please note that Leeds Community Healthcare NHS Trust accepts no responsibility for damage to or loss of personal property.

We may terminate your right to attend at any time either by giving seven days' written notice to you or immediately without any notice if you are in breach of any of the terms or conditions described in this letter or if you commit any act that we reasonably consider to amount to serious misconduct or to be disruptive and/or prejudicial to the interests and/or business of Leeds Community Healthcare NHS Trust or if you are convicted of any criminal offence. Your substantive employer is responsible for your conduct during this research project and may in the circumstances described above instigate disciplinary action against you.

Leeds Community Healthcare NHS Trust will not indemnify you against any liability incurred as a result of any breach of confidentiality or breach of the Data Protection Act 1998. Any breach of the Data Protection Act 1998 may result in legal action against you and/or your substantive employer.

If your current role or involvement in research changes, or any of the information provided in your Research Passport changes, you must inform your employer through their normal procedures. You must also inform your nominated manager in Leeds Community Healthcare NHS Trust.

Yours sincerely



Terry Noon
Recruitment Assistant

cc: Linda Dobrzanska, R&D office at NHS Leeds
HR Department,

Chair: David Richardson CBE

Chief Executive: Rob Webster

Appendix XVI

NHS ethics approval - substantial amendment


Health Research Authority
NRES Committee Yorkshire & The Humber - Leeds West

 First Floor
 Millside
 Mill Pond Lane
 Leeds
 LS6 4RA

 Tel: 0113 30 50118
 Fax:

02 January 2013

Mr Muhammad Hadi
 PhD student
 School of Healthcare, Faculty of Medicine and Health, University of Leeds
 LS2 9UT

Dear Mr Hadi

Study title: THE EVALUATION OF A NURSE/PHARMACIST
 MANAGED PAIN CLINIC: A MIXED METHODS STUDY
REC reference: 11/YH/0415
Protocol number: N/A
Amendment number: 1
Amendment date:
IRAS project ID: 87848

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The Committee was concerned about the scientific value of the proposed reduced outcome measurement thus suggested that you agree to sample size reduction but continue with original protocol in other respects. You agreed to retain SF36 for participants at the beginning and end of the study and discuss the changes proposed with your supervisor before proceeding.

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Cover letter-List of changes made in the protocol	N/A	30 November 2012
Protocol	2.0	30 November 2012
Notice of Substantial Amendment (non-CTIMPs)	1	

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

11/YH/0415:	Please quote this number on all correspondence
-------------	--

Yours sincerely

p.p. 

Dr Rhona Bratt
Chair

E-mail: nrescommittee.yorkandhumber-leedswest@nhs.net

Enclosures: List of names and professions of members who took part in the review

*Copy to: NHS Leeds
Mrs Rachel E de Souza, University of Leeds*

Appendix XVII

Brief Pain Inventory (BPI)

STUDY ID# _____	HOSPITAL # _____	
DO NOT WRITE ABOVE THIS LINE		
Brief Pain Inventory (Short Form)		
Date: _____ / _____ / _____	Time: _____	
Name: _____		
Last	First	Middle Initial

1. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?

1. Yes	2. No
--------	-------

2. On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.

3. Please rate your pain by circling the one number that best describes your pain at its worst in the last 24 hours.

0	1	2	3	4	5	6	7	8	9	10
										Pain as bad as you can imagine

4. Please rate your pain by circling the one number that best describes your pain at its least in the last 24 hours.

0	1	2	3	4	5	6	7	8	9	10
										Pain as bad as you can imagine

5. Please rate your pain by circling the one number that best describes your pain on the average.

0	1	2	3	4	5	6	7	8	9	10
										Pain as bad as you can imagine

6. Please rate your pain by circling the one number that tells how much pain you have right now.

0	1	2	3	4	5	6	7	8	9	10
										Pain as bad as you can imagine

7. What treatments or medications are you receiving for your pain?

8. In the last 24 hours, how much relief have pain treatments or medications provided? Please circle the one percentage that most shows how much relief you have received.

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
No Relief										Complete Relief

9. Circle the one number that describes how, during the past 24 hours, pain has interfered with your:

A. General Activity

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

B. Mood

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

C. Walking Ability

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

D. Normal Work (includes both work outside the home and housework)

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

E. Relations with other people

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

F. Sleep

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

G. Enjoyment of life

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

Appendix XVIII

Hospital Anxiety and Depression Scale (HADS)

Hospital Anxiety and Depression
Scale (HADS)

This questionnaire is designed to help your clinician to know how you feel. Read each item below and **underline the reply** which comes closest to how you have been feeling in the past week. Ignore the numbers printed at the edge of the questionnaire.

Don't take too long over your replies, your immediate reaction to each item will probably be more accurate than a long, thought-out response.

FOLD HERE

A	D			A	D
		I feel tense or 'wound up'	I feel as if I am slowed down		
3		Most of the time	Nearly all the time	3	
2		A lot of the time	Very often	2	
1		From time to time, occasionally	Sometimes	1	
0		Not at all	Not at all	0	
		I still enjoy the things I used to enjoy	I get a sort of frightened feeling like 'butterflies' in the stomach		
0		Definitely as much	Not at all	0	
1		Not quite so much	Occasionally	1	
2		Only a little	Quite often	2	
3		Hardly at all	Very often	3	
		I get a sort of frightened feeling as if something awful is about to happen	I have lost interest in my appearance		
3		Very definitely and quite badly	Definitely	3	
2		Yes, but not too badly	I don't take as much care as I should	2	
1		A little, but it doesn't worry me	I may not take quite as much care	1	
0		Not at all	I take just as much care as ever	0	
		I can laugh and see the funny side of things	I feel restless as if I have to be on the move		
0		As much as I always could	Very much indeed	3	
1		Not quite so much now	Quite a lot	2	
2		Definitely not so much now	Not very much	1	
3		Not at all	Not at all	0	
		Worrying thoughts go through my mind	I look forward with enjoyment to things		
3		A great deal of the time	As much as I ever did	0	
2		A lot of the time	Rather less than I used to	1	
1		Not too often	Definitely less than I used to	2	
0		Very little	Hardly at all	3	
		I feel cheerful	I get sudden feelings of panic		
3		Never	Very often indeed	3	
2		Not often	Quite often	2	
1		Sometimes	Not very often	1	
0		Most of the time	Not at all	0	
		I can sit at ease and feel relaxed	I can enjoy a good book or radio or television programme		
0		Definitely	Often	0	
1		Usually	Sometimes	1	
2		Not often	Not often	2	
3		Not at all	Very seldom	3	

Now check that you have answered all the questions

A D
□ □

Appendix XIX

SF-36

Your Health and Well-Being

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. *Thank you for completing this survey!*

For each of the following questions, please tick the one box that best describes your answer.

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
▼	▼	▼	▼	▼
<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

2. Compared to one year ago, how would you rate your health in general now?

Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago
▼	▼	▼	▼	▼
<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, limited a lot ▼	Yes, limited a little ▼	No, not limited at all ▼
a. <u>Vigorous activities</u> , such as running, lifting heavy objects, participating in strenuous sports.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
b. <u>Moderate activities</u> , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
c. <u>Lifting or carrying groceries</u>	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
d. <u>Climbing several flights of stairs</u>	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
e. <u>Climbing one flight of stairs</u>	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
f. <u>Bending, kneeling, or stooping</u>	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
g. <u>Walking more than a mile</u>	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
h. <u>Walking several hundred yards</u>	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
i. <u>Walking one hundred yards</u>	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
j. <u>Bathing or dressing yourself</u>	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Cut down on the <u>amount of time</u> you spent on work or other activities	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
b. <u>Accomplished less</u> than you would like	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
c. Were limited in the <u>kind</u> of work or other activities	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
d. Had <u>difficulty</u> performing the work or other activities (for example, it took extra effort)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

5. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Cut down on the <u>amount of time</u> you spent on work or other activities	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
b. <u>Accomplished less</u> than you would like	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
c. Did work or other activities <u>less carefully than usual</u>	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours, or groups?

Not at all	Slightly	Moderately	Quite a bit	Extremely
▼	▼	▼	▼	▼
<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

7. How much bodily pain have you had during the past 4 weeks?

None	Very mild	Mild	Moderate	Severe	Very severe
▼	▼	▼	▼	▼	▼
<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
▼	▼	▼	▼	▼
<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Did you feel full of life?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
b. Have you been very nervous?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
c. Have you felt so down in the dumps that nothing could cheer you up?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
d. Have you felt calm and peaceful?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
e. Did you have a lot of energy?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
f. Have you felt downhearted and low?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
g. Did you feel worn out?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
h. Have you been happy?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
i. Did you feel tired?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

11. How TRUE or FALSE is each of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
	▼	▼	▼	▼	▼
a. I seem to get ill more easily than other people.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
b. I am as healthy as anybody I know.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
c. I expect my health to get worse.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
d. My health is excellent.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

Thank you for completing these questions!

Appendix XX

Chronic Pain Grade Questionnaire (CPG)

For the following questions with a scale of 1-10 please circle one number only

1. How would you rate your pain on a 1-10 scale at the present time, that is right now, where 0 is "no pain" and 10 is "pain as bad as could be"?

No pain												Pain as bad as could be
	0	1	2	3	4	5	6	7	8	9	10	

2. In the past six months, how intense was your worst pain rated on a 0-10 scale where 0 is "no pain" and 10 is "pain as bad as could be"?

No pain												Pain as bad as could be
	0	1	2	3	4	5	6	7	8	9	10	

3. In the past six months, on average, how intense was your pain rated on a 1-10 scale, where 0 is "no pain" and 10 is "pain as bad as could be"? (That is, your usual pain at times you were experiencing pain.)

No pain												Pain as bad as could be
	0	1	2	3	4	5	6	7	8	9	10	

4. About how many days in the last six months have you been kept from your usual activities (work, school or housework) because of this pain?

0-6 days	
7-14 days	
15-30 days	
31 or more days	

5. In the past six months, how much has this pain interfered with your daily activities rated on a 1-10 scale where 0 is "no interference" and 10 is "unable to carry on activities"?

No interference												Unable to carry on activities
	0	1	2	3	4	5	6	7	8	9	10	

6. In the past six months, how much has this pain changed your ability to take part in recreational, social and family activities where 0 is "no change" and 10 is "extreme change"?

No change												Extreme change
	0	1	2	3	4	5	6	7	8	9	10	

7. In the past six months, how much has this pain changed your ability to work (including housework) where 0 is "no change" and 10 is "extreme change"?

No change												Extreme change
	0	1	2	3	4	5	6	7	8	9	10	

Appendix XXI

Topic guide for qualitative interviews

Expectations

What were your expectations from the pain clinic?

Have these changed now?

Has the care provided by NPMPC met your expectations? Disappointed?

Expectations of prognosis

Is this different from before?

Efficacy

Did it help?

What was the most helpful part?

How did it help?

Did they help you to manage problems with your pain medication?

Understanding and Self-management

Did it help you to understand your problem?

Was the information provided adequate?

Do you feel you have control over problem?

Do you think you can now manage your problem better on your own?

Interaction with Nurse and Pharmacist

Did they communicate well? Listened to your problem?

Did they encourage you to be active and self manage?

Did they give you enough time?

Have you had any problems in following their instructions?

Could they have done any better?

Anything particularly good or bad about the service?

Do you agree with their pain management approach?

Overall Satisfaction

Any other issues?

How do you think care could have been improved?

How do you compare it with other treatments?

Note: In the beginning of each interview, patients were also asked about their history of chronic pain, its impact on their lives and their experiences of dealing with various healthcare professionals in relation with its management.