INTEGRATIVE MEDICINE FOR MUSCULOSKELETAL DISORDERS: A MIXED METHODS STUDY

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Abstract

The rising prevalence and burden of musculoskeletal disorders (MSDs) is a major health concern, affecting quality of life and causing an economic burden to the individual as well as society as a whole. Integrative medicine (IM), a complex intervention which includes complementary and alternative medicine (CAM) and conventional medicine, emphasising a holistic approach and patient-practitioner relationship, is a popular option for people with MSDs. The Medical Research Council's (MRC) framework for evaluating complex interventions was used to explore IM for MSDs and to provide future guidance. The aims of this research study were to develop a theoretical understanding of IM; and to determine the feasibility of carrying out a mixed methods study of IM for MSDs in the UK.

For the initial development stage of the MRC framework, a mixed methods review consisting of a mapping review, a systematic review, and a narrative review was performed to develop a theoretical understanding of IM for MSDs. There was promising evidence for integrative treatments provided for low back pain and patients perceived benefits in receiving CAM for their MSDs. However, the components identified in the review as essential in IM were rarely discussed or reported in research. The lack of a standard definition of IM and an absence of guidelines for reporting IM has hindered the process of developing its evidence base. Identification of authentic IM research was challenging, and evidence on IM for MSDs remains inadequate. In particular, no research studies explored IM as a package of care for MSDs in a secondary National Health Service (NHS) setting in the United Kingdom (UK).

As part of the second stage of the MRC framework, the feasibility stage, a mixed methods research study was conducted to assess the feasibility of evaluating IM for MSDs at the Royal London Hospital for Integrated Medicine (RLHIM). The results of this mixed methods study of 60 patients followed up over 12 months suggested that the approach was generally feasible. Feasibility was reflected in four aspects: 1). Integrative treatments potentially produced moderate pain relief and improved health related quality of life (HRQoL) at four months which was sustained at 12 months, 2). Patients' general acceptability of treatment was good, 3). Patients demanded integrative treatment, and 4). Overall research design was feasible with patients reporting positive experiences by participating in the research study. Issues and

challenges were identified in the research procedure, including difficulties identifying and recruiting eligible patients, working with busy NHS practitioners, and failure of accessing unit cost data from the hospital. These issues need to be considered in future IM research. In addition, patients suggested particular outcome measures, and a narrative approach was preferred. An IM model was hypothesised from the findings of this research study which represented patients' perception of good IM care.

This research study is the first step in evaluating IM for MSDs. It has provided essential information needed to move the evidence base for IM; and provided original data on the feasibility and practicality of conducting the study. Following the next stage of the MRC framework, future research evaluating IM effectiveness, exploring the potential interaction between the components of the model, and whether these components were associated with the overall effects of IM, using a mixed methods design under a pragmatic approach is warranted.

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List of Abbreviations

ADRs	adverse drug reactions
AE	adverse event
AMED	allied and complementary medicine
ANOVA	analysis of variance
BAcC	British acupuncture council
BMAS	British medical acupuncture society
BMD	biomedically trained doctors
CAHCIM	consortium of academic health centers for integrative medicine
CAM	complementary and alternative medicine
CAQDAS	computer assisted qualitative data analysis software
CBT	cognitive behavioural therapy
CCGs	clinical commissioning groups
CDCP	centre for disease control and prevention
CDR	clinical data repository
CHM	Chinese herbal medicine
CI	confidence interval
CINAHL	cumulative index to nursing and allied health literature
CLT	central limit theorem
CM	conventional medicine
CNHC	complementary and natural healthcare council
CONSORT	consolidated standards of reporting trials
COREQ	consolidated criteria for reporting qualitative research
CPGS	chronic pain grade scale
DH	department of health
DNA	did not attends
EBM	evidence-based medicine
EI	epidural injection
EMDR	eye movement desensitization and reprocessing
EPR	electronic patient record
EV	external validity
FDA	food and drug administration
GP	general practitioner
HADS	hospital anxiety and depression scale
HCAMQ	holistic complementary and alternative health questionnaire
HRQoL	health-related quality of life
ICD	international classification of diseases
IHC	integrative health care
IM	integrative medicine
IPA	interpretative phenomenological analysis
IPC	inter-professional collaboration
ITT	intention-to-treat
IV	internal validity

JOA	Japanese orthopaedic association score
LBP	low back pain
LDH	lumbar disk herniation
LTCs	long term condition
MANOVA	multivariate analysis of variance
MCAR	missing completely at random
MCS	mental component summary
MD	mean difference
ME	myalgic encephalopathy
mJOA	modified Japanese orthopedic association
MMR	mixed-methods research
MPQ	McGill pain questionnaire
MRC	medical research council
MSDs	musculoskeletal disorders
MUS	medically unexplained symptoms
N/A	not available
NHNN	national hospital for neurology and neurosurgery
NHS	national health service
NICE	national institute for health and care excellence
NRS	numerical rating scale
NSAIDs	non-steroidal anti-inflammatory drugs
OA	osteoarthritis
ODI	Oswestry pain disability index
PCS	physical component summary
PCT	primary care trust
PDI	pain disability index
PEQ	patient expectation questionnaire
PHIND	public health intervention development scheme
PPM	personalised and precision medicine
PR	patient representative
PRISMA	preferred reporting items for systematic reviews and meta-analyses
PRO	patient reported outcome
PROM	patient report outcome measure
PSD	patient service department
QALY	quality adjusted life year
QUAL	qualitative
QUAN	quantitative
RA	rheumatoid arthritis
RCT	randomised controlled trial
RLHIM	Royal London hospital for integrated medicine
RNOH	Royal National Orthopaedic Hospital
SMD	standardised mean differences
SR	systematic review
SRM	standardised response mean
STRICTA	standards for reporting interventions in clinical trials of

	acupuncture
STROBE	strengthening the reporting of observational studies in epidemiology
TCAMP	traditional, complementary and alternative medicine practitioners
TCM	traditional Chinese medicine
TENS	transcutaneous electrical nerve stimulation
TKM	traditional Korean medicine
TMD	temporomandibular disorder
TMS	transcranial magnetic stimulation
UCH	university college hospital
UK	United Kingdom
USA	United States of America
VAS	visual analogue scale
WHO	world health organisation
WSR	whole system research

Chapter 1 Introduction

1.1 Overview of thesis

This thesis describes mixed-methods research (MMR) on the use of integrative medicine (IM) for musculoskeletal disorders (MSDs). IM in this study represents a holistic approach that usually involves complementary and alternative medicine (CAM) and the use of conventional treatment. This research study was designed in alignment with the Medical Research Council's (MRC) framework for evaluating complex interventions, and used pragmatism as the philosophy underpinning the research study. In alignment with the MRC framework, the aims of this research study were: 1). To develop a theoretical understanding of IM; and 2). To determine the feasibility of carrying out MMR on integrative treatment for MSDs in a National Health Service (NHS) hospital in the United Kingdom (UK).

The thesis comprises seven chapters, with each chapter (except Chapters 1 and 7) beginning with an introduction and concluding with a summary. An outline of each chapter is given below.

Chapter 1 (introduction) provides an overview of the structure of the PhD thesis and outlines each chapter. The research student's personal background and philosophical stance in conducting and interpreting this research study are discussed. A brief review on the epidemiological background of MSDs, including their definition, prevalence, and currently available interventions, are given. How IM is considered as a complex intervention and the conceptual MRC framework used to guide evaluating IM as a complex intervention is discussed. This is followed by the aims and objectives of the whole research study and how it was aligned with the framework of this research study.

In keeping with the MRC framework development stage and the first research aim, Chapter 2 (literature review) explores the theoretical background and evidence for IM as a complex intervention. It consists of three distinct Sections: 1). Background of IM, including terminology, current available definitions; and the key elements and possible components in defining IM; 2). A systematic review evaluating integrative treatment for low back pain (LBP); and 3). A narrative review exploring patients' experiences in receiving CAM treatment for MSDs. The reasons for choosing the topic LBP for the systematic review and CAM for MSDs for the narrative review are given in detail in chapter 2.

Chapter 3 (methodology and methods) presents the overarching methodology and detailed methods of the mixed methods feasibility study, which is in alignment with the feasibility stage of the MRC framework and the second research aim. The chapter starts with justification of each aspect of study design, followed by a full description of the procedure of the convergent mixed methods feasibility study. Details of the research procedures, outcome measures, data collection and analysis are presented separately for quantitative and qualitative design, followed by the methods used in interpretation and reporting of the final MMR results. Ethical considerations at the design stage are presented at the end of this chapter.

Chapter 4 presents the results of quantitative data collected in the feasibility study. Findings on response and completion rate, participants' sociodemographic and other baseline characteristics are presented. A summary of the integrative treatments provided for MSDs at the Royal London Hospital for Integrated Medicine (RLHIM), with changes in primary and secondary outcome measures perceived during the study period are reported. At the end of the chapter, potential predictors of treatment effects and subgroup analyses are explored.

Chapter 5 presents the results of the two qualitative studies, one of which was conducted immediately before participants' initial hospital appointments and the other one year after. In order to ensure interviewed participants were representative of the total sample, their baseline characteristics are compared with those not interviewed. Themes and sub-themes generated from the pre-treatment and follow-up interviews are reported separately (Sections 5.2-5.8, and Sections 5.9-5.15 respectively). A summary of the pre-and-follow-up interview results, pointing out similarities and differences between the two, is presented at the end of this chapter (Section 5.16).

Chapter 6 is where the quantitative and qualitative results are compared and triangulated. Final results on feasibility are presented in terms of the limited-outcome testing, acceptability, and demands for the integrative treatments provided for MSDs; and the feasibility of research design and details in research procedures. Both quantitative and qualitative findings are presented using side-by-side comparison tables as the final MMR findings.

Chapter 7 discusses the findings of both the theoretical understanding of IM identified from the mixed methods review in Chapter 2 and the findings from the mixed methods feasibility study. Patients' perspectives on the essential components of IM identified from this research study are discussed and an IM model hypothesised. This is followed by a discussion on the triangulated feasibility findings in terms of the four Bowen's feasibility issues. Strengths and limitations of conducting the research study, original contribution to knowledge, and implications and future research directions are discussed. At the end of the thesis, the final conclusion of the research study is given.

1.2 Personal background

The research student is aware that her worldview, values, sociodemographic and educational background, and her experiences may naturally influence the research process (Creswell and Clark, 2011). The research student was born in China. She was originally educated at Nanjing University of Traditional Chinese Medicine, graduating with a BSc (Hons) in acupuncture and tuina, and gained two years clinical experience in two Chinese integrative medicine hospitals in Beijing. Growing up in China, where Chinese medicine (part of CAM in the west) and western medicine (conventional medicine in the west) are highly integrated in terms of education, practice, insurance, policy and regulation, the research student, her family and friends experienced the benefits of being able to access an integrative treatment approach for various conditions. After her clinical internship in China, she obtained an MSc in musculoskeletal science at University College London and conducted her masters project on balance assessment for joint hypermobility syndrome at the Royal National Orthopaedic Hospital (RNOH). This was her first exposure to an NHS setting in the UK and she realised that CAM and IM practices and their regulations in the UK were different compared to her experience in China. These experiences allowed the research student to be an 'insider' regarding certain CAM treatments such as acupuncture, but an 'outsider' sociodemographically (Dwyer and Buckle, 2009).

IM is an emerging and a potentially promising field in the UK. Considering the high prevalence and the research student's interests in MSDs, she was passionate to add knowledge to the field, especially in understanding and exploring the potential of IM

models, and particularly in the NHS setting. This also fitted with her previous education, research and clinical experiences.

1.3 Epistemological and ontological stance

In order to create knowledge, achieve credibility and provide the 'power to elicit belief', researchers should critically examine their own ontological perspective and determine an appropriate worldview and assumptions, aims and objectives of the research and methodological approaches (O'Leary, 2004). To understand the researcher's philosophical belief is vitally important for both researchers and readers as this influences and informs the research student's decisions in selecting research questions, designing the study, and reflexivity during the research processes and interpretation of results (Morgan, 2007).

An understanding of the underlying paradigm is essential to provide a world view and social contexts, guide actions, and allow a framework for research design (Morgan, 2007). Researchers should be able to rigorously defend their paradigmatic stance. The research student's epistemological and ontological stances, which were bound with methodology (Greene, 2007) were taken into consideration throughout the research study.

She was born and educated in a country where two medical systems, namely Chinese medicine and western medicine, are both implemented and integrated. Her ontology of evidence-based western medicine and traditional Chinese medicine (TCM) based on Confucianism and Taoism has been gradually influencing her perspective throughout her life. This has been further developed after she took undergraduate and postgraduate courses in both the east and west, where she understood the conflict in philosophical concepts between the two medical paradigms; and differences in ways of evaluation. Originally, the effects of TCM therapies were based on explanations of experts' or practitioners' experiences in treating individuals and collecting a series of case reports. This empirical approach of assessing is very different from evidence-based medicine (EBM), which has developed in western medicine. In evidence based research, evaluating the efficacy of target treatment in ideal clinical circumstances with a specifically selected population using a randomised controlled trial (RCT) design, under a reductionist framework, which can be measured scientifically and is supposedly devoid of subjective bias, is seen as

representative (Sackett et al., 1996). Similarly, other therapies that may be involved in IM are yoga and Ayurveda which originated from Hindu/Buddhist philosophies.

Pragmatism is a philosophical concept which originated in the United States of America (USA) around 1870, developed by Charles Sanders Peirce (1839–1914), William James (1842–1910) and John Dewey (1859–1952). It is the third research paradigm, seeking the middle ground between (post) positivism/objectivism on which pure quantitative approaches are based and interpretivism/constructivism on which pure qualitative approaches are based (Johnson and Onwuegbuzie, 2004). Pragmatism, as a philosophical concept, goes well beyond "what works" (John Dewey), and points to the importance of joining beliefs and actions in a process of inquiry that underlies any search for knowledge, including the specialised activity referred to as research (Morgan, 2007). Pragmatism considers resolving the problem as the priority, using the best philosophical or methodological approach to answer a research question (Mackenzie and Knipe, 2005). Pragmatists believe both positivist and constructivist paradigms share many commonalities with seeking truth and pays more attention to 'lines of action', 'warranted assertions', and 'workability' (Morgan, 2007).

By re-evaluating the research student's epistemological stance in researching IM as part of this research study, pragmatism was considered appropriate as it aligns well with the research topic and research methodology. Integration of the two medical paradigms requires an inclusive ontological stance to understand, research, and practice IM. Clinically, IM treatments provide complex optimum treatments to suit personalised needs (Section 2.2). Epistemologically, IM acknowledges the importance of a real world environment and non-specific aspects of treatment; it is not purely radical empiricism as it emphasises the importance of evidence-based research. Methodologically, MMR including a qualitative approach to explain certain phenomena in IM (e.g. patients' perception and experience with practitioners and treatments) is considered essential (Section 3.1). Both are addressed by the aims of pragmatism to "use pluralistic approaches to derive knowledge about the problem" (Creswell and Clark, 2011). A pragmatic approach has been suggested as the most appropriate methodology for exploring complex interventions such as IM as it reflects model validity and credibility in real world routine practice (MacPherson, 2004b; Witt, 2009).

1.4 Epidemiology and treatment of musculoskeletal disorders

1.4.1 Definition of MSDs

As defined by the Centre for Disease Control and Prevention (CDCP), MSDs are "injuries or disorders of the muscles, nerves, tendons, joints, cartilage, and disorders of the nerves, tendons, muscles and supporting structures of the upper and lower limbs, neck, and lower back that are caused, precipitated or exacerbated by sudden exertion or prolonged exposure to physical factors such as repetition, force, vibration, or awkward posture" (CDCP, 2012). The World Health Organisation (WHO) International Classification of Diseases (ICD) version 10 categorises diseases of the musculoskeletal system and connective tissue (Chapter XIII, M00-M99) to include; arthropathies, systemic connective tissue disorders, dorsopathies, soft tissue disorders, osteopathies and chondropathies, and other disorders of the musculoskeletal system and connective tissue (ICD-10, 2010). The importance of MSDs was highlighted by the following statement by the director-general of the WHO (WHO Scientific Group, 2003), page 1:

> *"Musculoskeletal or rheumatic diseases are the major cause of morbidity throughout the world, having a substantial influence on health and quality of life, and inflicting an enormous burden of cost on health systems."*

1.4.2 Prevalence of musculoskeletal disorders

MSDs are associated with pain and impaired mobility, and affect people's lives and work. In the UK, 70%-84% of adults experience nonspecific low back pain (McIntosh and Hall, 2011) and 70% experience neck pain during their lifetime (Falco *et al.*, 2009; Falco *et al.*, 2012). The incidence of MSDs appears to be increasing, with a corresponding impact on primary health care provision (Cimmino *et al.*, 2011). The Department of Health (DH) suggests that MSDs are the most common reason for general practitioner (GP) consultation (DH, 2006). One in four UK adults has been affected by chronic MSDs and 60% of occupational sick leave is caused by MSDs (DH, 2006).

Long term MSDs are closely associated with multi-morbidity (Fisher, 2015), which now has a huge impact on elderly people, with earlier onset (Barnett *et al.*, 2012), and is strongly associated with polypharmacy and adverse drug reactions (ADRs)

(Nobili *et al.*, 2011). This leads to the economic burden of increasing complex and chronic disease, including both direct and indirect costs (Thorpe *et al.*, 2004). Estimates suggest that with the modern epidemic of chronic disease as well as an ageing population, indoor living, fragmented families/communities, environmental toxicity, nutrition, sedentary lifestyle, chronic stress, and poverty, the costs of chronic disease today in the USA ($1.3 trillion) may increase to $4.2 trillion in 15 years (Jones *et al.*, 2009). As an example, medical costs for MSD treatments was $389 million to the retail industry in the USA in 2007 (Bhattacharya and Leigh, 2011). Data reported for the UK in 2007 estimated costs of approximately £ 7.4 billion and caused 9.5 million lost working days (The Work Foundation, 2007). MSDs accounted for 29% of all illnesses and injuries that required days off work in 2012 as reported by the U.S. Bureau of Labor Statistics; and the incidence of MSDs among the working-age population is anticipated to increase (Summers *et al.*, 2016).

1.4.3 Available therapies for MSDs – a brief introduction

Since MSDs may be associated with multi-morbidity and the complexity of which challenges a single-disease framework, management of MSDs may typically involve a multidisciplinary team approach. Medication is the most commonly used treatment for MSDs, which includes simple analgesics such as paracetamol, non-steroidal anti-inflammatory drugs (NSAIDs, such as ibuprofen), taken topically or systemically, opioids and tricyclic antidepressants.

Other therapies such as physiotherapy and occupational therapy are also given to MSD patients, to help improve their functional ability and to alleviate pain. In severe or complicated cases, orthopaedic surgery may be necessary, to help with deformities, repair or replace lesions. Apart from these, conventional management of MSDs also includes reduction in workload, increased rest, stress management, and behavioural intervention.

CAM is commonly used to treat musculoskeletal conditions, especially for back, neck and shoulder pain (Thomas *et al.*, 2003; Kanodia *et al.*, 2010; Smith *et al.*, 2000). The National Institute for Health and Clinical Excellence (NICE) guidelines on non-specific low back pain recommends consideration of manual therapy and acupuncture (NICE, 2009). The prevalence of the use of CAM in Europe varies (0.3-86%), with herbal medicine as the most commonly given treatment (Eardley *et*

al., 2012). Systematic reviews have identified limited but promising evidence for several treatments such as acupuncture (Vickers *et al.*, 2012), manipulation (Chou *et al.*, 2007; Bronfort *et al.*, 2008a), herbs (Gagnier *et al.*, 2004), mind and body therapy (Theadom *et al.*, 2015) and nutraceuticals (Goldberg and Katz, 2007) for treating various musculoskeletal conditions.

1.5 Conceptual framework of this research study

As well as pragmatism being the paradigmatically based philosophical belief of the research student, recognition of the conceptual framework is a methodological necessity to help clarify theory prior to evaluation, and to ensure rigour of the research (Evans *et al.*, 2011). The research student adopted the initial two stages of the MRC complex intervention guidance in evaluating complex intervention as a framework to inform the study design (Campbell *et al.*, 2000; Craig *et al.*, 2008). Why IM is considered a complex intervention, the purpose and contents of the MRC framework, and how it guided this research study will be introduced in this section.

1.5.1 IM as a complex intervention

As defined by the MRC framework, a complex intervention comprises of several interacting components (Campbell *et al.*, 2000; Craig *et al.*, 2008). IM treatments for MSD patients were considered as complex interventions due to containing a number of components.

Firstly, IM practice for MSDs is complex as it may involve a variety of therapies or diagnostic approaches, which need coordination from a variety of professionals, including the orthopaedic consultants, rheumatology consultants, neurologists, physiotherapists, occupational therapists, and CAM practitioners. Each of these treatments may be an important contributor to the effectiveness of a package of IM intervention and it is therefore difficult to decide which is/are the “active ingredient(s)” of the intervention (Campbell *et al.*, 2000).

IM is a holistic approach tailored to the individual’s physical, psychological, biological and emotional well-being, and takes the context of environment into consideration. This requires an individualised treatment and individualised life style advice or self-management advice from either a single practitioner in cooperation with a group of health professionals, or multidisciplinary team health professionals

(Hu *et al.*, 2015b) (Section 2.2). A complex intervention may work best in an individualised rather than completely standardised environment (Craig *et al.*, 2008). Similarly, IM emphasises the interaction between patients and practitioners. Active interaction and effective communication among collaborative team members is essential in providing complex interventions in an integrative setting. These aspects may be considered as potential components of IM that contribute to the treatment effects. Details of the components of IM will be explored under the guidance used for this framework and will be presented in Chapter 2 (Section 2.2).

1.5.2 MRC framework for evaluating complex interventions

In 2000, the MRC released a guidance framework for development and evaluation of RCTs for complex interventions to improve health (Campbell *et al.*, 2000). Since then, increasing numbers of evaluations have used the MRC framework to report interventions where patients are provided with individualised packages of care using complex interventions in multi-disciplinary environments (Datta and Petticrew, 2013; Beswick *et al.*, 2008). In the 2008 update, the framework recommended a four stage 'development, feasibility/piloting, evaluating, implementation' process. The MRC framework points out the importance of developing appropriate theory and identifying the available evidence for the target intervention, testing the feasibility of or piloting a study, before establishing definitive effectiveness evaluations in a real world clinical setting (Campbell *et al.*, 2000; Craig *et al.*, 2008). The MRC also fund early phase developments of public health interventions (Public Health Intervention Development Scheme (PHIND), to develop a solid theoretical framework and generate evidence on the design specification and feasibility of interventions (MRC, 2015). This guidance addresses the complicated issues in studying the various components and their interactions involved in a complex intervention, and to investigate whether a complex intervention is effective and how it works (Campbell *et al.*, 2000; Craig *et al.*, 2008).

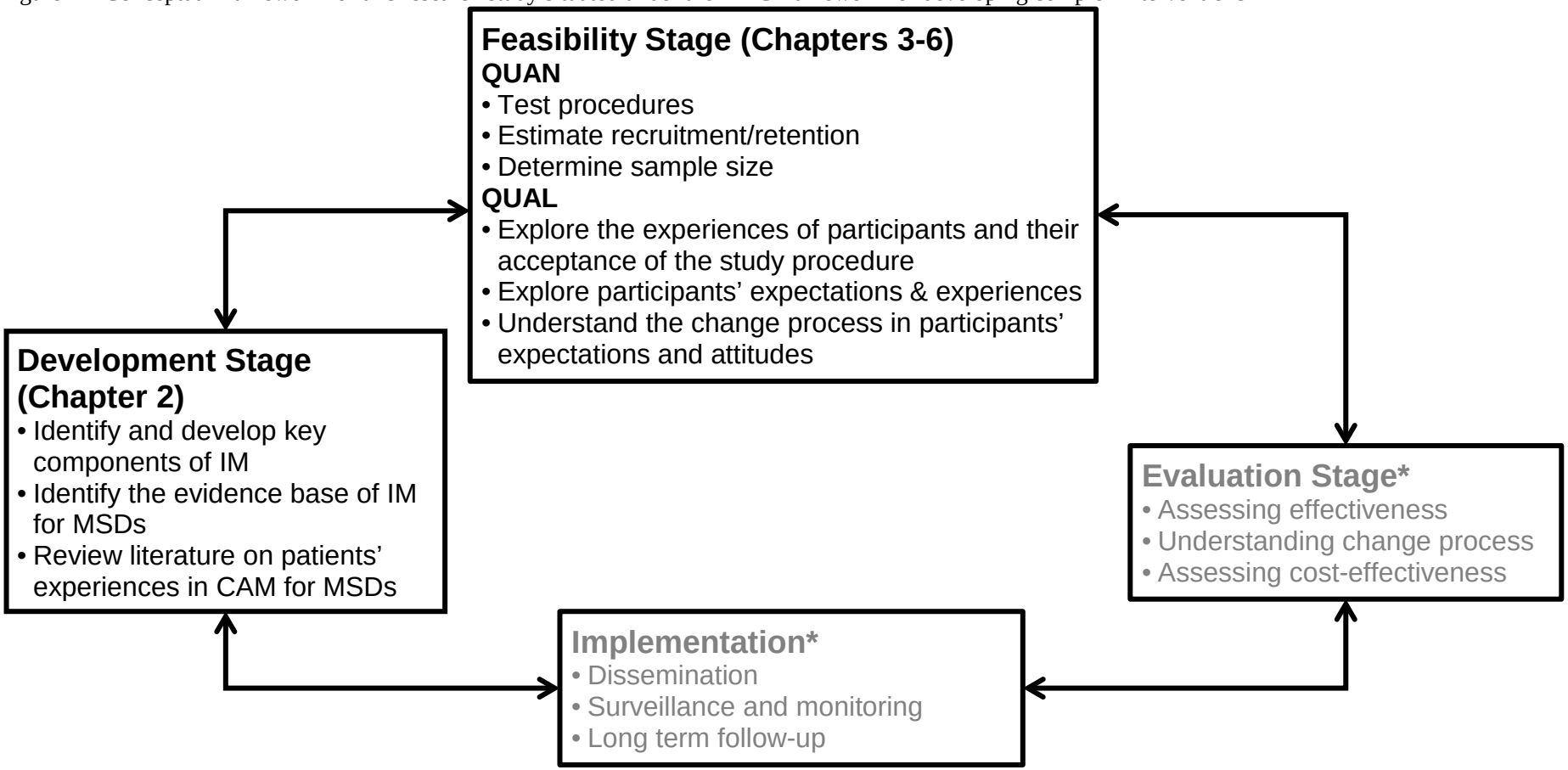
Although the MRC framework is mainly designed for evaluating complex interventions using RCTs for evaluation, it can guide observational studies (Craig *et al.*, 2008) and it has been adopted in this research study because of the lack of conceptual clarity for IM. The precise definition of IM is not clear. IM is not widely practised in most western countries and has different meanings depending on the

country and its access to health care (Section 2.2). The other reason is that there is no clear understanding about the "mechanism of action" of IM. The "active ingredient" of an intervention might be nonspecific, for example, does the effectiveness depend on the success of patient-practitioner relationship, or the achievement of a holistic approach; or was it a specific component such as acupuncture, or medication, or the practitioner's empathy that contributed to the overall effects of the treatment. These are potential active components influencing the effects of IM (e.g. how each intervention relates/interacts with each other is not clear).

1.5.3 The conceptual framework map for this research study

This research study adapted the initial two stages (development and feasibility) of the MRC framework as a general guide of the overall study design (Figure 1.1). In order to suit the complex nature of IM, aspects of MMR are added in as a feature in the feasibility stage (details in Section 3.1.1).

Figure 1 1 Conceptual framework for this research study situated under the MRC framework for developing complex interventions



QUAN and QUAL represent the quantitative and qualitative strands in a convergent mixed methods design
*Evaluation and implementation stages were not part of this research study

In the development stage (Chapter 2), issues of terminology, definition, and evidence of IM are reviewed and discussed. As suggested in the MRC framework, theory and modelling are not two separate phases and always occur at the same time (Campbell *et al.*, 2000). Key components of IM were identified to build up the theoretical basis of IM (Section 2.2); but how those components relate to and impact on each other, as well as how each IM element affects outcomes and the study design, were not modelled as it was anticipated the feasibility study would provide information on this. Available evidence of IM for MSDs from the current literature was identified using LBP as an example in a systematic review (Section 2.3); a narrative review was conducted on patients' expectations and experiences of receiving CAM for MSDs (Section 2.4).

In the feasibility and piloting stage (Chapter 3-6), to understand the change process and provide detailed reporting on clinical outcomes, context and interventions (Datta and Petticrew, 2013), the procedures of the whole feasibility study, recruitment and retention were recorded throughout the study, with effect sizes reported for future sample size calculation. Participants' expectations and their experiences of participating in the study and their acceptance of the procedures were explored through a qualitative approach. These data resulted from a mixed methods approach and will help with finalising the future study design for the evaluation stage.

This framework directed the research student in developing all the stages of this research study, which included developing study aims, conducting literature reviews, identifying an appropriate study design, and exploring the most appropriate way of interpreting and analysing the results.

1.6 Aims and objectives of the research study

The aims and objectives of this research study were developed in alignment with the two stages of the MRC framework:

To develop a theoretical understanding of IM

- To review IM definitions and identify the components of IM
- To review the current evidence for the effectiveness and safety of integrative treatment for LBP
- To review patients' experiences of receiving CAM for MSDs

To determine the feasibility of carrying out a mixed methods study of IM for MSDs in the UK

- To evaluate 'real world' clinical outcomes associated with integrative treatment for MSDs
- To explore patients' expectations and experiences of receiving integrative treatments for MSDs
- To identify practical issues in conducting a mixed methods feasibility study
- To determine patients' expectations and experiences in participating in the research study

Chapter 2 Review of Musculoskeletal Disorders and Integrative Medicine

Aims and structure

Due to the pluralistic aims mentioned above, a mixed methods review (Grant and Booth, 2009), also called an 'integrative review' was performed. Such reviews provide a broad summary based on a specific concept or content, with both empirical and theoretical, and qualitative and quantitative literature utilised (Whittemore, 2005) and usually contain a systematic review (Grant and Booth, 2009). They fill the gap between rigorous systematic reviews and traditional literature reviews (Evans, 2007).

The mixed methods review reported in this chapter consists of three parts. Firstly, to align with the MRC framework requirement to identify theory (Figure 1.1), a mapping review on the available definitions of IM was conducted to identify and categorise potential components of IM (Section 2.2, Appendix 2.1). Secondly, an exploratory systematic review evaluating clinical effectiveness and safety of integrative treatment for LBP was conducted (Section 2.3, Appendix 2.2). The reason for selecting LBP as the topic for this systematic review is provided in Section 2.3. Thirdly, a narrative review on qualitative research explored patients' experiences in receiving CAM treatments for MSDs was performed; the reason that a search was conducted on CAM rather than IM treatment is explained in Section 2.4.

To ensure only rigorous research was included to build the evidence base, critical appraisal was only conducted for the trials included in the systematic review. This was not adopted in the mapping review or the narrative review as critical appraisal is not essential for these types of reviews (Grant and Booth, 2009).

The main search of the systematic review on integrative treatment for LBP was conducted in Jan 2013 (Appendix 2.2) while the main search of the qualitative review was conducted in November 2014. In August 2015, an updated search was conducted for all three parts of the mixed methods review. The search strategies and inclusion criteria in update searches followed the same procedures described in the

main searches, except that Chinese literature was not searched for the systematic review due to inadequate access to Chinese databases in the update search.

2.1 What is Integrative Medicine?

According to the MRC complex intervention framework (Section 1.4.2), it is essential that components of the target intervention are explored. In this section, the change and understanding in terminology of IM over time is explained, followed by a mapping review of the definitions of IM, to identify the potential key components of IM. A paper on the issues discussed in this section has already been published (Hu *et al.*, 2015b) (Appendix 2.1).

2.1.1 Transformation in terminology

The terms integrative medicine, also called integrated medicine, integrative healthcare, or integrated healthcare are frequently used inter changeably in different healthcare systems, education, research, and clinical practice (Bell *et al.*, 2002; The Consortium of Academic Health Centers for Integrative Medicine, 2009). The terminology in the field has evolved over the past 20 years, from "unconventional medicine" to "holistic" to "CAM", to "integrative medicine," reflecting the dynamic state of this field and its terminology. IM is not the same as CAM, nor is it simply a combination of CAM and conventional treatment (Bell *et al.*, 2002; Osher Center for Integrative Medicine, 2015; Rees and Weil, 2001; National Institute of Integrative Medicine, 2015; Boon *et al.*, 2004; Snyderman and Weil, 2002). Stumpf *et al.* (2008) described this change in definition as a destined transformation of CAM going mainstream.

2.1.2 Available definitions of IM

Though there are many difficulties in defining IM, defining the concept of IM is believed to be the first step towards understanding the phenomenon (Stumpf *et al.*,

2008). Before defining IM, it is important to state the definition of CAM and the potential problems in defining it.

The WHO Collaborating Centres for Traditional Medicine defined CAM as follows (World Health Organization, 2015a):

> "*The terms "complementary medicine" or "alternative medicine" are used inter-changeably with traditional medicine in some countries. They refer to a broad set of health care practices that are not part of that country's own tradition and are not integrated into the dominant health care system*".

This definition indicates CAM treatments are defined differently internationally. There are controversies on whether one specific discipline is regarded as complementary treatment or alternative treatment. And some researchers are intent on distinguishing their particular CAM discipline from other CAM treatments (Broom *et al.*, 2012) . Similar to CAM, IM is defined variously across nations (Boon *et al.*, 2004; Caspi *et al.*, 2003). In general, IM appears to be determined or categorised by the use of a combination of conventional allopathic medicine and CAM in order to address the biological, psychological, social, and spiritual aspects of health and illness (MeSH, 2015). It also emphasises the importance of wellness and healing of the whole person and developing an effective practitioner-patient relationship, all of which is to be informed by evidence (Bell *et al.*, 2002; The Consortium of Academic Health Centers for Integrative Medicine, 2009).

However, this definition is not agreed by everyone. Researchers suggested IM is not simply a synonym of conventional medicine with CAM (Bell *et al.*, 2002; The Bravewell Collaborative, 2015; Osher Center for Integrative Medicine, 2015; Rees and Weil, 2001; National Institute of Integrative Medicine, 2015; Boon *et al.*, 2004). Studies simply combining CAM and conventional treatment without providing more details on the model/framework of integration are not regarded as true IM practice (Caspi, 2001; Morrell, 2001; Woolfson, 2001). For example, receiving acupuncture

and medication at the same time may not be equal to having IM treatment, as they might be provided by two unrelated professions, with no interaction between them. Also, there is no clear boundary between CAM and conventional medicine in some cases. For example, dietetics and nutrition are two types of therapies with overlap in several aspects but some differences in training and regulation. As another example, it is difficult to categorise acupoint injection with medications into either CAM or conventional medical treatment. Currently, osteopathy and chiropractic are the only two CAM therapies in the UK that are regulated in the same way as conventional medicine through statutory professional regulation (NHS choices, 2012). Other CAM therapies are regulated through voluntary self-regulation organisations or the Health and Care Professions Council, e.g. Complementary and Natural Healthcare Council (CNHC), and the British Acupuncture Council (BAcC).

The mapping review

A mapping review has been conducted in order to get a clear idea of the definition and the potential key components of IM (publication in Appendix 2.1). In order to provide an international context covering different cultural backgrounds and models of IM practice, this mapping review focused on available definitions and IM models in four countries, namely: UK, USA, Australia and China.

Data sources and search strategies

A range of data sources (published between 1990 and 2014) including government, key authorities, academic organisations, clinical sites, academic journals, textbooks, and research papers were searched for definitions of IM. Search terms included ‘integrative medicine’, ‘integrated medicine’, ‘integrative health(care)’, ‘integrated health(care)’. The list of 54 resources searched is available in Appendix 2.1 (Table 1).

Key definitions of IM identified

Of those searched, 17 (31%) provided specific definitions of IM and were extracted. These were identified from the USA (13), China (2), UK (1), and Australia (1). The full seventeen definitions are available in Appendix 2.3. The most commonly cited definition was that developed by the Consortium of Academic Health Centres for Integrative Medicine (CAHCIM) (The Consortium of Academic Health Centers for Integrative Medicine, 2009):

> *Integrative medicine is the practice of medicine that reaffirms the importance of the relationship between practitioner and patient, focuses on the whole person, is informed by evidence, and makes use of all appropriate therapeutic approaches, healthcare professionals and disciplines to achieve optimal health and healing.*

In 2015, the consortium changed their name to the Academic Consortium for Integrative Medicine & Health (The Consortium) and updated their definition of IM (The Academic Consortium for Integrative Medicine & Health, 2015):

> *Integrative medicine and health reaffirms the importance of the relationship between practitioner and patient, focuses on the whole person, is informed by evidence, and makes use of all appropriate therapeutic and lifestyle approaches, healthcare professionals and disciplines to achieve optimal health and healing.*

Recently, the consortium carried out a survey to re-evaluate the definition of IM which was closed in July 2015 and the results of this survey have not yet been published.

2.1.3 Key components of integrative medicine

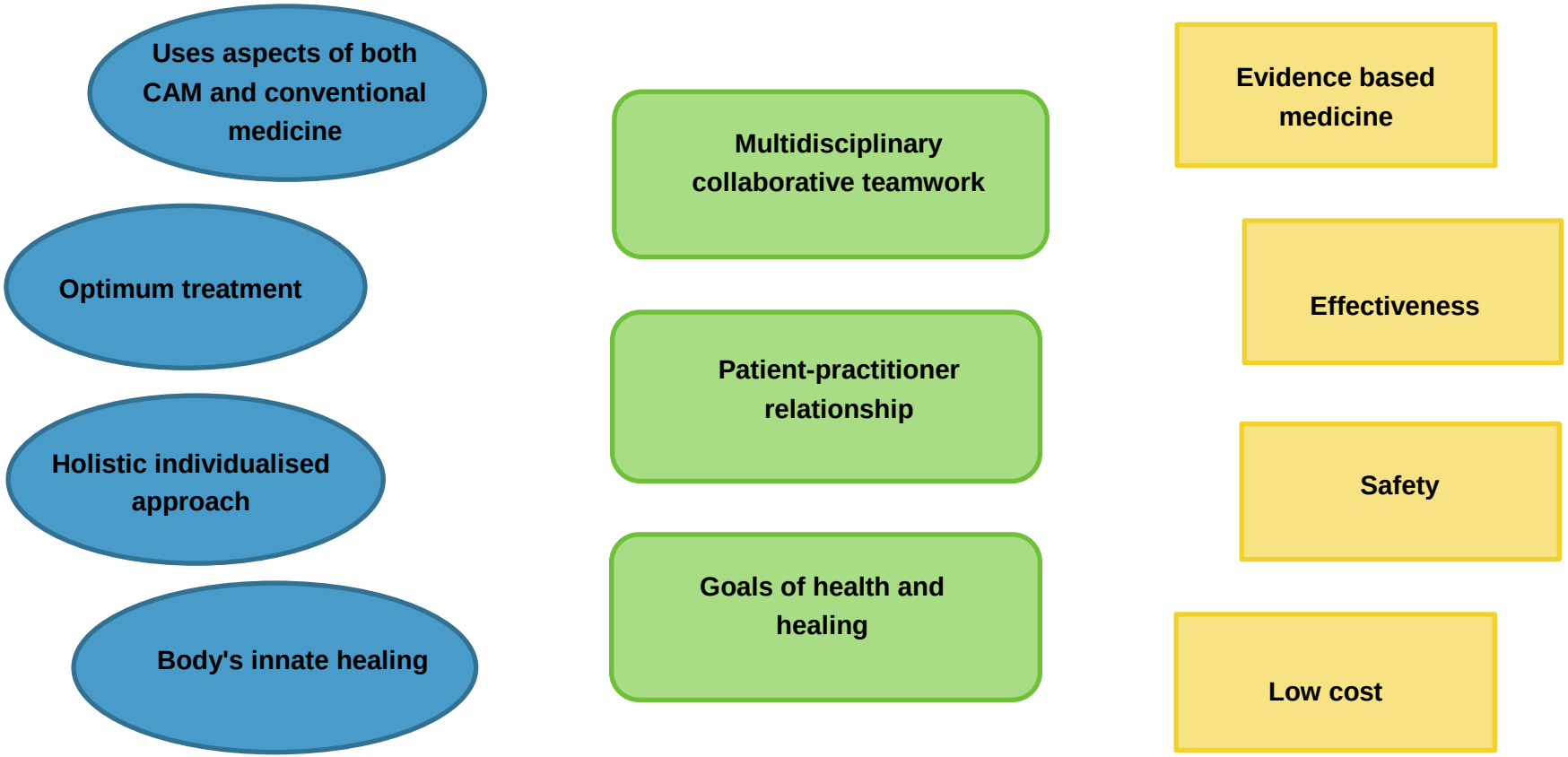
Key elements characterising IM were identified and categorised in a thematic approach, in order to determine and define the elements of IM for future narrative and systematic reviews, to provide guidance and stimulate wider discussion in the

research community. Figure 2.1 shows the components identified from the 17 definitions of IM.

The most common component, emphasised by thirteen (out of 17), was the integration of CAM and conventional approaches, followed by goals of health and healing (12/17), holistic individualised approach (12/17), optimum treatment (8/17), and the body's innate healing response (4/17). Though multidisciplinary team work has for some time been emphasised as an integral component of complex interventions (Lewith, 2005), only four definitions identified in the mapping review emphasised a collaborative approach to patient care.

Many definitions included elements which also define conventional medicine and so are not unique to IM. These were: patient-practitioner relationship (12/17), evidence-based (9/17), effectiveness (5/17), safety (4/17)(National Center for Complementary and Alternative Medicine, 2015; Rakel, 2012; Chen, 2005; Royal London Hospital for Integrated Medicine, 2015) (National Center for Complementary and Alternative Medicine, 2015; Rakel, 2012; Chen, 2005; Royal London Hospital for Integrated Medicine, 2015), and low cost (2/17).

Figure 2 1 Key components identified from seventeen selected definitions of IM from four countries



Key: Blue: aspects of CAM/IM; Green: aspects also important in conventional medicine (not unique to IM); Yellow: originated from conventional medicine (not unique to IM)

In addition to the 11 components identified, the Chinese definition (Baidu Baike, 2015) emphasises that integration can occur at theoretical, diagnostic, and therapeutic levels. Integration in at least one of the three levels, with a consideration of the key components suggested in Figure 2.1 would be regarded as IM for the purpose of this research study.

2.2 A systematic review of integrative treatment for low back pain

In alignment with the MRC framework for designing complex interventions (Campbell *et al.*, 2000; Craig *et al.*, 2008), the systematic review reported in this section answers the research aim 'to develop theoretical understanding of IM' by identifying evidence base of IM for MSDs.

Clinical evidence for IM studies consist largely of individual CAM practices. The research evidence on the effectiveness of IM as a package is currently still limited due to its complex nature and a lack of standardisation in terminology, definition and reporting, and the challenges in methodological design (Khorsan *et al.*, 2011; Shepperd *et al.*, 2009; Marcus and McCullough, 2009; Nahin and Straus, 2001; Hu *et al.*, 2015a).

In this section, the topic LBP was selected as being representative of MSD. The research student initially conducted a review on IM for MSDs and identified over 2000 articles after deleting duplicates, and screening titles and abstracts. This high number may have been due to a lack of standard terminology for IM. The research student included the search term 'CAM' and various CAM therapies to capture a variety types of CAM therapies used in IM, and randomised controlled trials published in both English and Chinese language databases. More than 1700 articles were published in Chinese.

It was therefore decided to limit the review to LBP as it is one of the most common MSDs, which is difficult to treat and a costly medical problem throughout the world (Andersson, 1999; Woolf and Pfleger, 2003). In addition, considering systematic reviews usually focus on a specific condition, rather than a group of conditions such as MSDs; and the fact LBP was the most common reason that patients were referred to the RLHIM, a systematic review evaluating the effectiveness and safety of

integrative treatment for LBP was conducted. This systematic review was published and is available in Appendix 2.2 (Hu *et al.*, 2015b).

The report of this systematic review follows the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guideline through all stages of the design, implementation, and reporting (Moher *et al.*, 2009). The protocol for the review was registered and is available online (CRD42013003916) (Hu, 2012). As IM is a complex intervention, with associated difficulties in identifying and synthesising trials, an exploratory review using broad search terms was conducted (Shepperd *et al.*, 2009)

2.2.1 Data Sources and search strategy

A literature search was carried out on eight English language databases: Pubmed, the Allied and Complementary Medicine (AMED), Embase, Cochrane Library resources, Cumulative Index to Nursing and Allied Health Literature (CINAHL), PsycINFO, ScienceDirect, Index to Theses (UK); and four Chinese databases: China National Knowledge Infrastructure (CNKI), VIP, Wanfang, Chinese BioMedical (CBM). All databases were searched from their inceptions to December 2012. An updated search was conducted in August 2015 (December 2012 – August 2015). Detailed search terms and strategies with limits used for each database are provided in Appendix 2.4.

2.2.2 Inclusion criteria

Published RCTs in English or Chinese, evaluating outcomes of clinical effectiveness, cost effectiveness, or safety of IM for LBP were included. Patients of all ages, with acute/sub-acute/chronic LBP (including pain in the lumbar or sacral regions, which may be associated with muscular-ligamentous sprains and strains; intervertebral disk displacement; and other conditions) were included. Only musculoskeletal related LBP was included. Internal/obstetrics and gynaecology related LBP were excluded. Research evaluating combined treatment in the same (group of) clinical setting(s) was included, with no limitations regarding the duration of the treatment and no limitations regarding additional (routine) care. For exercise interventions, the decision as to whether it was CAM or CM was based on whether it potentially involved a mind-body interaction in the intervention process. RCTs

comparing combined CAM and CM therapies plus usual care with usual care alone; and combined therapies with CAM or CM were included.

2.2.3 Outcome measures and data collection

Primary outcome of this review included any form of pain measurement or back pain functional status. Secondary outcomes included patients' quality of life, mental condition, adverse events (AEs). Both English and Chinese research was searched and screened by the research student and another independent researcher. None of the reviewers were blinded to the authors' affiliations, journal of publication, or trial results of the selected articles at this or any stage of the review.

2.2.4 Quality analysis and risk of bias assessment

The quality of reporting in selected trials was critically appraised using the Consolidated Standards of Reporting Trials (CONSORT) for all included trials (Moher *et al.*, 2001) and additional standards for reporting interventions in clinical trials of acupuncture (STRICTA) checklist for reporting trials that investigated acupuncture (MacPherson *et al.*, 2002). A score (Yes=1, No=0, Cannot tell/Partial/ Not available=0.5) was given for each question for each included trial. A percentage (sum of the scores/number of questions) was generated to show the overall reporting score combining CONSORT and STRICTA of the individual trials. Appendix 2.5 provides the detailed scores of each item for the reporting included trials.

Methodological quality was assessed using the 2009 updated method guidelines for systematic review from the Cochrane Back Review Group (CBRG) (Furlan *et al.*, 2009). Yes (Y) = Low risk of bias, No (N) = High risk of bias, Unclear (U) = Insufficient information or rationale.

2.2.5 Data extraction

Basic characteristics of the included trials were extracted; including: authors' initials and published year, whether the trial was labelled as 'IM' or not, sample size and condition of LBP, the nature of practice and practitioner, comparison groups, treatment regimen and notes, outcome measures, and end point.

All included trials were independently scored with data extracted by the research student and at least one independent reviewer, with disagreements resolved through discussion with a third researcher to achieve final consensus.

2.2.6 Summary measures and synthesis of results

All statistical analysis was conducted using the Review Manager (version 5.2). Pre-set I^2 values of 50% or more were considered to be highly heterogeneous (Higgins and Thompson, 2002). Mean difference (MD) and 95% confidence intervals (CI) were calculated. Relevant parameters were compared with sensitivity analysis if the data were adequate. For cases where there was missing data or the data were analysed using an inappropriate test, the data were reported separately. As there were various combinations of treatments, if a meta-analysis could not be carried out, a narrative description of selected trials was reported.

2.2.7 Description of trials

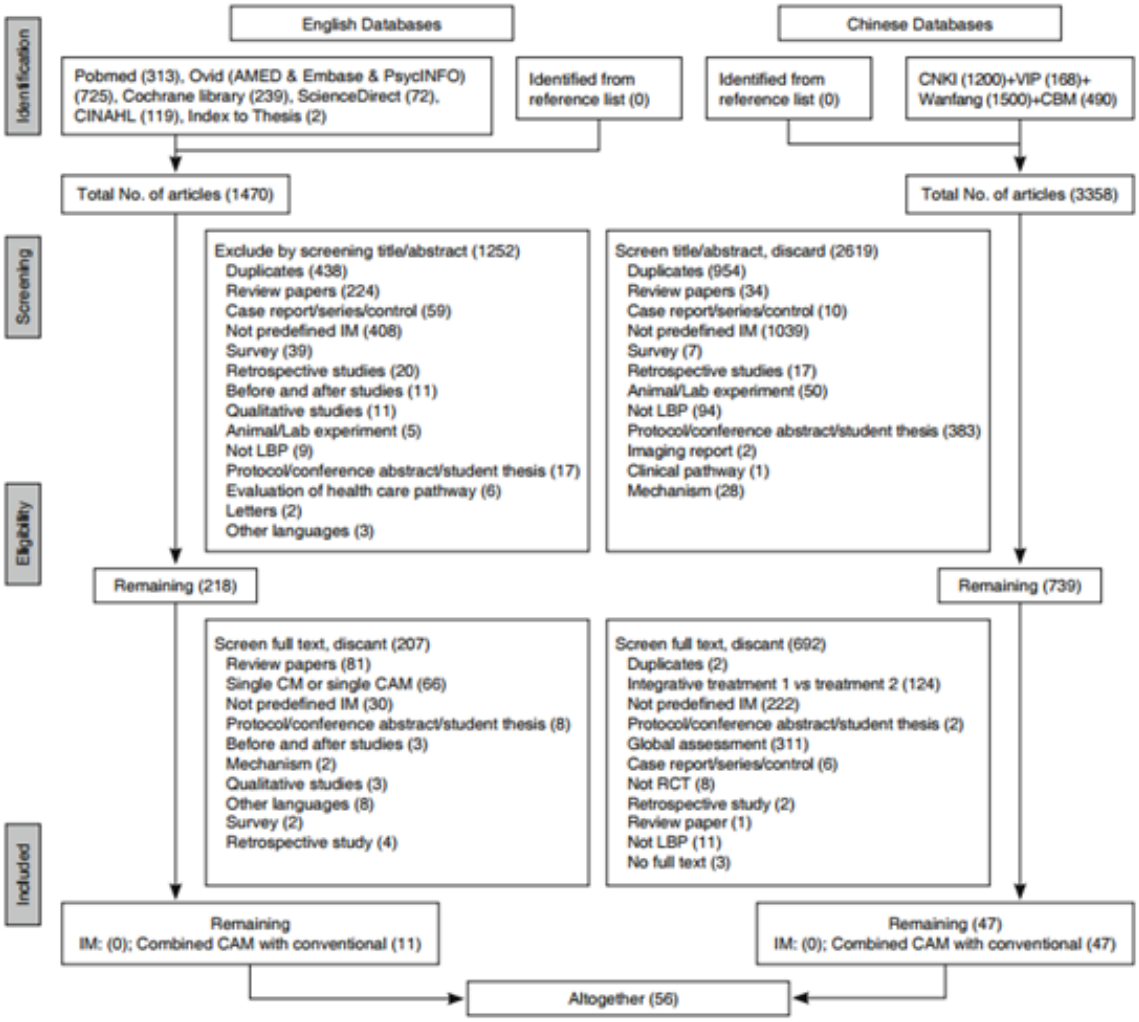
An initial search identified 1470 English and 3358 Chinese potential relevant studies. After excluding ineligible studies by screening titles and abstracts, 218 English and 739 Chinese articles remained. By applying inclusion and exclusion criteria to full text articles, a final total of 56 RCTs consisting of 58 articles remained (Figure 2.2).

A total of 6616 patients (ranging from 20 to 681 per study) were involved in the 56 RCTs (Appendix 2.6). Among the trials identified, six used the term ‘integrative traditional and western medicine’ [中西结合] or ‘integrative’ (Eisenberg *et al.*, 2012; Sundberg *et al.*, 2009; Zeng, 2011; Qin *et al.*, 2007; Yuan *et al.*, 2012; Cai and Fang, 2011). The most common condition (77%) was lumbar disk herniation (LDH), with duration of treatment varied from one off treatment to three months. Nearly half of the trials published in Chinese were conducted in a Western medical hospital, while most trials (67%) published in other countries were carried out in government regulated organisations.

A dispersed combination of integrative treatments was reported, with acupuncture plus traction (8/56) was the most commonly received, followed by a package of CAM treatments (7/56), tuina plus epidural injection (6/56), and Chinese herbal

medicine (CHM) plus traction (5/56). Details of the interventions are available in Appendix 2.6.

Figure 2 2 PRISMA 2009 flow diagram: screening process



N.B. Duplicates has been checked among English and Chinese databases

2.2.8 Quality of the selected articles

Quality of reporting was assessed using STRICTA and CONSORT checklists. Approximately half items in CONSORT (mean: 49%) and STRICTA (mean 52%) were reported (Appendix 2.5, using the method explained in section 2.2.4).

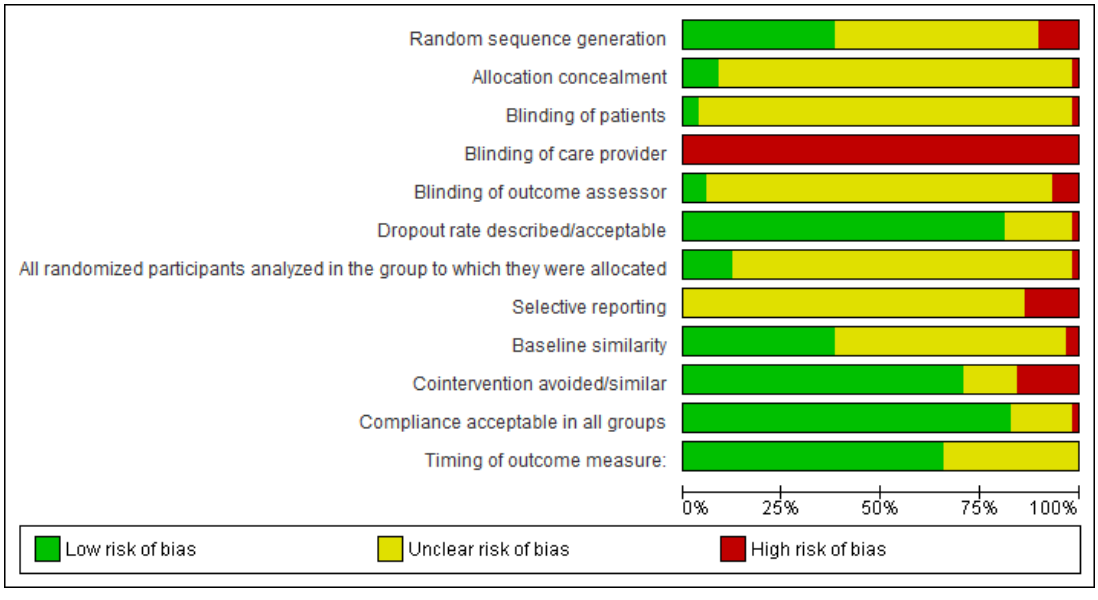
The risk of bias varied across the included trials (Figure 2.3). Regarding random sequence generation, eight trials used computer generated statistical software for randomisation (Zaringhalam *et al.*, 2010; Molsberger *et al.*, 2002; Leibing *et al.*, 2002; Meng *et al.*, 2003; Hurwitz *et al.*, 2002; Sundberg *et al.*, 2009; Eisenberg *et al.*, 2007; Little *et al.*, 2008); Fifteen used random number tables (Zeng, 2011; Liang, 2010; Li and Wang, 2008; Tuo *et al.*, 2011; Zhong and Wu, 2013; Qu *et al.*,

2010; Wang, 2007; LI *et al.*, 2011; Wen *et al.*, 2012b; Zhang, 2012; Song, 2010; Zhu *et al.*, 2012; Ma, 2012; Xiao *et al.*, 2012; Grunnesjo *et al.*, 2011); and six were generated sequentially by date of presentation (Qin *et al.*, 2007; Cai and Fang, 2011; Chen and Tang, 2012; Jiang *et al.*, 2010; Zheng *et al.*, 2012; Zhou, 2008), which potentially had a high risk of bias. Other trials (n=24) only mentioned 'patients were randomised' without any detailed information, thus an unclear risk of bias was given for those trials.

Regarding allocation concealment, apart from six trials (Molsberger *et al.*, 2002; Zaringhalam *et al.*, 2010; Meng *et al.*, 2003; Hurwitz *et al.*, 2002; Grunnesjo *et al.*, 2011; Eisenberg *et al.*, 2007) which had central control, and one trial (Sundberg *et al.*, 2009) reported that the research coordinator was informed about the allocation and then enrolled the patient, none of the other trials provided details regarding allocation concealment.

Regarding blinding, two trials (Molsberger *et al.*, 2002; Leibing *et al.*, 2002) reported using double blinding (both participants and examiner were blinded) in verum and sham acupuncture by inserting needles superficially, outside meridians, with no 'de qi'. Other trials did not give information on blinding, or reported blinding was impossible in patients and practitioners (Meng *et al.*, 2003).

Figure 2 3 Risk of bias graph: review authors' judgments about each risk of bias item presented as percentages across all included studies



2.2.9 Effects of interventions

Included trials were grouped into three groups of comparisons: integrative treatment versus conventional treatment and integrative treatment versus CAM for equal or less than three months and for more than three months respectively. Different comparisons with different outcome measures were discussed separately in the subgroup analyses.

Integrative treatment vs conventional treatment (equal or less than 3 months)

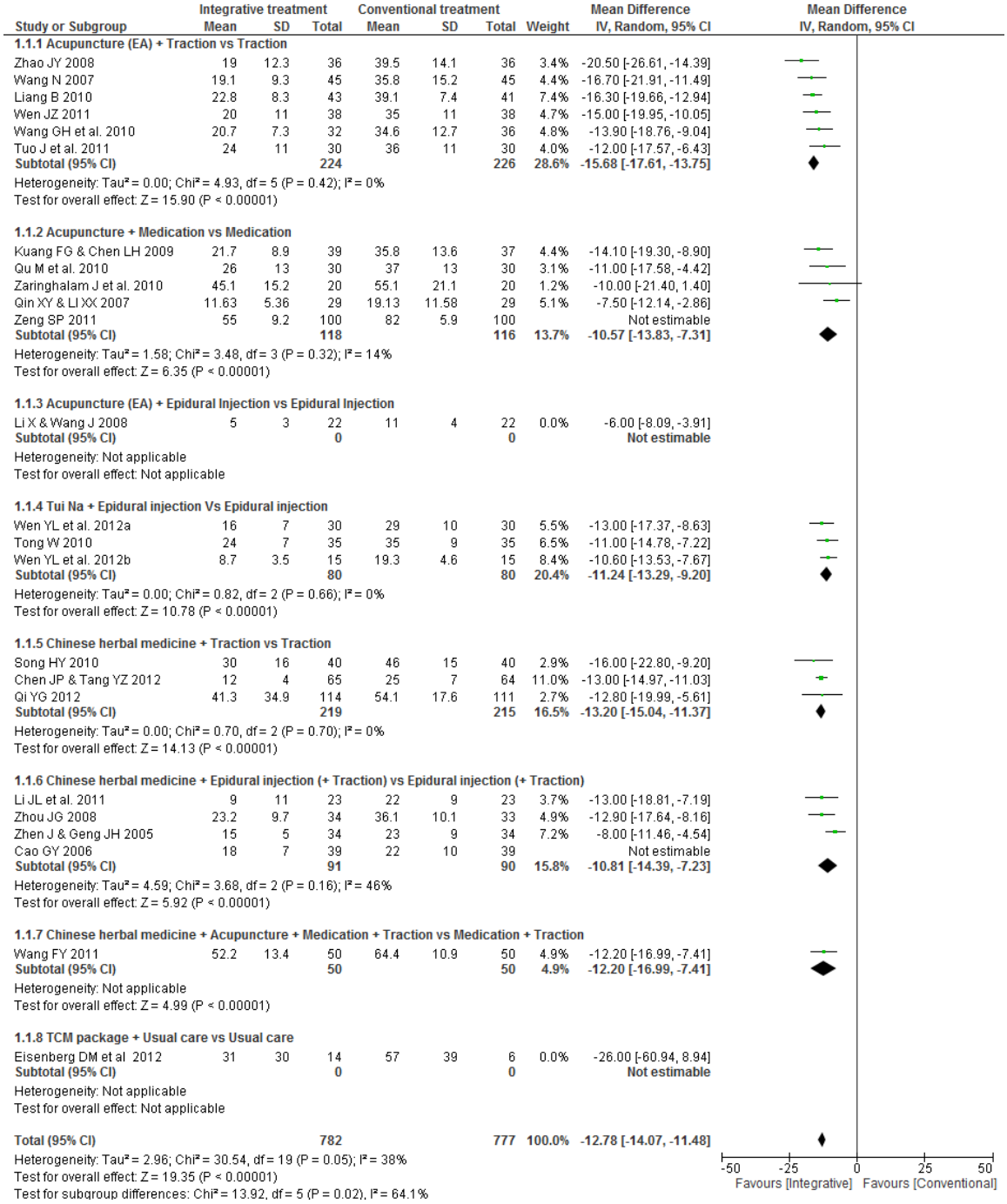
Pain scale

Favourable effects were shown in integrative treatment over conventional treatment as measured by pain scales using visual analogue scale (VAS) and numerical rating scale (NRS) with MD -12.78, 95% confidence interval (CI) [-14.07, -11.48], p=0.05, I^2= 38% in 20 trials (Figure 2.4, four trials were removed due to high heterogeinety): Six trials favoured acupuncture plus traction over traction alone (n=450, MD -15.68, 95% CI [-17.61, -13.75], p=0.42, I^2=0%) (Zhao, 2008; Wang, 2007; Liang, 2010; Wen, 2011; Wang *et al.*, 2010; Tuo *et al.*, 2011); Four trials favoured acupuncture plus medication over medication alone (n=234, MD -10.57, 95% CI [-13.83, -7.31], p=0.32, I^2=14%) (Kuang and Chen, 2009; Qu *et al.*, 2010; Zaringhalam *et al.*, 2010; Qin *et al.*, 2007) (one study (Zeng, 2011) was excluded from meta-analysis as it showed large heterogeneity I^2 = 95% if it was included); One study favoured acupuncture plus EI over EI alone (MD -6.00, 95% CI [-8.09, -3.91]) (Li and Wang, 2008); Although these presented positive results, because of insufficient original data results of three trials evaluating acupuncture plus usual care versus usual care alone were not synthesised in this analysis (Molsberger *et al.*, 2002; Meng *et al.*, 2003; Leibing *et al.*, 2002).

Three trials favoured tuina plus EI over EI (n=160, MD -11.24, 95% CI [-13.29, -9.20], p=0.66, I^2=0%) (Wen *et al.*, 2012b; Wen *et al.*, 2012a; Tong, 2010); but failed to show a favourable effect in tuina plus traction (Heng, 2011; Zhang, 2012). Three trials favoured CHM plus traction over traction alone (n=434, -13.20 [-15.04, -11.37], p=0.70, I^2=0%) (Song, 2010; Chen and Tang, 2012; Qi, 2012); Three trials favoured CHM plus EI over EI alone (n=181, -10.81 [-14.39, -7.23], p=0.16, I^2=46%) (Li *et al.*, 2011; Zhou, 2008; Zhen and Geng, 2005) (if included one study (Cao, 2006), large heterogeneity I^2=73%); One study showed favourable

improvement in CHM plus acupuncture, medication and traction over medication and traction -12.20 [-16.99, -7.41]; Two trials evaluated tuina plus traction versus tuina alone -13.59 [-33.77, 6.59] (Zhang, 2012; Heng, 2011) and one study on a package of care (included Swedish massage, manipulative therapy, shiatsu, acupuncture, qigong) plus usual care versus usual care with -26.00 [-60.94, 8.94] which failed to establish a favourable effect (Eisenberg *et al.*, 2007).

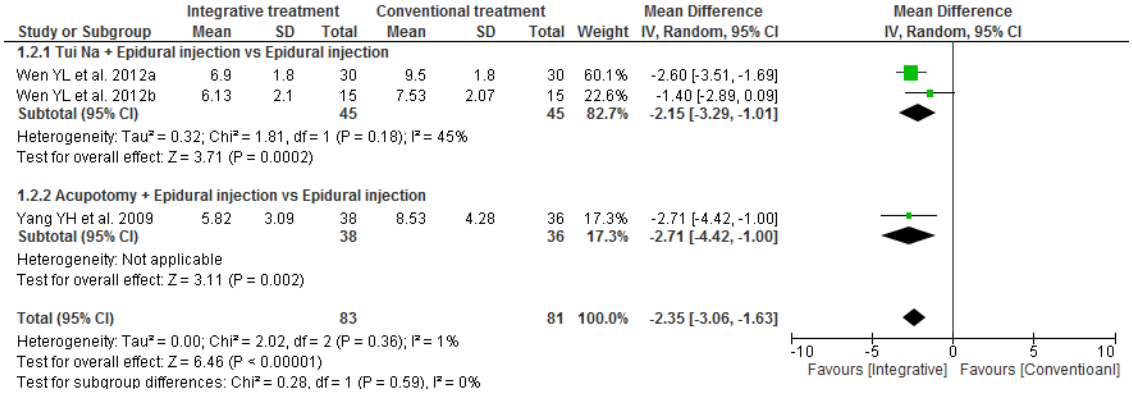
Figure 2 4 Integrative treatment versus conventional treatment as measured by pain scales



Modified Japanese orthopaedic association (mJOA) score

Favourable effects were shown in integrative treatment over conventional treatment as measured by mJOA with -2.35 [-3.06, -1.63] in three trials (Figure 2.5): two trials favoured tuina plus EI over EI (n=90, -2.15 [-3.29, -1.01], p=0.18, I^2=45%) and one study favoured acupotomy plus EI over EI -2.71 [-4.42, -1.00] (Yang *et al.*, 2009).

Figure 2 5 Integrative treatment versus conventional treatment as measured by mJOA

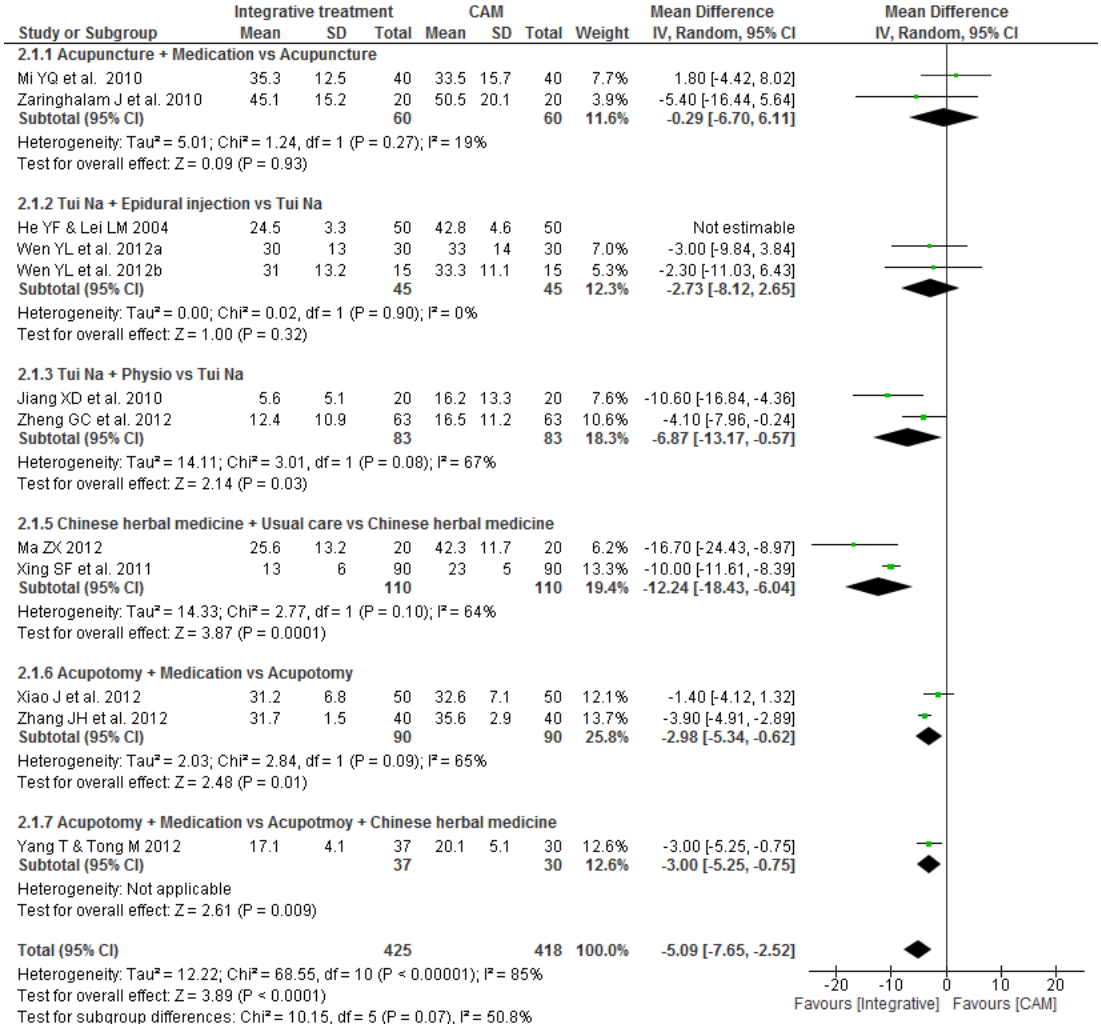


Integrative treatment vs CAM (equal or less than 3 months)

Pain scale

Favourable effects were shown in integrative treatment over CAM as measured by pain scales with MD -5.09 [-7.65, -2.52] in 12 trials (Figure 2.6): two trials favoured tuina plus physiotherapy over tuina alone (n=166, -6.87 [-13.17, -0.57], p=0.10, I^2=67%) (Jiang *et al.*, 2010; Zheng *et al.*, 2012); Two trials favoured CHM plus usual care over CHM (n=220, -12.24 [-18.43, -6.04], p=0.09, I^2=65%) (Ma, 2012; Xing *et al.*, 2011); Two trials favoured acupotomy plus medication over acupotomy alone (n=180, -2.98 [-5.34, -0.62], p=0.09, I^2=65%) (Xiao *et al.*, 2012; Zhang, 2012); and one showed a favourable improvement in acupotomy plus medication over acupotomy plus CHM (-3.00 [-5.25, -0.75]) (Yang and Tong, 2012).

Figure 2 6 Integrative treatment versus CAM as measured by pain scales



(Modified) Japanese orthopaedic association score

Two trials evaluated acupuncture plus medication over medication alone and three trials evaluating tuina plus EI over EI alone failed to show a favourable improvement in mJOA with an effect size of MD -0.29 [-6.70, 6.11] (Mi *et al.*, 2010; Zaringhalam *et al.*, 2010) and -2.73 [-8.12, 2.65] (He Yufeng, 2004; Wen *et al.*, 2012b; Wen *et al.*, 2012a) respectively. Two trials reported positive results comparing tuina plus EI with tuina alone (-2.87 [-4.16, -1.58] (Sun *et al.*, 2003); -1.80 [-3.18, -0.42] (Wen *et al.*, 2012a). One reported positive results when comparing CHM plus usual care with CHM alone as measured by JOA (7.20 [5.53, 8.87]) (Yang *et al.*, 2012). Two failed to prove integrative treatments were superior to CAM (Gu, 2007; Wen *et al.*, 2012b).

Integrative treatment vs CAM (long term follow up > 3m)

Ten trials considered long term follow up for more than three months and six trials reported positive improvement with statistical significance: Acupuncture plus medication versus medication at six months follow up as measured by the Oswestry pain disability index (ODI) with MD -1.10 [-1.56, -0.63] (Zheng, 2012); acupuncture plus usual care versus usual care at three months follow up measured by VAS with MD -13.00 [-20.64, -5.36] (Molsberger *et al.*, 2002); at six months follow up as measured by the VAS with MD -8.00 [-16.03, 0.03], pain disability index (PDI) with MD -6.70 [-11.53, -1.87], and hospital anxiety and depression scale (HADS) with MD -2.30 [-4.48, -0.12] (Leibing *et al.*, 2002); EI plus tuina versus EI at three and six months follow up measured by VAS with MD -20.80 [-30.49, -11.11] and MD -9.50 [-18.85, -0.15], versus tuina at three and six months follow up measured by VAS with MD -21.50 [-32.20, -10.80] and MD -24.10 [-35.68, -12.52] (LI *et al.*, 2011); one study evaluated chiropractic plus physical modalities versus chiropractic alone at 6/12/18m as measured by mean differences of NRS (most severe pain) with MD -0.15 [-0.85, 0.55], -0.34 [-1.05, 0.36], and 0.25 [-0.49, 0.98], NRS(average pain) with MD -0.26 [-0.81, 0.29], -0.56 [-1.13, 0.02], and 0.12 [-0.46, 0.71], and Roland-Morris Disability score with MD 0.12 [-1.15, 1.38], -0.92 [-2.26, 0.42], and -0.01 [-1.35, 1.32] (Hurwitz *et al.*, 2002; Hurwitz *et al.*, 2006).

One study evaluated Alexander technique plus exercise versus usual care with positive improvements only perceived when as measured by Roland Morris disability score (number of activities impaired by pain) with MD -1.29 [-2.25, -0.34]; but not in SF36 (physical) with MD 1.9 [-1.97, 5.79], and SF36 (mental) with MD 0.9 [-2.8, 4.6] (Hollinghurst *et al.*, 2008).

Two trials were unable to show statistical improvement: package of care (including Swedish massage, manipulative therapy, shiatsu, acupuncture, qigong) plus usual care compared with usual care alone at 16w follow up as measured by SF36 bodily pain with MD 2.10 [-7.99, 12.19] and NRS (disability) with MD -0.70 [-2.13, 0.73] (Sundberg *et al.*, 2009); Integrative treatment package plus usual care versus usual care as measured by modified Roland Disability Questionnaire with MD -7.10 [-14.73, 0.53], NRS (bothersomeness of worst symptom) with MD -4.30 [-7.53, -1.07], SF12 (physical) with MD 5.80 [-4.92, 16.52], and SF12 (mental) with MD

0.00 [-11.65, 11.65]. The only positive result was obtained in NRS (pain) with MD -4.40 [-7.43, -1.37] (Eisenberg *et al.*, 2012).

2.2.10 Adverse events

Thirteen out of 56 articles (23%) reported information on adverse events (AEs) in detail: Acupuncture related AEs (6/13) included pain (Qin *et al.*, 2007; Li and Wang, 2008; Eisenberg *et al.*, 2012), circulatory problems (Qin *et al.*, 2007), minor aching, bruising, light-headedness (Meng *et al.*, 2003); minor discomfort, soreness (Eisenberg *et al.*, 2007). One trial reported no adverse events during treatment (Qu *et al.*, 2010). Two trials reported that the acupuncture group experienced significantly fewer side effects (Leibing *et al.*, 2002; Meng *et al.*, 2003). CHM related AEs (1/13) included dizziness, nausea and vomiting (Zhou, 2008). Acupotomy related AEs (1/13) included dizziness, nausea, vomiting and headache (Xiao *et al.*, 2012). Chiropractic and massage related AEs (1/13) included: minor discomfort and soreness (Eisenberg *et al.*, 2007). Four trials (29%) reported that no AEs were experienced by participants (Qi, 2012; Xing *et al.*, 2011; Qu *et al.*, 2010; Hurwitz *et al.*, 2002). One trial reported no crucial AEs in patients who withdrew from the study (Sundberg *et al.*, 2009).

2.2.11 Sensitivity analysis and publication bias

There was a high heterogeneity in the seven subgroup comparisons, the results of which have been presented as a narrative. Sensitivity analysis was not conducted due to the insufficient number of trials in the subgroups (two/three trials). Asymmetrical funnel plots suggested potential publication bias.

2.2.12 Summary of evidence

Though RCTs evaluating integrative treatment for LBP were reviewed, identification of whether a trial used IM (as defined in the mapping review) was difficult due to the lack of standardised use of the term and reporting guidelines for IM. The defining elements of IM proposed in Section 2.2 (Hu *et al.*, 2015b) were not sufficiently well reported, particularly whether the interventions used a holistic approach. It was also unclear whether the patient-practitioner relationship was considered or involved active communication. There were no trials with sufficient details to determine whether treatments were explicitly an IM approach.

The meta-analysis showed a favourable effect of integrative treatment over conventional treatment in back pain and back function measured by pain intensity scales and mJOA at three months or less follow up. It also showed improvement from integrative treatment compared to CAM in back pain intensity and back function. For trials with a longer follow up period (> 3m), 60% reported statistically significant improvements in back pain and back function. However, this evidence is limited because of the relatively small number of included trials in each subgroup analysis measuring back function, high heterogeneity, and low methodological quality of the included trials.

Many trials report minor AEs from CAM therapies but there is inadequate information on possible AEs resulting from the interaction of CAM and conventional treatment.

2.3 A narrative review on patients' experiences in receiving CAM/IM therapies

In alignment with the MRC framework stage of developing and identifying theory, this section reviews qualitative studies exploring patients' experiences of receiving CAM treatments for MSDs. The search focused on CAM rather than IM treatments because there was inadequate qualitative research which can be defined as IM.

This narrative review further adds to the overall mixed methods review, by identifying and understanding patients' experiences of receiving CAM treatments for their MSDs. This may help in refining research questions, explaining the meta-analysis synthesis results, assisting interpretation of the significance and applicability of the mixed methods review, and in giving recommendations (Evans, 2007). Adding qualitative findings to a trial can also help explore perceptions about the content of intervention and delivery, outcomes, trial design, conduct and process, and measures of process and outcome (Lorenc *et al.*, In process). It can help identify unanticipated phenomenon which may be difficult to detect using a targeted outcome measure and quantitative approach, especially for complex interventions like IM.

Exploring patient experiences using a qualitative approach is one way of evaluating the treatment outcome. In CAM, mixed methods or qualitative studies are still rare: a systematic review conducted in 2012 found 84% of the studies published in the top

10 CAM journals were quantitative research; only 4% reported mixed methods studies and 1% a solely qualitative approach (Bishop and Holmes, 2013).

Therefore, in order to explore patients' experiences of receiving CAM/IM treatment, a search was conducted in five English language databases: Web of science, AMED, EMBASE, OVID medicine, and PsycINFO, from their inceptions to November 2014. An updated search was conducted in August 2015. The key words such as "qualitative" AND "experience(s)" were searched. A detailed search strategy is provided in Appendix 2.8. Included qualitative studies were analysed using a thematical analysis approach, with themes identified and presented in section 2.4.3.

2.3.1 Characteristics of included qualitative studies

The search identified nineteen qualitative studies exploring patients' experiences of receiving CAM treatments for MSDs (Hughes, 2009; Beattie *et al.*, 2010; Cartwright, 2007; Zhang and Verhoef, 2002; Park *et al.*, 2011; Bronfort *et al.*, 2011; Rowell and Polipnick, 2008; Therkleson, 2010; Son *et al.*, 2013; Galantino *et al.*, 2004; Cramer *et al.*, 2013; Galantino *et al.*, 2012; Ahn *et al.*, 2007; MacPherson and Thomas, 2008; MacPherson *et al.*, 2006; Hsu *et al.*, 2010; Andersson *et al.*, 2012; Westrom *et al.*, 2010; Brien *et al.*, 2012), of which twelve used a mixed methods design (Andersson *et al.*, 2012; Westrom *et al.*, 2010; Hsu *et al.*, 2010; Galantino *et al.*, 2004; Cramer *et al.*, 2013; Bronfort *et al.*, 2011; Ahn *et al.*, 2007; Park *et al.*, 2011; Rowell and Polipnick, 2008; MacPherson and Thomas, 2008; MacPherson *et al.*, 2006; Beattie *et al.*, 2010).

The method of collecting qualitative data included interviews (Westrom *et al.*, 2010; Hsu *et al.*, 2010; Cramer *et al.*, 2013; Bronfort *et al.*, 2011; Rowell and Polipnick, 2008; MacPherson and Thomas, 2008; MacPherson *et al.*, 2006; Beattie *et al.*, 2010; Cartwright, 2007; Zhang and Verhoef, 2002; Therkleson, 2010; Galantino *et al.*, 2012; Son *et al.*, 2013; Brien *et al.*, 2012; Hughes, 2009); focus group interviews (Park *et al.*, 2011; Closs *et al.*, 2007); observation (Ahn *et al.*, 2007; Galantino *et al.*, 2012); and diaries/drawings (Therkleson, 2010). These qualitative studies focused on a variety of MSDs, e.g. back pain (Westrom *et al.*, 2010; Hsu *et al.*, 2010; Galantino *et al.*, 2004; Cramer *et al.*, 2013; Bronfort *et al.*, 2011; Rowell and Polipnick, 2008; MacPherson and Thomas, 2008; MacPherson *et al.*, 2006; Beattie *et al.*, 2010), osteoarthritis (Park *et al.*, 2011; Therkleson, 2010; Zhang and Verhoef, 2002; Son *et*

al., 2013), or other musculoskeletal related pain conditions (Ahn *et al.*, 2007; Cartwright, 2007; Galantino *et al.*, 2012; Hughes, 2009; Brien *et al.*, 2012).

2.3.2 Positive experiences in various types of CAM

Patient-reported positive experiences have been reported in qualitative findings for various CAM therapies, including acupuncture (Ahn *et al.*, 2007; MacPherson and Thomas, 2008; MacPherson *et al.*, 2006; Hughes, 2009), yoga (Galantino *et al.*, 2004; Cramer *et al.*, 2013; Park *et al.*, 2011; Galantino *et al.*, 2012), moxa (Son *et al.*, 2013), ginger compress therapy (Therkleson, 2010), chiropractic (Westrom *et al.*, 2010; Bronfort *et al.*, 2011; Rowell and Polipnick, 2008), Reiki (Park *et al.*, 2011), TCM (Zhang and Verhoef, 2002), homeopathy (Brien *et al.*, 2012) and other CAM treatments (Westrom *et al.*, 2010; Beattie *et al.*, 2010; Cartwright, 2007).

Physical improvements and reduction in medication

Patients in many qualitative studies reported that CAM therapies had helped manage their MSD symptoms, which include physical symptoms such as pain (Hsu *et al.*, 2010; Cramer *et al.*, 2013; Park *et al.*, 2011; Cartwright, 2007; Zhang and Verhoef, 2002; Galantino *et al.*, 2012; Son *et al.*, 2013; Hughes, 2009). They experienced functional improvements with more flexibility, mobility and comfort (Hsu *et al.*, 2010; Cramer *et al.*, 2013; Park *et al.*, 2011; Cartwright, 2007; Zhang and Verhoef, 2002; Therkleson, 2010; Galantino *et al.*, 2012; Son *et al.*, 2013; Hughes, 2009; Brien *et al.*, 2012). They also found that CAM treatments helped with their breathing (Therkleson, 2010), reduced analgesics (Son *et al.*, 2013), increased their energy (Hsu *et al.*, 2010; Therkleson, 2010; Galantino *et al.*, 2012), and gave them a more balanced and natural body perception (Cramer *et al.*, 2013).

Emotional improvements

Patients with MSDs experienced emotional improvement, including: relief of stress and anxiety (Hsu *et al.*, 2010; Cartwright, 2007; Galantino *et al.*, 2012); feeling calm, relaxed, releasing tension, providing emotional soothing, comforting and feeling more cheerful (Therkleson, 2010; Hsu *et al.*, 2010; Galantino *et al.*, 2004; Cramer *et al.*, 2013; Ahn *et al.*, 2007; Park *et al.*, 2011; Hughes, 2009), and being listened to and understood (Brien *et al.*, 2012).

Mind body interaction was one of the features patients reported as improved with CAM treatments. Patients have reported being more 'even-tempered' if they used CAM therapies, thus more likely to accept and cope with their disability (Cramer *et al.*, 2013). Patients also experienced increased body/muscle awareness, which they described as an important precondition to help them avoid movements which aggravate pain (Galantino *et al.*, 2004; Cramer *et al.*, 2013; Hsu *et al.*, 2010). They also perceived a heightened sense of connection of mind, body, and spirit (increased mindfulness) (Hsu *et al.*, 2010).

One qualitative study found that patients realised the importance of breathing as a result of learning yoga (Galantino *et al.*, 2012). It has also been reported that ginger compression therapy could help produce constant penetrating body warmth throughout the body, and induce a meditative-like stillness and emotional relaxation for patients with osteoarthritis (Therkleson, 2010).

Improved social interaction

Qualitative data also suggested improved social interaction among patients receiving CAM treatment, including positive changes to social opportunities (Therkleson, 2010), improved receptivity towards others (Therkleson, 2010); re-engagement with activities, more self-determined lives; improved efficiency in work and social lives (Cramer *et al.*, 2013); and becoming more interested in the world, with positive changes in their outlook (a positive shift in thinking, leading to renewed interest and confidence in relationship with others) (Therkleson, 2010).

Self-reflection

Patients were also aware of the fact that, following CAM treatment, rather than expecting a complete cure, they had realised that MSDs were degenerative chronic conditions and they wished to maintain physical and social functioning within these constraints (Cartwright, 2007), and to improve their general well-being (Park *et al.*, 2011; Brien *et al.*, 2012). They had greater acceptance of their pain and life burden (Cramer *et al.*, 2013); and changed their way of thinking to increase their ability to cope with musculoskeletal pain (Hsu *et al.*, 2010).

Empowerment

After CAM treatment, patients obtained a sense of control because of reduced anxiety and a return to normal functioning (Cramer *et al.*, 2013; Hsu *et al.*, 2010; Cartwright, 2007); and realising the importance of camaraderie, community and sharing (Galantino *et al.*, 2012).

Patients' understanding of CAM

Patients felt that CAM is an important adjunct to conventional medical care (Cartwright, 2007). Patients perceived several differences between CAM therapies and conventional medicine. They reported that conventionally trained physicians were 'excessively dependent on diagnostic tools' and would only help by slowing down the progression, but not treating the root of the condition, and did not pay much attention to patients' experiences and explanations (only looking at patients' biomedical results in their notes) (Zhang and Verhoef, 2002); CAM practitioners are more likely to trace back through patients' medical histories (Zhang and Verhoef, 2002). Patients also reported that CAM provides a whole package of individualised care whereas conventional medicine was associated with impersonal experiences (Cartwright, 2007).

Qualitative research also suggested that patients required practitioners who were understandable, proactive, and provided timely information. They wished to receive treatments from caring practitioners who believed in patients, understood their concerns, listened; and who were knowledgeable, experienced, and actively managed patients. Patients also wished to receive quality care with an exchange of information, and treatment provided with kindness (Rowell and Polipnick, 2008).

Patients' perception of the challenges of CAM

Patients stated that they need a long term intervention with continuous treatment (Son *et al.*, 2013). They recognised the barriers to accessing CAM therapies as they were aware of the cost and restrictions to healthcare systems, as CAM are not covered by most national healthcare insurance schemes (Zhang and Verhoef, 2002). This may also lead to the issue of not having practitioners sufficiently trained in the field (Zhang and Verhoef, 2002).

Self-management

Many chronic MSD patients, generally the older patients, had developed self-care management strategies by actively engaging in various activities. Attending these activities was one of the most common ways they exchanged medical advice and obtained support from their peer group (Zhang and Verhoef, 2002). Patients also reported yoga as a self-care coping strategy used to help reduce and prevent pain (Cramer *et al.*, 2013).

2.4 Chapter Summary

In this chapter, a mapping review of IM definitions identified potential key components of IM. IM was identified as the optimum treatment which considers aspects of both CAM and conventional medicine. It is a holistic individualised approach which uses the body's innate healing response, emphasises the patient-practitioner relationship and multidisciplinary collaborative teamwork, and has the goals of both health and healing. It also emphasised the need to improve the evidence base, effectiveness, safety, and low cost.

The systematic review on integrative treatments for LBP showed that integrative treatments appear to be useful for relieving pain and improving function in LBP, though evidence is limited due to heterogeneity between studies, the relatively small numbers available for subgroup analyses and the low methodological quality of the trials. Identification of studies of true IM treatments that report the components of IM above was not possible due to lack of reporting of the intervention details.

Qualitative research on patients' experiences of receiving CAM for a variety of MSDs indicates that patients perceive various physical and emotional improvements from receiving these treatments. They perceived improved self-reflection and shared their understanding of CAM. Patients felt empowered, and learnt self-management techniques from receiving CAM treatments, as well as improved social interaction. However, some of the components identified above were not reported by patients in qualitative studies, such as perspectives of multidisciplinary teamwork, or their relationship with practitioners.

These reviews have identified the need for further research to consider the components identified in this review; investigate the effectiveness of providing integrative treatment for MSDs; and explore patients' experiences of receiving IM treatments, especially in an NHS environment. Since no research study was identified exploring IM as a package of care for MSDs in a secondary NHS setting in the UK, in line with the MRC framework (Section 1.4.3), a mixed methods feasibility study on integrative treatment for MSDs in the UK was considered to be an appropriate way forward.

Chapter 3 Methodology and Methods

Aims and structure

Following the MRC framework for complex interventions, a feasibility study on integrative treatment for MSDs using a mixed methods design was conducted. This chapter presents the overall methodology and detailed methods of conducting the feasibility study. The structure of this chapter is as follows:

Section 3.1 justifies the use of a mixed methods approach to determine the feasibility of carrying out a pragmatic observational research study. It links the research student's epistemology (Section 1.3), conceptual framework (section 1.4) and the key components of IM (as identified in Section 2.2). Validation of this mixed methods design is stated (Section 3.2). The detailed procedures of this research study, including recruitment procedures, inclusion and exclusion criteria, outcome measures selected, data collection, and quantitative and qualitative data analysis are given, with reasons for their choice (Sections 3.3-3.6). In Section 3.7, techniques used in interpreting and triangulating quantitative and qualitative results are described. Finally, ethical issues are discussed in Section 3.8, followed by a summary of this chapter (Section 3.9). Supporting materials are provided in appendices (Appendices 3.1-3.7).

The mixed method feasibility study is reported according to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement for the observational quantitative data (von Elm *et al.*, 2014), and the Consolidated Criteria for reporting qualitative research (COREQ) for qualitative data (Tong *et al.*, 2007).

3.1 Justification of the study design

This section specifies and justifies the methodology used for this research study. Under a pragmatic epistemology, mixed-methods research (MMR) is the overall study design. Given the complex nature of IM discussed in Section 2.2, pragmatic observational approaches were used. Details of the rationale for choosing these designs are discussed in this section.

3.1.1 Mixed methods research

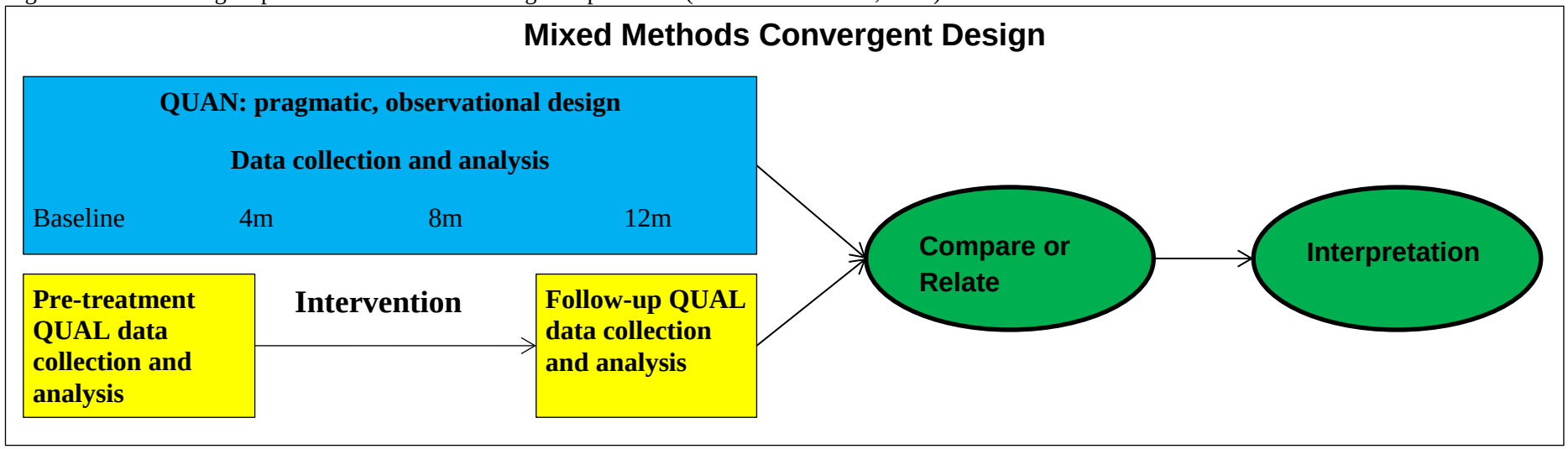
The rationale for using a mixed methods design in this research study was briefly introduced in Section 2.5. Qualitative research helps to uncover the complex

experiences of patients, ensure the comprehensiveness of findings and stimulate reflexive analysis (Broom, 2005; Paterson and Britten, 2003). Therefore a qualitative design and a quantitative approach with comprehensive multiple outcome measures were adopted to provide a comprehensive understanding of IM practice. A previous review conducted by the research team suggested that although adding a qualitative approach in CAM trials is still relatively rare, it can help explain and interpret trial results, improve future study design and identify unexpected outcomes of trials (Lorenc *et al.*, In process).

This research study adopted a convergent parallel mixed methods design as described by Creswell and Clark (2011). In convergent MMR, qualitative and quantitative data are given equal priority with concurrent timing of the strands, and using them to explore the same topic, to better understand a phenomenon (Creswell and Clark, 2011). This feasibility study was considered as a fixed convergent mixed methods design, as the use of quantitative and qualitative strands were predetermined at the start of the research process, due to the complexity of IM as discussed in Chapter 2 (Section 2.2). Quantitative and qualitative approaches were carried out with the same overarching aim, which was to determine the feasibility of evaluating integrative treatments for MSDs in NHS in the UK.

One important aspect of MMR is when and how the two strands interact. The interaction may happen during interpretation, data analysis, data collection, or at the level of design (Creswell and Clark, 2011). Convergent MMR design includes concurrent but independent quantitative and qualitative data collection, separate quantitative and qualitative analyses, and mixes the two data sets only at the overall interpretation stage (Creswell and Clark, 2011), which was when main interaction between the two strands happened in this research study. Figure 3.1 presents the convergent MMR adopted in this research study. Methods of data analysis reflecting the convergent design is provided in Sections 3.5 & 3.6.

Figure 3 1 The convergent parallel mixed methods design adapted from (Creswell and Clark, 2011)



QUAN=quantitative, QUAL=qualitative

3.1.2 Feasibility study design

Feasibility studies are designed to produce a set of findings which will help determine whether an intervention should be recommended for efficacy/effectiveness testing or not. In line with the recommendations in the MRC complex intervention framework, a feasibility stage was implemented due to a lack of published research specifically referring to IM (Craig *et al.*, 2008). In particular there is a lack of information on IM for MSDs in NHS settings, including patients' acceptance of integrative treatment and taking part in research, recruitment rate and retention, variability, and the effect size for appropriate sample size calculation. This study aims to assess the feasibility of researching IM, rather than being a pilot study which is the pre-run of a small scale study to inform a future study using the same study design (Arain *et al.*, 2010).

Feasibility of research is crucial for evaluating complex interventions as there may be issues around recruitment and retention, intervention delivery and fidelity, and potential inadvertent treatment effects (Clark *et al.*, 2014). It has been suggested that IM, as a complex intervention, should be evaluated using a pragmatic approach to mimic clinical practice and its outcomes (Witt, 2009). In general IM practice, participants may have different individualised treatments, beginning at different times and having different lengths of treatment. Although there may be a prescribed follow up period, some participants may not have finished their sessions at the hospital when the final evaluation took place. Variations in the number and types of integrative treatments may cause issues in achieving statistical significance, as there might be inadequate numbers of participants having the same combination of integrative treatments or similar complexities of integrative treatment. In addition, the reliability and validity of using multiple outcome measures, and information on effect-size estimation can be assessed during the feasibility phase (Craig *et al.*, 2008).

Though studies have been conducted in the RLHIM on acupuncture/acupressure (Fisher and Hughes, 2014; Cummings, 2011a; Cummings, 2011b; Hughes *et al.*, 2013), autogenic training (Bowden *et al.*, 2012), and herbal medicine (Berkovitz *et al.*, 2013), no study has been conducted specifically on MSDs. The information collected from this research study was essential to inform the design of a future

large scale evaluation. Feasibility designs can test the fit of interventions in real-world settings and can fill gaps in the literature, providing new criteria and suggesting measures to evaluate relevant outcomes (Glasgow *et al.*, 2006). This is essential in confirming the details of recruitment, study timelines, and to propose outcome measures to suit the complex nature of IM.

3.1.3 Pragmatic study design

Clinical trials can either be designed as explanatory, in which the aim is to assess efficacy, robustly comparing with a sham group under controlled conditions; or pragmatic, which aims to evaluate effectiveness of a therapy as practised in routine daily clinical practice (Schwartz and Lellouch, 2009). A pragmatic design overcomes the issues of controlling for the everyday practice of complex interventions, especially when a varied complex package of care is provided (Bonell *et al.*, 2012; Campbell *et al.*, 2000).

There are many challenges in assessing IM using conventional research methodologies such as RCTs. Similar to CAM treatments, IM rarely lends itself to being administered in a standardised or randomised manner, due to the individualised and holistic nature of IM. Randomisation is difficult as some patients who wish to try certain CAM treatments might have a belief in them and would insist on receiving the true intervention or may withdraw from the study if randomised to a control group. The components that contribute to the effects of IM treatment are difficult to be detected due to a lack of randomisation, e.g. is A or B treatment providing the treatment effect or is it an interaction of A plus B; is the treatment effect affected by patients' preference/choice or their expectations; how does the patient-practitioner interaction contribute to the effects etc.

Blinding is a challenge for complex and non-pharmaceutical interventions that involve face to face interactions such as IM. It is nearly impossible to blind practitioners in IM, and many research studies criticised the blinding of patients in IM. For example, with integrative treatment, practitioners often do not provide uniform treatment, as considering all aspects of a person rather basing treatment on a single disease is fundamental to IM, which is tailored to an individual's needs, with varied types and frequency of treatments. The 'flexible', 'unrepeatable'

interventions that require skills by practitioners lead to a lack of internal validity (IV) as sham/blinding is often impossible in face-to-face involved interventions.

It has been suggested that pragmatic designs can overcome the difficulties of conducting explanatory trials of CAM or complex interventions, especially when testing a package of care (Bonell *et al.*, 2012; MacPherson, 2004b). Pragmatic designs may result in higher external validity (EV) as it is situated in real world routine clinical practice (Campbell *et al.*, 2000). Comparing the package of complex interventions to another treatment rather than a sham intervention may provide evidence to help policy makers, researchers, practitioners and patients to choose between the target complex intervention and the standard or routinely accepted treatment (MacPherson, 2004b). In this pragmatic approach, one can reflect the situation in routine care and provide realistic benefit estimation for future health care research (Bonell *et al.*, 2012). A pragmatic approach is therefore ideal for the research question (Section 3.1) of this feasibility study as it explores packages of integrative treatment in an NHS setting in routine clinical care.

3.1.4 Observational study design

The published trials identified in Section 2.3 compared integrative treatment with CAM or conventional treatments; no trial was identified investigating the efficacy or effectiveness of IM treatment. It is difficult to design a control group to evaluate the efficacy or effectiveness of IM. For example, patients in a control group who receive standard usual care may use CAM on their own initiative or from another provider. In addition, due to the complex situation of IM intervention (including the influence of patients' preferences, using individualised treatment, variation in practitioners' skills, and the issues of conducting placebo-controlled studies), observational approaches have been recommended in healthcare research (Concato *et al.*, 2000; Benson and Hartz, 2000), as well as in the field of CAM (MacPherson, 2004b; Harlan, 2001; Vickers *et al.*, 1997) and IM (Herman *et al.*, 2014; Bell *et al.*, 2002). Prospective observational study designs have also been successfully used in other research areas such as pharmacoepidemiology (Hallas and Pottegard, 2014), mental health care (Pratt *et al.*, 2012), and cardiology (Ramsay *et al.*, 2011).

There are potential methodological issues in adopting an observational study design with no comparison group as it can be argued that the effects are not related to the

intervention (Hallas and Pottegard, 2014). The limitations of using an observational design are discussed in Section 7.6.2.

3.2 Validation of mixed methods research

In terms of the rigour of the methodology, quantitative rigour in positivist paradigm is measured by reliability and validity. Application of reliability and validity to qualitative research is problematic and may not be the most appropriate tools for demonstrating robustness. However, if the concepts of validity and reliability are rejected the concept of rigour is rejected (Morse *et al.*, 2002). Therefore, alternatives can be used to validate qualitative trustworthiness (authenticity/goodness), as subscribed by interpretivist/constructivist, radical/critical, and post structural/postmodern paradigms (Lincoln and Guba, 1985; Andrew and Halcomb, 2009). One such alternative is that proposed by Morgan, which uses a classic pragmatic emphasis on abduction, inter subjectivity, and transferability, created a range of new opportunities for thinking about classic methodological issues in the social sciences (Morgan, 2007).

Validation in qualitative research uses many notions such as credibility (in preference to IV), dependability (in preference to reliability), transferability (in preference to EV or generalisability), and confirmability (in preference to objectivity) (Tobin and Begley, 2004; Lincoln and Guba, 1985; Malterud, 2001). Validation of the qualitative approach in this research study is discussed (Section 7.6.3) following Guba's four criteria to ensure trustworthiness, which are credibility, transferability, dependability, and confirmability (Lincoln and Guba, 1985; Shenton, 2003).

When quantitative and qualitative methods are mixed within a study, they are usually taken from a single worldview or paradigm. Many suggested one should differentiate the numerous strategies for validating MMR within different research paradigms and a 'dominant paradigm' should be examined (Andrew and Halcomb, 2009). The researcher should be 'vigorously self-aware' of how his/her paradigmatic position may influence decisions concerning validation (Lather, 1986), and whether more than one set of validation strategies should be applied (Andrew and Halcomb, 2009). The process of MMR validation should shift depending on either QUAN or QUAL is dominant within the research study

(Andrew and Halcomb, 2009). Methods chosen to ensure MMR validity need to reflect the ontology and epistemology and to fit with methodology which are congruent with the topic specific overall research aim (Andrew and Halcomb, 2009). For this research study, as described in Section 3.1.1, quantitative and qualitative approaches shared equal priority and the whole research study was conducted under an epistemology of pragmatism. Since this research study used a convergent mixed methods design, quantitative and qualitative data were collected and analysed separately. Validation of each strand was conducted separately.

Validation of the quantitative approach used in this research study was more recognised than the qualitative approach. A research protocol was published in 2013 at the design stage, to improve reliability by showing consistency in the research aims and use of outcome measures and to allow potential reproduction of results (Hu *et al.*, 2013). IV was enhanced by the three outcome measures, VAS, sfBPI and SF36 (details in Sections 3.4.4 and 3.4.5), measuring the pre-set objectives of this study, namely to assess the feasibility of evaluating effectiveness of integrative treatment for MSDs. EV (generalisability) was weakened due to small sample size from a single geographic location. Therefore, findings of this observational design should be interpreted with caution when considering application to a wider context or different population. Other limitations in quantitative data analysis were that selection bias may have been produced by using complete-case analysis, as longitudinal data might violate the assumption of missing completely at random (MCAR) (Graham, 2009); and there were inadequate participants for subgroup analysis, which is common for observational research in such a complex environment. Missing data in completed questionnaires were rare, which may be due to the research student completing the first questionnaire with the participants, which may have enhanced their understanding of the questionnaire content and the process of participating in the research study.

3.3 Research setting and recruitment

This section introduces the routine clinical practice at the RLHIM for MSDs, and the recruitment procedure used for this research study.

3.3.1 Routine Practice for Musculoskeletal Disorders at the RLHIM

RLHIM is the largest public sector provider of IM in Europe. The hospital receives 20,000 to 30,000 patient referrals every year, of which MSDs are the most frequent (mean percentage over four years: 19%) patient referrals (including both new referrals and follow-up patients) to the hospital (Table 3.1). As an integrated hospital that is affiliated to University College Hospital (UCH) and working closely with the National Hospital for Neurology and Neurosurgery (NHNN), the RLHIM aims to integrate safe and effective CAM with conventional interventions, with practitioners and healthcare professionals from different departments working closely together.

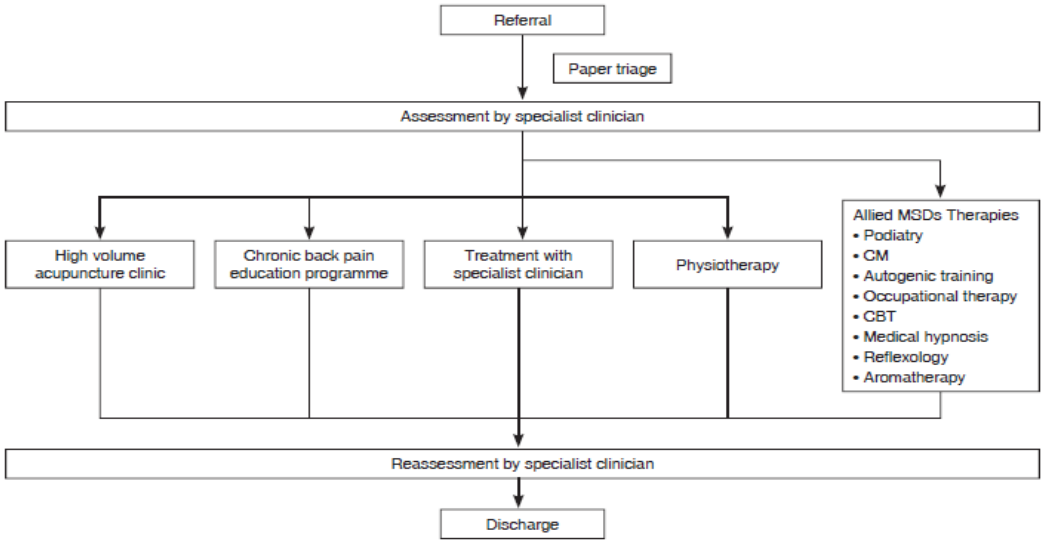
Table 3 1 Number of all referrals and musculoskeletal referrals per year 2010-2014

Year*	All Referrals, n	MSDs Referrals, n (%)
2010-2011	29247	6892 (23.6%)
2011-2012	26914	5207 (19%)
2012-2013	28159	3219 (11%)
2013-2014	20941	4594 (22%)

*Financial year (from the 1st April to 31st March).

In routine standard practice, all MSD patients referred for RLHIM treatment receive an appointment with a MSD specialist approximately 2 months after their initial GP referral letter. At this time point their healthcare problems are assessed and if necessary they are triaged by a specialist clinician and referred to the department(s) that suits their condition most (Figure 3.2). All patients are reassessed by the same specialist clinician before being discharged.

Figure 3 2 Musculoskeletal care pathway at the RLHIM (UCLH, 2015)



Key: CM=Chinese medicine; CBT=cognitive behaviour therapy

Patients who present with MSDs typically receive integrative packages of care at the RLHIM. The integrative packages of care combine conventional and complementary approaches.

Treatment may include: acupuncture and trigger point therapy, osteopathy and spinal manipulation, physiotherapy, injection therapy, exercise therapy, Pilates, back pain education, and podiatry (UCLH, 2015b). Some patients may have a one-off treatment, some may start their treatment immediately and some may be put on a waiting list which could potentially last for up to 5 months before they receive treatment. Routine packages of treatment at the hospital are individualised with a varying number of treatments depending on patient individualised condition and practitioners' recommendation. Normally, the average course of treatment is 6-8 sessions, and lasts approximately 2-3 months. More than one course of treatment may be offered. Patients are routinely discharged from the hospital if they fail to attend for an appointment on two consecutive occasions.

3.3.2 Inclusion, exclusion criteria, and sample size

Since a feasibility study does not require a calculation of the sample size, this study used a convenience sample, including all newly referred eligible patients with MSDs attending RLHIM between January 2013 and April 2014. All eligible patients who provided informed consent and indicated they were willing to participate in the study during the 12-month period were recruited. A large sample

size with a more heterogeneous mix of participants has been suggested for a pragmatic design as variation between participants may dilute the treatment effect (MacPherson, 2004b). Wide inclusion criteria were set to target the maximum number of MSD patients.

Though previous qualitative studies have suggested saturation occurs at the 12th interview with most themes identified within the first six interviews (Guest *et al.*, 2006), saturation as a conceptual guide may not provide practical guidance on deciding sample size prior to data collection, as the number of interviews needed to reach saturation highly depends on the nature of the research question and the target sample group (Baker & Edwards, 2012). Considering the feasibility nature of this research study and the fact that the research student's first language was not English, it was felt that more than 12 interviews may be needed to reach saturation. Therefore, 30 participants in the quantitative part of the research study were interviewed before and at one year follow-up as it was anticipated that this would provide a sufficiently large enough sample to ensure theoretical saturation of emergent categories and themes (Baker & Edwards, 2012). Details on questionnaire completion, those who were interviewed and drop outs is provided for the participants recruited into the study in table 4.1.

The inclusion criteria were:

1). New referrals to RLHIM for MSDs, including all MSD patients who had received previous treatment for MSDs but were presenting for a new episode of care (either a single MSD diagnosis or with a combination MSD diagnoses were included);

2). Male or female patients 16 years or older;

3). Patients with a primary diagnosis of an ICD-10 code under musculoskeletal system and connective tissue disorders (ICD-10, 2012);

4). Able to take part in the study for 12 months.

The exclusion criteria were:

1). Unwilling to take part in the study;

2). Unable to communicate in English;

3). Unable to read and therefore understand the written study documents and the patient consent form or patient information form;

4). Severe progressive disorders, life threatening conditions or poor prognosis;

5). Patients diagnosed with cognitive impairment such as dementia or psychological disorders.

3.3.3 Participant Recruitment

3.3.3.1 Participant recruitment for the quantitative part

Patients were recruited between January 2013 and April 2014. A musculoskeletal clinician who triaged and conducted assessments for patients screened and selected eligible patients to the study. A sticker was placed in each eligible participant's clinic notes to allow patient service department (PSD) staff, clinicians to distinguish participating patients. The PSD sent patients the information sheet and cover letter explaining the research study to the patients with their routine appointment letter. The information sheet contained details of the observational study and is provided in Appendix 3.1. The research student's contact details were provided and the patients were asked to contact her directly if they were interested in taking part in the study.

Approximately one week after the new MSD patient's initial referral, the PSD at the RLHIM routinely contacts patients to confirm hospital appointments. As part of this confirmation, they reminded those patients whose clinical notes had a sticker on them about the study. The PSD asked interested patients for permission to pass their contact details onto the researcher. The research student then contacted the patients (Section 3.3.2) by telephone. Study eligibility was then verified and the study explained. For those who expressed interest in the study, a questionnaire package including a consent form (Appendix 3.2), sociodemographic questionnaire (Appendix 3.3), and Patient Expectation Questionnaire (PEQ) (Appendix 3.3) with a reply paid envelope was posted. These questionnaires were sent at this point as the feedback was required prior to the first interview. Patients who had not consented by post, but were willing to participate, were able to join the study on the

day of their first assessment appointment. A flowchart showing the screening, recruiting, and follow-up process is available in figure 3.3 (page 65).

3.3.3.2 Participant recruitment for the qualitative study

Qualitative data were collected before participants' initial appointment and at 12 months post their initial appointments. Pre-treatment qualitative study recruitment took place at the same time as recruitment for the whole study when the information sheet and consent form was sent to the patient. At the same time, patients were phoned about taking part in the quantitative part of the study, they were also asked whether they would be willing to take part in an interview.

In order to produce contrasting cases (comparability), the research student planned to recruit a purposive sample using multiple purposive techniques: (homogeneous and intensity sampling) (Teddlie and Yu, 2007). It was intended to select several participants with high PEQ scores and several with low PEQ scores through intensity sampling technique; and to select participants on the basis of their age and gender by homogeneous sampling. The decision of sample size for the two qualitative parts was discussed in Section 3.3.2.

The pre-treatment interviews were arranged immediately before the patients' initial hospital appointment, after they completed the questionnaires or at another date and venue convenient for the patient (prior to their initial consultation/assessment at the RLHIM). The research student invited eligible patients to come to the hospital at least 30 minutes (quantitative part only) or 90 minutes (quantitative and qualitative parts) before their initial appointment.

3.4 Integrative medicine outcome measures and baseline characteristics

This section details the baseline characteristics collected from participants: sociodemographic and lifestyle (smoking and drinking history) characteristics; expectations; participants' GPs' locations; and a range of patient reported outcomes (PROs) including measures of pain, health related quality of life (physical and emotional function), and resource use, in order to understand the holistic healing process and whether this changed.

GP practice locations were calculated from practice postcodes. All other measurements were collected using the package of questionnaires sent to the

participants. Participants' sociodemographic and lifestyle characteristics were collected once, prior to their initial appointment at baseline; PRO measures were collected at four time points (five if participants were on waiting list): baseline, four, eight, and 12 months after baseline. All participants completed the first questionnaire package guided by the researcher to facilitate patients who may have had difficulty in understanding and completing the measurements. Completion of the whole questionnaire package took approximately 20 to 30 minutes. All questionnaires are available in Appendix 3.3.

3.4.1 Sociodemographic questionnaire

The sociodemographic questionnaire was designed for the research study by the research team, adopting the census categories (Office for National Statistics, 2011). It included: age, gender, marital status, education, occupational status, mother tongue, ethnic origin, and religious affiliation. It took less than 5 minutes to complete, and was administered once at the baseline in the period between the first appointment being booked and on attending the hospital appointment.

3.4.2 Patient Expectation Questionnaire

Though patient expectation measurement has not been rigorously investigated using standardised measurement, surveys or scales have been developed to measure and quantify expectancy (Schutzler and Witt, 2013; Sherman *et al.*, 2014). Various measures have been used to evaluate patient expectations of CAM, including those with chronic pain (Tsao *et al.*, 2005), hypersensitivity illness (Launso *et al.*, 2007), patients using homeopathic treatment (Thompson *et al.*, 2007), CAM therapies in general (Himmel *et al.*, 1993); and patient expectations in using acupuncture/massage treatment with chronic pain (Linde *et al.*, 2007; Sherman *et al.*, 2010; Kalauokalani *et al.*, 2001).

Assessment of patients' expectations of care and treatment has been recommended in IM and has been found essential to help understand the patient's perspective and improve patient-practitioner communication (Bowling *et al.*, 2012). Expectation of benefit has been shown to impact clinical effectiveness (Mondloch *et al.*, 2001). A review identified 71 PRO measures for an integrative medicine primary care setting, from which two were related to patients' attitudes or beliefs towards CAM

(Hunter and Leeder, 2013): the holistic complementary and alternative health questionnaire (HCAMQ) (Hyland *et al.*, 2003), and the CAM belief inventory (Bishop *et al.*, 2005). Both instruments have been validated and are thought to be reliable. The latter is a 17-item questionnaire which measures belief in natural treatments, holistic health, and additionally, participation in treatment (Bishop *et al.*, 2005). A more recent systematic review identified 49 trials which measured expectations of benefit from acupuncture, of which most used a Likert scale or NRS followed by a question such as "How confident [sure] do you feel [are you/would you be] that this treatment can alleviate/control…" (Prady *et al.*, 2015). However, the authors concluded that there is no standard or well tested instrument to assess patients' expectation in the IM primary care setting (Prady et al., 2015).

In this research study, patients' expectation is seen as a potential predictor of integrative treatment for MSDs provided at the RLHIM. Adapted from Borkovec and Nau (Borkovec and Nau, 1972), two questions asked "How much do you believe that the treatment you will receive at the RLHIM will make your condition better?", and "How much faith do you have in complementary therapies in general?", followed by a 0 to 10 VAS below each question to assess participants' expectations.

3.4.3 Referrals and Participants' GPs' Location

Participants' referral data were collected from the hospital clinical data repository (CDR) workstation (the electronic hospital system). The number of participants whose initial appointments were cancelled or changed was recorded. Length of the time interval between participants receiving their referral letter and their initial appointment and the length of time they were on a waiting list were also recorded.

The postcodes of the participants' GPs were extracted from the RLHIM hospital system and then grouped into those within North East London (postcodes start with 'N' or 'E'), non-North East London (in greater London, apart from North East London), and outside greater London. Their postcodes were also converted to latitude and longitude (LatLong, 2015), and then entered onto a map of the UK with SPSS (map downloaded from Statslik) (StatSilk, 2015). Table 3.2 lists the North East London clinical commissioning groups (CCGs) who have contracts with the RLHIM.

Table 3 2 Codes and names of North East London CCGs (NHS England, 2013)

CCG name
NHS Barking & Dagenham CCG
NHS Barnet CCG
NHS Camden CCG
NHS City and Hackney CCG
NHS Enfield CCG
NHS Haringey CCG
NHS Havering CCG
NHS Islington CCG
NHS Newham CCG
NHS Redbridge CCG
NHS Tower Hamlets CCG
NHS Waltham Forest CCG

3.4.4 Primary outcome measures: improvement in pain

There are many scales available to evaluate pain intensity or pain impact for adults, including pain VAS, short form brief pain inventory (sfBPI), NRS for pain, (short form) McGill pain questionnaire (MPQ), short form-36 bodily pain subscale (SF36 BPS), chronic pain grade scale (CPGS), measure of intermittent and constant osteoarthritis pain (ICOAP), and pain impact question (Hawker *et al.*, 2011).

The ICOAP is an osteoarthritis specific pain measurement, while the CPGS focuses only on chronic pain. MPQ was not considered in this research study as it takes approximately 20 minutes to complete and focuses more on pain intensity and pain quality (sensory, affective, evaluative, and miscellaneous) (Burckhardt, 1984). Both MPQ and sf MPQ require sufficient experience to adequately complete them (Hawker *et al.*, 2011). Therefore, VAS and SF36 BPS were pre-set as primary outcome measures; and other dimensions of SF36 and sfBPI were pre-set as secondary outcome measures. Reasons for using the two as primary outcome measures are provided in this section (Section 3.4.4.a). SfBPI was used as a secondary outcome measure which is discussed in the next section (Section 3.4.5).

3.4.4.a) Pain visual analogue scale

Pain VAS is a single-item scale, which has been widely used in diverse populations to monitor variations in intensity of pain, due to its simplicity and adaptability (McCormack *et al.*, 1988), including within the field of IM (Hunter and Leeder, 2013). VAS has good reliability and moderate validity, and is sensitive to change (Hunter and Leeder, 2013).

In this research study, a horizontal VAS line of 100 mm in length was used, anchored by minimal extreme as 'no pain' and maximum extreme as 'worst pain'. Participants were asked to place a vertical mark on the scale to represent their pain on the day of completion. Since literature suggested that VAS might be difficult for some people (Hawker *et al.*, 2011), an example of how to complete the VAS was given to the participants on the same page.

3.4.4.b) The SF-36 ™ health survey – bodily pain dimension

SF-36™ Health Survey (SF-36™) is a health-related quality of life (HRQoL) questionnaire and is a multi-purpose, short-form health survey with 36 questions (Jenkinson *et al.*, 1996). It has eight multi-item scales of functional health and well-being scores as well as psychometrically-based physical and mental health summary measures. It is a generic measure, as opposed to one that targets a specific age, disease, or treatment group. The SF-36™ is divided into two summary measurements: physical component summary and the mental component summary. The internal consistency of the SF-36™ had been extensively evaluated with most studies finding a reliability coefficient (Cronbach alpha) over 0.80 (Lyons *et al.*, 1994). SF-36™ has been used and validated with numerous studies in a variety of patient populations, including patients with MSDs (Hunter and Leeder, 2013; Kosinski *et al.*, 1999; Kiebzak *et al.*, 2002; Angst *et al.*, 2001), but the research student needed to be cautious as there is a high ceiling effect and substantial floor effect (O'Mahony *et al.*, 1998; Busija *et al.*, 2011). This measure has been recommended for routine use within the NHS (Garratt *et al.*, 1993).

Bodily pain (item 21 and 22) as one dimension of SF-36™ has been extensively evaluated with most studies finding it is an acceptable, validated and reliable sub-

scale, useful for making comparisons across populations (Hawker *et al.*, 2011). It provides additional confirmation together with the VAS to validate patients' reports of pain.

3.4.5 Secondary outcome measures

3.4.5.a) The SF-36™ Health Survey – Other Dimensions

In addition to the SF-36™ bodily pain dimension, there are 34 questions on physical function (PF, items 3-12), physical role limitations (RP, item 13-16), general health (GH, items 1 and 33-36), and mental health (MH, items 24-26, 28, 30), emotional role (RE, items 17-19), social function (SF, items 20 and 32) and vitality/energy or fatigue (VT, items 23, 27, 29, 31).

3.4.5.b) Short Form Brief Pain Inventory

The short form brief pain inventory (sfBPI) is a valid and reliable tool for evaluating pain status, and it has been suggested to be sensitive to change in the field of IM (Hunter and Leeder, 2013; Mendoza *et al.*, 2006; Mathias *et al.*, 2011). It has been used widely for various kinds of pain, especially musculoskeletal pain (Mendoza *et al.*, 2006). It includes 9 questions and provides information on the intensity of pain (four questions), along with the degree to which the pain interferes with everyday functioning (seven questions) (Cleeland and Ryan, 1994). The internal consistency of the sfBPI has been extensively evaluated with studies finding a reliability coefficient (Cronbach alpha) of 0.77 to 0.91 (Zelman *et al.*, 2005). Numerous studies have used the sfBPI in a variety of patient populations, including patients with musculoskeletal disorders (McDonald *et al.*, 2008). It is routinely used for patients with MSDs at RLHIM. The BPI-sf takes approximately five minutes to complete.

3.4.5.c) Modified Client Service Receipt Inventory

It has been suggested that CAM may have the potential for reducing health and social costs, and it is recommended that cost is evaluated for at least 6 months following treatment (Robinson *et al.*, 2006). Health and social care service

utilisation was explored by asking participants about the quantity/frequency of service use. The Client Service Receipt Inventory (CSRI) is an internally validated and a widely used instrument originally developed by researchers at the London School of Economics (Chisholm *et al.*, 2000). A modified version of the CSRI (mCSRI) was designed to collect data on the impact of integrated treatments for MSDs on use of health and social care services. The mCSRI took approximately 10 minutes to complete.

In this research study, an economic advisor (AP) who helped to design the economic outcome measure questionnaire (mCSRI) was involved. This questionnaire was designed for this particular study, with relevant IM interventions. The mCSRI is an eight pages questionnaire with 15 questions that covered the items below (Table 3.3). These questions focussed on service use for MSDs and other conditions in the past 3 months.

Table 3 3 Items covered in the mCSRI

NHS or social services cost	• GP, physiotherapist, occupational therapist; • Hospital services (A&E, inpatient, outpatient); • Social services (e.g. meals on wheels, home help etc); • Hospital tests/investigations • Medication (prescribed and OTC); • CAM treatments
Private healthcare cost	• Private health insurance; • Private healthcare consultation; • CAM treatments
State benefit	• E.g. Attendance allowance, disability living allowance etc
Personal cost	• E.g. travel costs, lost earnings due to sick leave • Regular physical activity

3.4.6 Interview questions

In this research study, two sets of interviews were conducted: one-to-one interviews prior to participants' initial appointment at the hospital (pre-treatment interview), and another in the forms of one-to-one and focus groups at 12 months after their initial appointment (follow-up interview).

All interview guides were developed iteratively by discussing with the research group and the patient representative. The questions developed were focused on the following research objectives: To explore patients' expectations and experiences of receiving integrative treatments for MSDs; To determine patients' expectations and experiences in participating in the research study; To identify practical issues in conducting a mixed methods feasibility study. Participants were interviewed using a semi-structured interview, with some pre-set open-ended questions and probes to direct the interviews. The topic guide was tested with a volunteer who had been suffering from MSDs for a long period of time, before the interviews taken place. The guide was revised as new questions emerged, e.g. in the follow-up interviews, participants talked about their experiences in communicating with the practitioners. This question was refined based on what the research student learnt from asking participants this question in the interviews.

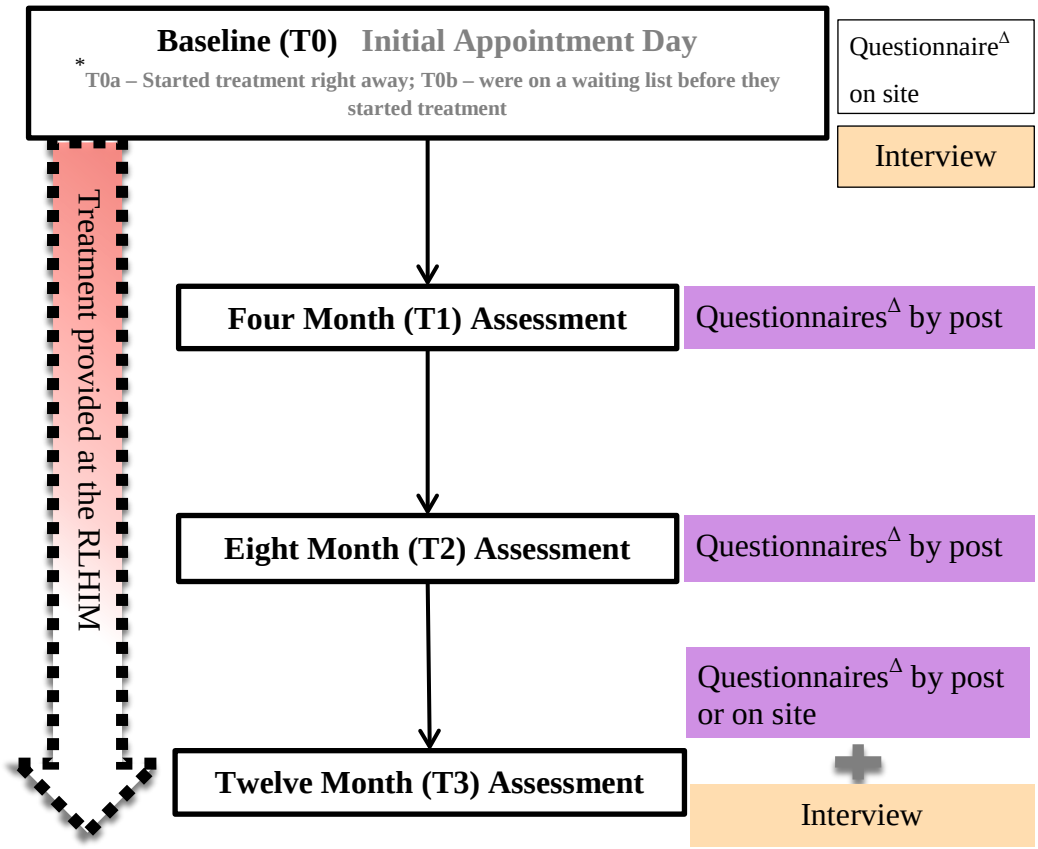
Specifically, for the pre-treatment interview, topic guide covered participants' MSD, previous treatment experiences, decision making process, referral pathway to RLHIM and patients' expectation of IM treatment at the RLHIM. Patients' previous experiences with healthcare services, including communication with healthcare professionals have been suggested to be the most common influences on patients' expectations (Bowling *et al.*, 2012).

The follow-up interviews were in the form of one-to-one interviews or focus groups depending on the participants' choice. Rationale for using one-to-one interview or focus groups are presented in Section 3.5.2. The follow up interviews covered questions exploring the patient's experiences of the integrated treatments they received at the RLHIM, and their experience of participating in the study and acceptability of the study design and outcome measures. Both one-to-one interviews and focus groups were digitally recorded and transcribed verbatim. Topic guides are available in Appendix 3.4.

3.5 Data collection

This research study used a convergent mixed methods design, with quantitative and qualitative data collected separately using different methods. The detailed data collection procedures are discussed in this section. Figure 3.3 provides the flow chart detailing the process of data collection procedures for the research study.

Figure 3 3 Study design and data collection for individual patients



$^{\Delta}$ Questionnaires include the SF-36^{TM} health survey, sfBPI, VAS, and mCSRI

Dashes and faded shading indicate that the treatment may or may not be still provided at each time point; this pattern was different for each individual.

Notes: *In routine practice, some patients may have had a one-off treatment or commenced their treatment immediately at T0a; some patients may have had to wait for their treatment. For those who were put on the waiting list (for up to 5 months), an additional evaluation was administered at T0b before their first treatment.

3.5.1 Quantitative data collection

In this research study, quantitative data were collected from three sources: 1). the completed questionnaires at four or five time points (sociodemographic and lifestyle characteristics, sfBPI, SF36, and VAS); 2). Participants' clinical notes, the RLHIM hospital system, and 3). The practitioner treatment log. Number of past/new referrals, number of participants' recruitment and follow-up at baseline and 4, 8, and 12 months post baseline, whether participants were on a waiting list,

and waiting time between getting referred and the initial appointment were also recorded (Table 3.4).

During recruitment, data were recorded on number of past/new referrals, eligible patients for the study, number of patients consenting/declining to take part, and reasons for not participating. At the end of the study, attendance at appointments, patient follow up, drop-out, and completion rates were generated from treatment logs and the CDR workstation. Rates of completion of the outcome measures, data collection and analysis were calculated by the research student. The study timeline as measured by the time taken to recruit and complete the study was presented.

Table 3 4 Sources of the quantitative data

Source	Information Obtained	Timing of data collection
Questionnaires (VAS, sfBPI, SF36, mCSRI)	Sociodemographic and lifestyle characteristics (baseline), expectation score, pain, HRQoL, and costs	Baseline(s), four, eight, and twelve months after baseline
Clinical data repository (CDR) Web and Workstation (Live: Version L1 R1 v1.0)*	Participants' GPs' postcode; date of each treatment; did not attend (DNA); date of initial record in CDR; date of initial record in CDR on RLHIM appointment	At baseline & April 2015
Clinical Notes	Participants' clinical notes (paper copies) – used to extract the types of treatments given only.	April 2015
Treatment Log	Practitioner-completed treatment log containing appointment date, ICD codes (primary and secondary), treatment provided, practitioners' initials, and an indication of participants' progress since last appointment.	April 2015
Recruitment log	Process evaluation of conducting and responding studies, including time	For the duration of the study
RLHIM data	Participants' ICD codes	April 2015

*The e-CareLogic (CDR Web and Workstation) is a clinical workstation used by UCLH

Data were collected at four time points (5 for waiting list participants) (Figure 3.3): baseline (T0a/T0b) data were collected face to face on the day immediately before their initial appointment/treatment at the hospital. At four and eight months (T1, T2), participants' outcome measures were collected via post. The last outcome measure point was at 12 months, which was collected through mail or face to face if the participants took part in the follow-up interview. At each of the follow-up time points, a questionnaire package including a copy of the SF36, BPI-sf, VAS and mCSRI was posted to patients with a reply paid envelope, with a follow up letter to remind them (Appendix 3.5).

As well as the measurements outlined in Sections 3.4.4 and 3.4.5, a treatment log for musculoskeletal practitioners to complete was put in the patient notes and collected by the researcher at the end of the study. Practitioners were asked to give their initials, ICD code of the patient, and a Likert scale rating their perception of the patients' progresses (Appendix 3.6). Each practitioner was invited to complete a treatment log on participants' progress each time they saw the participants.

3.5.2 Qualitative data collection

Three main categories of qualitative data collection: collected directly in the words of the participant (interview/focus group and tape recorded); collected once or throughout a process of change (reflective journals/field notes); and collected during the event(s) being studied (Anecdotal evidence and logs/observations/student log) (James *et al.*, 2008). In this research study, qualitative data were collected at two time points; once before participants received their initial appointment at the RLHIM, using semi-structured, one-to-one, face to face interviews; and 12 months later, using either semi-structured, one-to-one interviews or focus groups.

Both in-depth interviews with individual participants and groups of participants (focus groups) were utilised in this research study, to explore potential differences by using varied data collection techniques (James *et al.*, 2008). Using a variety of types of qualitative data collection methods aligns well with the epistemological underpinning of pragmatism, using whichever approaches prove themselves to be useful (Ritchie and Spencer, 1994). Focus groups usually comprise a small group of 8-12 participants, in which interaction and debate between participants is encouraged (Byers and Wilcox, 1991). It enables normalisation in understanding among a group of participants, provides an opportunity to share health experiences and information, and to explore similarities and differences between individuals (Bloor *et al.*, 2001). Field notes were taken in both one-to-one interviews and focus groups. In one-to-one interviews, the research student took notes on phenomena which she felt may help further explain results, e.g. "This participant has severe hand deformity due to RA and influenced questionnaire completion (cannot even sign)"; field notes were also taken of words that the research student was unfamiliar with, in order to secure accuracy and minimise the disadvantage of being a foreign

interviewer. All focus groups were facilitated with at least one of the research student's supervisors (NR or AL) and notes were taken to capture interaction in each focus group. A reflective diary (Appendix 3.7) was kept through the whole process of the research study and was partially reported in qualitative results, to ensure the flexibility required in reviewing data and the methods used to collect them (Chapter 5). But the researcher was aware that reflexivity is essential in providing transparency and rigour in qualitative research, rather than ensuring strong evidence or direct methodology, and therefore should be interpreted with caution (Creswell and Clark, 2011). Details in the reflective diary may also inform future studies. Observational data from the field notes such as [laugh], [started crying] were recorded with '[]' in the transcripts.

All the interviews were conducted in a quiet room, in the same building as the RLHIM. It was planned that the follow-up interviews might take place at another location convenient for participants as it was anticipated that there would be participants who had already stopped attending RLHIM but would like to be interviewed. Some interviews were disrupted or took place not in the pre-set student room in the same building of the hospital. Five were interrupted with phone calls or texts; four were conducted with in a limited time due to being conducted immediately before their consultation at the RLHIM; three interviews were not conducted at RLHIM as a room was not available (two interviews were conducted in a café nearby, one in the park nearby). Though the study planned to interview only eligible participants in the study, three brought family members to the interview. One focus group [FG4] was conducted by the research student alone because although a pre-set time was sent to participants, no one confirmed their attendance. The research student still went along on the day just in case and conducted a focus group with two participants.

3.6 Data Analysis

As planned in this convergent mixed methods study, quantitative and qualitative data were analysed separately. This section firstly describes the quantitative data analysis methods (Section 3.6.1). Qualitative data were analysed using a framework analysis approach (Section 3.6.2). The timeline of this research study was planned to inform the development of a future study by providing data which could be used

to calculate the sample size for a future full pragmatic trial/observational study, with data being used to calculate the effect size.

3.6.1 Quantitative data analysis

Data collected from the three sources mentioned in Section 3.4.1 were entered directly to IBM® Statistical Packages for Social Sciences® Statistics (version 21, Armonk, NY, USA). Data on VAS were raw data extracted (in mm) directly from the initial completed questionnaires. Raw data from the sfBPI and SF36 were computed according to their scoring guidelines (Cleeland CS, 2009; Ware *et al.*, 1993).

SfBPI can be assessed with two sub outcome variables – sfBPI pain severity and sfBPI pain interference. sfBPI pain severity is a mean score of worst, least, average, and pain right now in the 24 hours of the completion time; the sfBPI pain interference is a mean score of seven daily activities for which participants filled in scores (0-10): general activity, mood, walking ability, normal work (includes both work outside the home and housework), relations with other people, sleep, enjoyment of life (Turk and Melzack, 1991).

The SF36 used in this research study is the second version of SF36 (SF-36v2™, in this research study, it is shortened to SF36), which corrected deficiencies identified in the original version (Ware, 2000). Physical health and mental health are the two sub outcome variables of SF36. All 0-6 or 0-5 scale raw data from SF36 questionnaires were transformed to a 0-100 scale (e.g. “1=0, 2=20, 3=40, 4=60, 5=80, 6=100”), then regrouped under the eight sub dimensions: bodily pain (BP), physical function (PF), role limitations due to physical health (RLPH), general health (GH), role limitations due to emotional problems (RLEP), energy/fatigue (EF), emotional well-being (EWB), and social functioning (SF). An average score was computed for each dimension (Ware *et al.*, 1993). These eight dimensions were grouped into physical health (BP, PF, RLPH, and GH) and mental health (RLEP, EF, EWB, SF). Before conducting any hypothesis tests to compare changes in physical health and mental health at different time points, separate files for baseline (T0a/b), 4 months (T1), 8 month (T2) and 12 months (T3) were set up, and then data from T0 were merged with T1, T2, and T3; and data at T1 were merged with T2 and T3, T2 with T3. Changes in the SF36 physical health and SF36 mental

health were calculated by the data in T0 subtracted from the data in T1, the data in T1 subtracted from the data in T2, and the data in T2 subtracted from the data in T3.

Normality of the changes in the five outcome variables (VAS, sfBPI pain intensity, sfBPI pain interference, SF36 physical health, SF36 mental health) was assessed by screening histogram graphs with a normal curve displayed. Approximate normality is seen as a priority for running two sample repeated measures paired t test, repeated measures one way ANOVA and repeated measures mixed ANOVA. Details in analyses conducted and the assumptions assessed are available in Sections 3.6.1.1 and 3.6.1.2. Preliminary analyses, primary analyses and supplementary analyses were employed at a predetermined alpha level of 0.05.

All statistical results are reported following the SAMPL Guidelines (Lang and Altmanb, 2013). Descriptive analyses were conducted on participants' sociodemographic characteristics, lifestyle characteristics, their expectation scores for treatment at the RLHIM and CAM treatment in general; participants' ICD codes; referrals and participants' GPs' location; treatment characteristics; and baseline on the three outcome measures (five outcome variables). Participants' sociodemographic characteristics were grouped into larger groups depending on the data (results presented in 4.2.1). Descriptive statistics were summarised using means and standard deviations (SD) for continuous variables, and frequencies and percentages for categorical variables.

3.6.1.1 Purpose, hypothesis, and the analyses

Two main research questions posed by this observational design were:

1). To assess whether participants' outcomes changed at 4, 8, or 12 months follow-up

- H_0: Means of VAS/sfBPI/SF36 are equal at 4, 8, and 12 months;
- H_A: Means of VAS/sfBPI/SF36 are significantly different at least 2 time points

In order to answer this research question and to provide a robust test, repeated measures ANOVA test was conducted, comparing mean scores of the 5 outcome

variables at four time points, followed by repeated measures paired t test to compare the changes in the outcome variables comparing pairs of time points.

2). To explore whether any confounding factors/predictors (e.g. sociodemographic, expectations etc.) are useful in explaining variability in the change of primary outcome measures

- H_0: There is no relationship between any factors/predictors and changes in primary outcome
- H_A: At least one factor/predictor could explain the changes in primary outcome

In order to answer the second research question, multiple linear regression with stepwise selection process (forward selection method) was performed to look at possible predictors of changes in primary outcome measures at the time point when most changes occurred. Forward selection is one of the methods of stepwise selection method. It starts with no variables in the regression model, and adds in variables by selecting a predictor which has the highest simple correlation with the target outcome variable, and retains the significant predictor(s) until no predictor improves the model (Field, 2013). However, there is a potential limitation of using stepwise selection method as it relies on the computer in selecting variables based upon mathematical criteria and assesses the fitness of a variable based on other variables in the model (Field, 2013).

Rather than trying to develop a model, given the study design and limited sample size in this research study, multiple regression was used to explore possible predictors. A stepwise method was therefore used, as particularly useful when researchers do not have a clear idea which variable may be a predictor of the outcome variable. If any significant predictor(s) were identified, it/they were left out with the regression analysis rerun, in order to further explore the relationship between the predictor(s) and changes in primary outcome measures.

3.6.1.2 Sensitivity analysis

Sensitivity analysis was performed to determine potential differences in baseline sociodemographic and lifestyle characteristics, expectations, and baseline outcome measures between participants who were still receiving treatment at one year follow-up, and participants who were no longer receiving treatment (results will be presented in Section 4.5), utilising independent t test for continuous variables and

chi-square tests for categorical variables.

3.6.1.3 Subgroup analysis

Subgroup analysis was performed on baseline characteristics of participants at the two baselines, in order to explore whether there were differences in participants' characteristics at the two baselines. Independent t tests were conducted for continuous variables and chi-square tests for categorical variables.

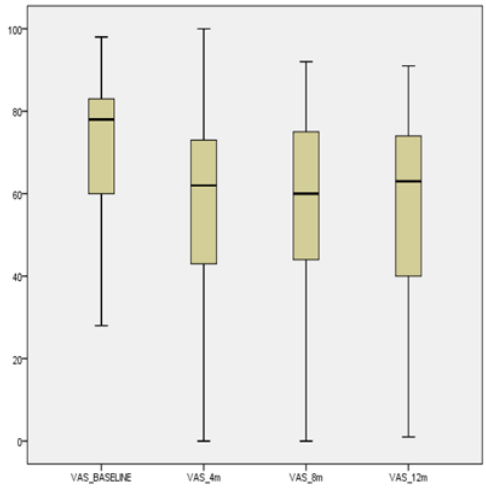
Subgroup analyses were also performed to determine potential differences in changes in primary outcome measures at the time point where most changes occurred between participants receiving different lengths of treatment (less than 12 months, equal or more than twelve month). Subgroup analysis was also performed on participants who received different complexity of integrative treatment (single or multiple modalities). Independent t tests were conducted for these subgroup analyses.

3.6.1.4 Assumptions of using appropriate statistical analyses

This section states the assumptions which need to meet before performing the five types of analyses stated previously in Sections 3.6.1.1-3.6.1.3, namely: 1). repeated measures ANOVA, 2) paired t test, 3). multiple regression, 4). independent t test, and 5) chi-square test. All assumptions were met otherwise explained when assumptions were violated.

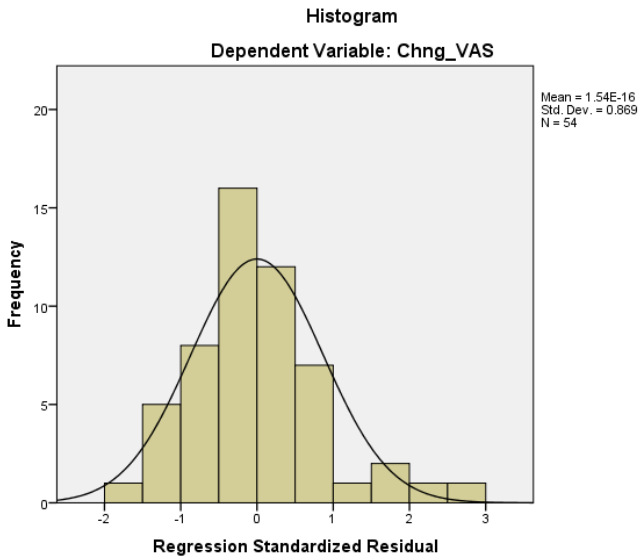
Five assumptions to meet for performing repeated measures ANOVA: 1). Participants' expectations, VAS, sfBPI, SF36 variables are continuous data; 2). Four time points as the within-subject factors; 3). No significant outliers: In this study, outliers were identified using boxplot (Figure 3.4). A boxplot was used - values greater than 1.5 (less than 3) box-lengths from the edge of the box were seen as outliers and those 3 or more box-lengths from the edge of the box were seen as extreme outliers (Field, 2013). Only extreme outliers were noted in the report of analyses. In cases where there were outliers in the data, these were checked accuracy and included in the analysis because they were rare cases reflecting the real world condition of participants' fluctuating pain and functional ability.

Figure 3 4 Example boxplot: No outliers identified in VAS at different time points



4). Approximately normally distributed: normality of all above data were checked using histograms with normality curve. A bell-shaped curve indicates data meets 'assumption of normality' (Figure 3.5). According to the central limit theorem (CLT), normality is not crucial for a standard t test or z hypothesis test if the sample size is larger than or equal to 30, and ANOVA is suggested to be robust regardless of normality (Field, 2013).

3 5 Example of histogram: approximately normally distributed in change in VAS at four month



5). Sphericity: This was checked by screening the Mauchly's Test of Sphericity table. It has been suggested by many textbooks that if data has violated the assumption of one-way repeated measures ANOVA, Greenhouse & Geisser correction should be used (Field, 2013). But in this research study, Mauchly's Test

of Sphericity was not taken as a necessary premise of performing repeated measures as it is suggested it lacks statistical power especially when the sample size is small (violations may not be detected) and is a less robust test compared to ANOVA (Baguley, 2004).

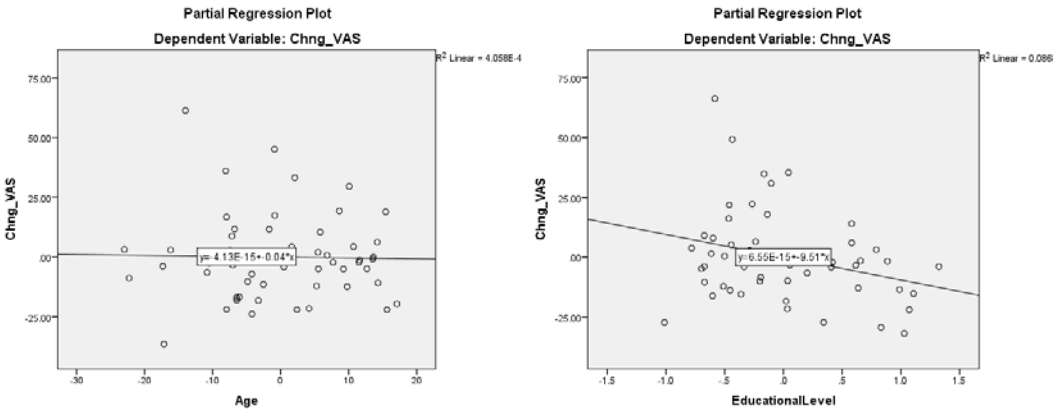
Four assumptions to meet for performing paired t test: 1). Continuous outcome variables, e.g. age, baseline outcome measure values; 2). Baseline data and post treatment data were seen as two related matched pairs; 3). No significant outliers; 4) Approximately normally distributed in targeted outcome variables between the two groups.

Six assumptions to meet for performing independent t test: 1): Outcome variables are continuous, e.g. baseline VAS, expectations etc; 2). Two groups of participants, e.g. participants on waiting list or not; 3). Independent observations in each group as they were not the same participants; 4). No significant outliers; 5). Outcome variables are approximately normally distributed; and 6). Homogeneity of variances. Equality of variance was checked using traditional Levene test. If the Levene test is statistically significant, the hypothesis of equality of variances will be rejected.

Six assumptions to meet for performing multiple regression:

1). Independence of errors (residuals): This was checked by Durbin-Watson test, a value close to 2 indicating that there is independence of errors (residuals); 2). A linear relationship between the predictor variables (and composite) and the dependent variable; 3). Checking homoscedasticity of residuals (equal error variances). The 2nd and 3rd assumption were checked by scatterplot, examples of linear relationship and an equally spread residuals are shown in scatter, which indicates a linear relationship and homoscedasticity (Figure 3.6).

Figure 3 6 Example scatterplots of relationship between participants' age (left) / educational level (right) and change in VAS at four months



4). No multicollinearity: No correlations larger than 0.7 were checked in correlation tables; all the tolerance values are greater than 0.1 (coefficients table); 5). No significant outliers or influential points: unusual data, outliers, high leverage points and highly influential points were checked. Checking outliers has been described previously.

Whether leverage values were above the safe value of 0.2 was checked by screening the data column LEV. Cook's distance was checked by screening the data column of COO. 6). Errors (residuals) are normally distributed: same as described previously.

Two assumptions to meet for performing chi-square test: 1). Target variables are nominal or dichotomous, e.g. gender, educational level etc.; and 2). There are two or more groups in each variable, e.g. female or male, secondary school or university degree or postgraduate. It is suggested that a maximum of 20% of counts should be less than 5 (Field, 2013). But it is anticipated that in the sensitivity analysis assessing difference between completers and participants who dropped out of the research study there may be low counts as the number of participants who dropped out may be small. This was seen as acceptable if all participant counts are 1 or greater (Yates *et al.*, 1999).

3.6.1.5 Missing data

There are several ways to address missing data. Last observation carried forward (LOCF) using repeat data from the last available time point is frequently used in pharmaceutical trials. However, it may elaborate the effect size (Field, 2013).

LOCF was felt to be inappropriate in this research study mainly due to the pragmatic nature of this research study and the complexity of length of treatment, e.g. participants may stop receiving treatment at very different time points. In order to present the real world data that suits the pragmatic exploratory nature of this study, casewise deletion was used to exclude all drop out patient data.

Since casewise deletion assumes strict missing completely at random (MCAR) to be valid, comparisons of baseline characteristics between participants who completed the one year follow-up and those who withdrew from the research study were assessed. If there was no significant difference between the groups, casewise deletion was implemented. Though the data of participants who dropped out were not used in quantitative analysis, they were invited to participate in the second part qualitative study to avoid bias.

3.6.1.6 Effect size

Effect sizes, known as Cohen's d, are defined as the mean change in primary outcome measures divided by the standard deviation the outcome measure in this study (Kazis *et al.*, 1989). In this research study, effect size was calculated using the below equation:

> Cohen's *d* = mean change in outcome measures / SD of change in outcome measures

Effect sizes for significance were reported for all three outcome measures at four, eight, and twelve months. Effect size was defined as 0.20 for small, 0.50 for medium, and 0.80 for large effects (Cohen, 1988).

3.6.1.7 Cost data analysis

The plan was that cost data would be analysed and evaluated. Unit cost of health and social care would be checked with the following resources: PSSRU unit cost of health and social care 2012; NHS reference costs; hospital cost data; British National Formulary; Health span/Nutri centre; Department of Work and Pension Data.

Cost data were planned to be depicted using with bar chart presenting the above costs for at each time point over one year: direct CAM costs, direct conventional medicine costs, and indirect costs; MSDs related and non MSDs related costs; total cost, NHS costs; and single CAM, single conventional cost, and integrative treatment costs. These cost data would then be analysed depending on disease severity, and risk (high/low) of patients.

However, there were insurmountable difficulties in obtaining unit costs, in particular to obtain the average market price and unit cost of the RLHIM treatment provided. In addition, obtaining the data were going to take longer than anticipated so has not been included in this thesis.

3.6.2 Framework analysis approach for the qualitative study

The qualitative analysis in this research study adopted a framework analysis approach, a relatively new method of qualitative data analysis, with a highly structured and systematic approach, and detailed practical guidance on how to perform analysis. It was initially developed in Britain for policy research by Ritchie and Spencer, and is now widely used in many areas of research (Ritchie and Spencer, 1994; Ritchie *et al.*, 2003) and is gaining popularity among healthcare research (Smith and Firth, 2011).

Framework analysis is a data analysis approach that does not align with a particular ontological or epistemological perspectives (Smith and Firth, 2011; Gale *et al.*, 2013; Ward *et al.*, 2013). It is appropriate where there is existing theory and can be placed on an inductive-deductive continuum depending on the research question (Gale *et al.*, 2013). In this research study, theoretical background of IM (following the MRC framework development stage) was explored by reviewing the IM literature; potential factors that may have an influence on IM were identified in that process, however, they were not adequate to understand the changes process. A purely inductive approach such as grounded theory was not seen as a potentially appropriate method. Considering the research topic and a lack of qualitative research experience of the research student, framework analysis with a step-by-step structure including a framework matrix output allowing systematic reduction of the data were adopted. Both pre-treatment interviews and follow-up interviews were analysed using framework analysis method. Framework analysis contains a five

stage process: data familiarisation, identifying a thematic framework, indexing, charting, mapping and interpreting (Ritchie and Spencer, 1994). Ritchie et al. identified an analytic hierarchy that is not included specifically in framework analysis, including data management phase (familiarisation; coding, identification of a thematic framework, inter-rater coding; indexing, charting); descriptive phase (mapping and descriptive analysis); explanatory phase (interpretation) and presentation phase (Ritchie *et al.*, 2003). This analytic hierarchy was followed in the analysis. Details of data management, descriptive are presented in Section 3.6.2.2.

3.6.2.1 Computer-assisted qualitative data analysis software

Before introducing the detailed steps in framework analysis used in this research study, the use of computer-assisted qualitative data analysis software (CAQDAS) is briefly discussed. CAQDAS is software for data administration and archiving, which can assist text retrieval, textbase management, coding and building code based theory etc (Ritchie and Lewis, 2013). It can be used to facilitate the organisation of large amounts of textual data, to make it more manageable, and to help facilitate teamwork on the same research, which could ultimately improve the rigour and consistency of the research (Weitzman, 2003).

In this PhD research project, all qualitative data were stored and coded with frameworks developed (for the first three phases) using the qualitative data organising software Nvivo (version 10, QSR International, Melbourne, Australia). The built-in function specifically for framework analysis in Nvivo, NatCen framework matrix, was used in indexing, charting, mapping, descriptive analysis and interpretation steps to build a framework matrix for cross row interpretation and analysis, and to provide an explicit, clearly visible record of how categories, and themes arising from the original data.

3.6.2.2 Detailed steps in framework analysis

Transcription: All interviews were transcribed verbatim by the research student. Long pauses, interruptions, laughter and nodding were noted, with ‘um’s, ‘you know’ and repetitions included. Unclear data were recorded with “???”; basic

observational data such as laughs or cry and research student's interpretation or notes were recorded using "[]". A detailed reminder of these is available at the beginning of the qualitative results (Chapter 5 aim and structure). Notes such as the differences observed between interview and questionnaires were recorded immediately after each interview in memos.

Familiarisation: All transcripts were checked at least twice by the research student listening to the audio records. All written transcripts were checked and read by her supervisors (NR & AL). Transcripts were printed out and read numerous times, with initial impressions written in the margins of transcripts. The researcher also highlighted potentially meaningful quotes.

Coding: This step was used to provide a mechanism for labelling and managing data for subsequent retrieval and exploration (Ritchie and Spencer, 1994). In this step, some initial codes were entered into NVivo10 (QSR International, Pty Ltd, Melbourne, Australia) at first after getting familiar with the transcripts, followed by adding in new codes as they emerged. Transcripts were coded following a coding instruction: code sentences and words; notes and ideas while coding were recorded in memo in NVivo. In this research study, the first three steps (transcription, familiarisation, and part of coding) occurred during data collection process.

Framework identification: The research student and her supervisors independently coded and categorised five transcripts (for both pre-treatment and follow-up interview data analysis) before meeting to discuss codes and constructing an initial framework. The researcher then re-evaluated the codes and grouped several codes together. All the codes were descriptively explained and grouped into different categories. The final framework was finalised by discussion with the supervisors until no new codes emerged. Changes made during updating and revising the framework were recorded and discussed in memos in NVivo (Appendix 3.7). This step was undertaken using NVivo10.

Inter-rater coding: In order to ensure transparency, rigour, and to have a diversity of viewpoints, inter-rater reliability coding of three transcriptions was performed independently by the research student and her supervisors (Pope *et al.*, 2006). Some codes were deleted or regrouped, or the description of codes changed by discussion on and consensus with supervisors. Regular meetings were held throughout data

analysis, facilitating further exploration of participants' responses, discussion of deviant cases, and agreement on recurring themes. Internal reliability was not assessed by providing alpha result as this was the first time the research student had worked on a qualitative project.

Indexing: Indexing is the process of comprehensively labelling all the data using the final consensus framework by marking quotations which belong to a code (Ritchie and Spencer, 1994).

Charting: Charting is the process of 'scissors and paste', with quotations firstly simplified and synthesised (Ritchie *et al.*, 2003). As much as possible, participants' own words were used during this step and the researcher only summarised the quotations without any interpretation. Nvivo was particularly useful in facilitating this step as target quotes can be easily found using the query function in Nvivo, and all quotations under a code can be exported to word from Nvivo. Since the researcher was not familiar with Nvivo when she analysed the pre-treatment interviews, the simplified quotations were then entered into Microsoft Office Excel (version 2010, Washington, D.C., USA), with one row per participant and one column per code with quotations and a spreadsheet for each theme. Page number and line number were noted in order to easily find the original quotations. Interesting quotations and important statements were marked by '*', with '***' indicates the most important and no mark for least important (Figure 3.7). With Nvivo, one can also re-code, un-code or combine codes during the charting with the whole project updated. For example, the code 'MSDs symptoms' was combined with code 'history of MSDs' because much fewer quotes were on their MSD history and symptoms is part of medical history.

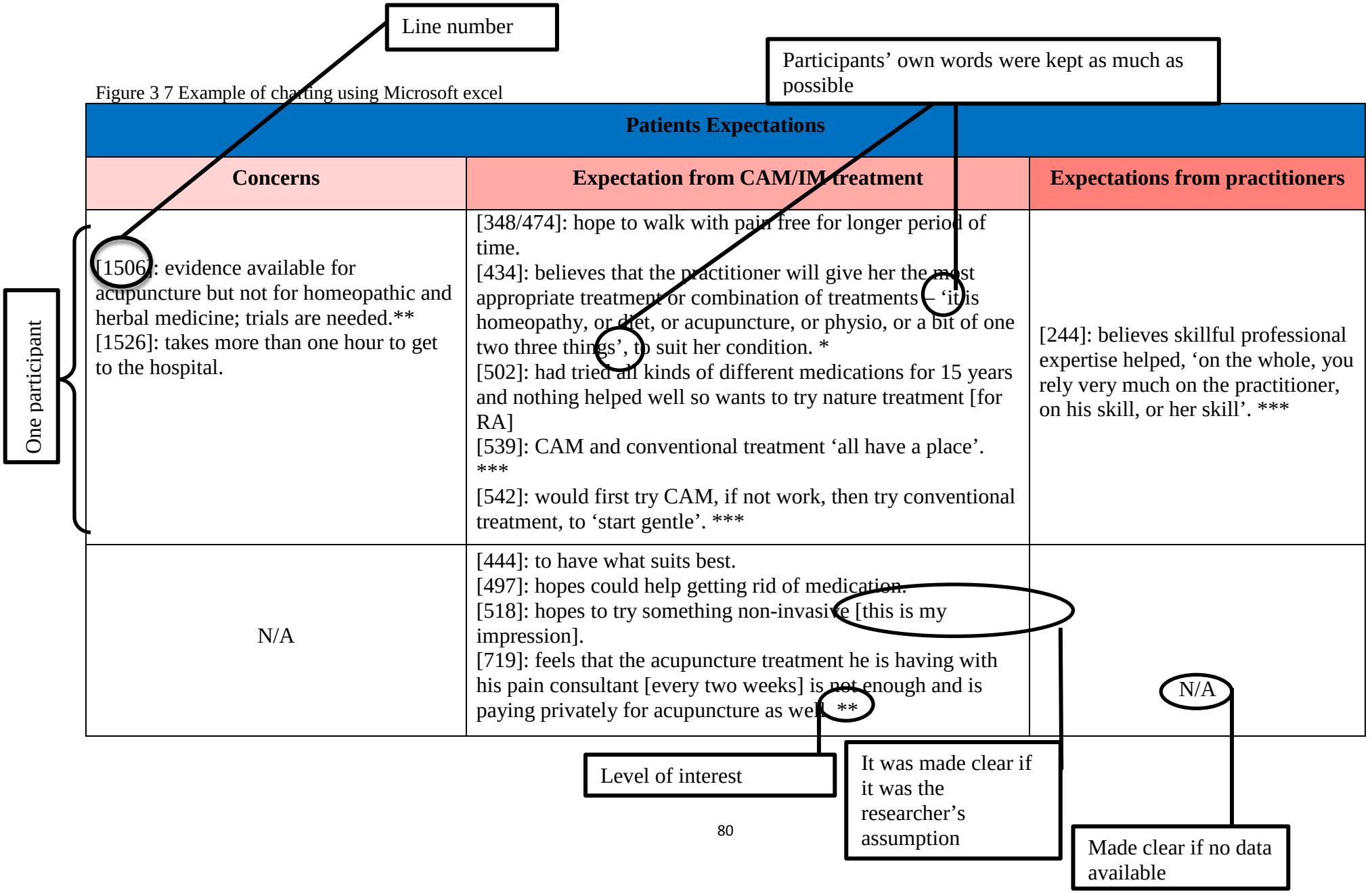


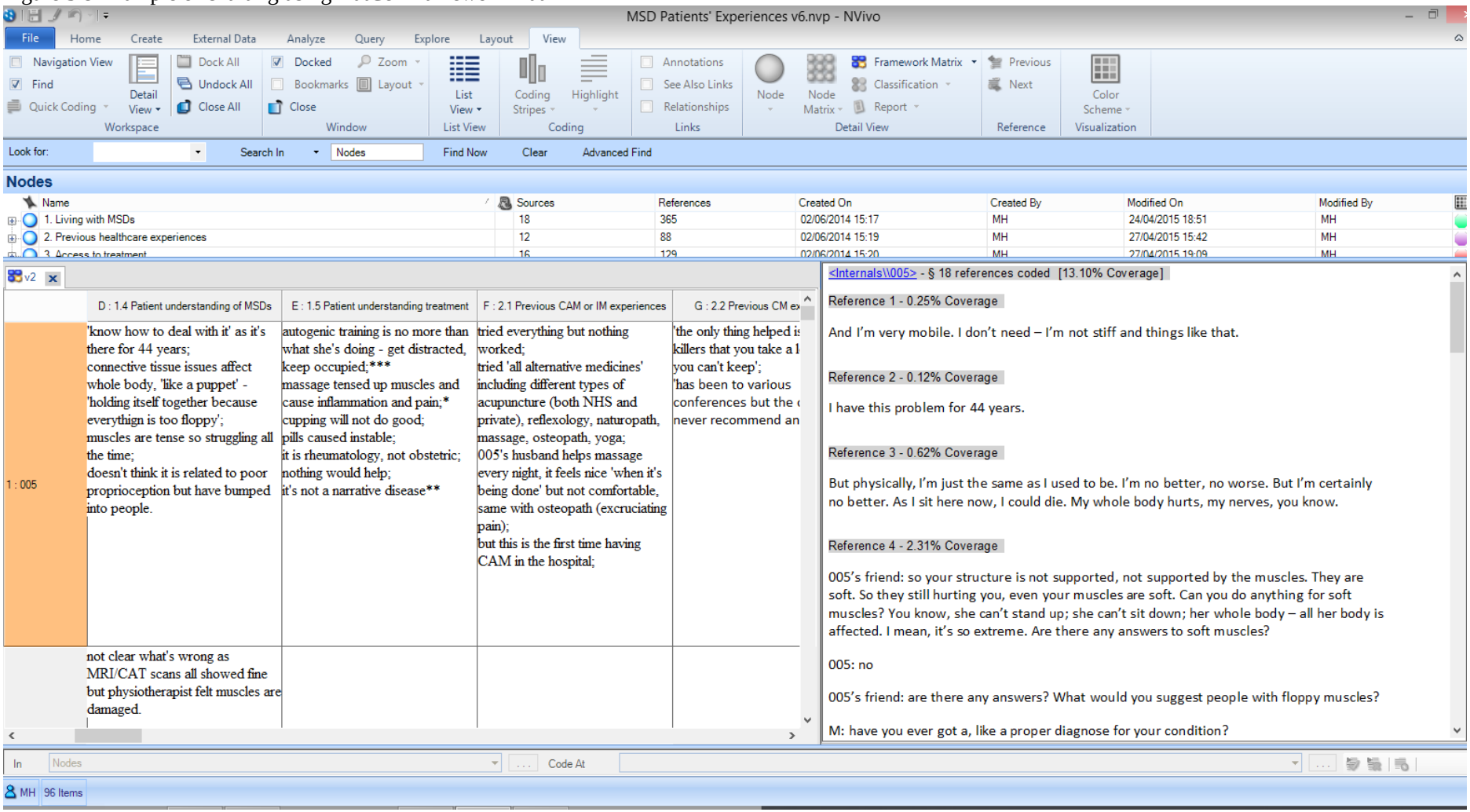
Figure 3 7 Example of charting using Microsoft excel

Patients Expectations		
Concerns	**Expectation from CAM/IM treatment**	**Expectations from practitioners**
[1506]: evidence available for acupuncture but not for homeopathic and herbal medicine; trials are needed.** [1526]: takes more than one hour to get to the hospital.	[348/474]: hope to walk with pain free for longer period of time. [434]: believes that the practitioner will give her the most appropriate treatment or combination of treatments – 'it is homeopathy, or diet, or acupuncture, or physio, or a bit of one two three things', to suit her condition. * [502]: had tried all kinds of different medications for 15 years and nothing helped well so wants to try nature treatment [for RA] [539]: CAM and conventional treatment 'all have a place'. *** [542]: would first try CAM, if not work, then try conventional treatment, to 'start gentle'. ***	[244]: believes skillful professional expertise helped, 'on the whole, you rely very much on the practitioner, on his skill, or her skill'. ***
N/A	[444]: to have what suits best. [497]: hopes could help getting rid of medication. [518]: hopes to try something non-invasive [this is my impression]. [719]: feels that the acupuncture treatment he is having with his pain consultant [every two weeks] is not enough and is paying privately for acupuncture as well. **	N/A

For the follow-up interview analysis, the NatCen framework matrix was used to generate the framework matrix automatically (Figure 3.8). Similarly, the automatically generated framework matrix contains case nodes (as rows) and theme nodes (as columns). By using the NatCen framework matrix, summarised and synthesised statements can be linked to the original quotations. Other advantages include easily browsing the framework matrix by exploring all participants' perspectives (down a column) and exploring how different themes relate to each other for a particular participant (across a row) with direct participants' quotations, field notes, observations, and memos by the researcher all systematically linked, which allowed conceptual thinking and insights to the data.

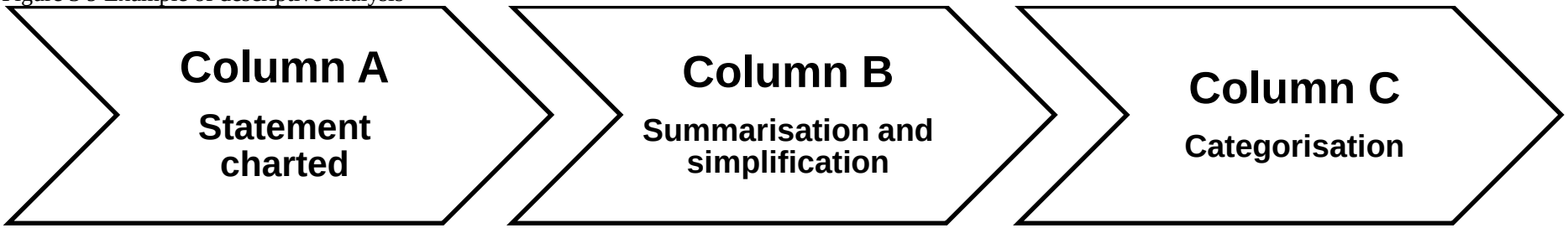
For the follow-up focus group interviews, case nodes were created manually for each participant in the same interview, followed by coding each participant' responses to their case node.

Figure 3 8 Example of charting using NatCen framework matrix



Descriptive analysis: This is the process of defining elements and dimensions, refining categories and classifying data, which involves abstraction and interpretation (Ritchie *et al.*, 2003). The framework matrix was exported from Nvivo to Excel. The descriptive analysis was completed in Microsoft Excel with three columns for each code. The research student was aware that this process was highly influenced by her epistemological perspective as data were analysed interpretatively (discussed in Section 1.2). Details and examples are given in Figure 3.9. The contents in column A were original descriptive data that the research student summarised in the charting step; column B represents refined data that was close to the original descriptive data in column A but simplified; column C presented higher level of abstraction, with ‘labels’ assigned and categorisation performed. However, in some cases, the statements in column A were quite simplified, then only two columns (A&C) were available.

Figure 3 9 Example of descriptive analysis



- [42]: felt ‘anxiety, depression, and isolation from social life, stress and tension’.*
- [184]: bad relationship with husband because she ‘has to lie down’ and ‘not go social evenings’.
- [721]: can’t sleep because of pain.
- [375]: not working because of a complex condition.**

- experienced emotional problems
- relationship with husband was affected due to MSDs
- poor sleep due to pain
- not working due to MSDs

- Emotional impact
- Family and friend impact
- Sleep disturbance
- Work impact

Mapping: In this step, the framework matrix was extensively read to generate understanding of each patient and similarities among patients and the codes. This is the step where thematic or cognitive maps were made of linkages or constructions within the data and themes identified (Ritchie and Spencer, 1994). By selecting and displaying all codes in both rows and columns, Nvivo can help generate a cross table matrix with a number given for each two codes (Figure 3.10). This number can be selected to reflect the number of participants/codes/word etc. coded under two codes. So the 'stand out combinations' can be given more attention. For example, relationship or interaction between code '1.5 patient understanding of MSDs' and code '6.5 experience of integration', were found to require further exploration in the present study. This function is very helpful in mapping the interaction between two codes (especially under two different categories).

Figure 3 10 Example of framework matrix built with Nvivo (cell content: number of participants)

	Z : 6.3 Changes per...	AA : 6.4 Side effects	AB : 6.5 Experience ...	AC : 6.6 Experience...
1 : 1.1 History of MSDs	5	0	1	1
2 : 1.2 Impact of MSDs	2	0	0	0
3 : 1.3 (Impact of) non-MSDs	0	0	0	0
4 : 1.4 Patient understanding of MSDs	0	0	1	0
5 : 1.5 Patient understanding treatment	5	2	8	3
6 : 2.1 Previous CAM or IM experiences	1	0	1	0
7 : 2.2 Previous CM experiences	1	0	0	0
8 : 3.1 Decision making process to come to RLHIM	0	0	0	0
9 : 3.2 Access to treatment - physical	0	1	0	0
10 : 3.3 Access to treatment - practical (Referral Pathway)	1	0	1	1
11 : 3.4 Patient understanding of treatment pathway	0	0	1	0
12 : 4.1 Participants' understanding of their expectations	0	0	0	0
13 : 4.2 Hopes or expectations for CAM or IM treatment	3	0	0	2
14 : 4.3 Hopes or expectations from practitioners	0	0	0	0
15 : 4.4 Hopes or expectations for future NHS CAM or IM access	2	0	0	1
16 : 4.5 Expectations in changes	0	0	0	1
17 : 5.1 Understanding of (Importance of) self-help	0	0	2	0
18 : 5.2 Reading and Learning	0	0	0	0
19 : 5.3 Emotional management	0	0	0	0
20 : 5.4 Physical management	1	0	1	0
21 : 5.5 Self-directed integrative treatment	0	0	2	0
22 : 5.6 Self-care	0	0	0	0
23 : 5.7 Things impact MSDs	1	0	0	0
24 : 6.1 Patient explanation of treatment details	11	3	10	9
25 : 6.2 Attitude or beliefs of treatment offered	14	1	6	5

Interpretation: The interpretation step includes thoroughly reading through the synthesised and categorised data, following leads as they are discovered, exploring the patterns, going backwards and forwards between the data, and developing emergent explanations (Ritchie and Spencer, 1994). At this stage, there are various different ways to further understanding of what is causing or influencing the phenomena to occur: for example, a chart with where the most interaction happened between codes was generated; context around certain target words were identified, and visualisation of words that were most frequently used was provided (Figure 3.11). Text and word frequency were used to search different themes for each

participant; searches were re-run when new words were found and applicable to a theme (QSR International, 2015). These functions were all essential and assisted in providing conceptual understanding in the mapping step.

Figure 3 11Nvivo word cloud for most recent 50 words (longer than four characters in transcripts)

N.B. certain words were removed from the figure: participants' ID, adverb such as 'also', 'maybe', 'just'; 'much'; and 'uhmm', 'much'.

Presenting: In order to provide a whole picture of the sample, the research student tried to include at least one quote from each participant if possible. Rare cases were reported. Omissions from quotes were recorded with "…". In some cases, notes were made when themes were merged depending on the research student's interpretation.

3.6.3 Feasibility frameworks used in interpretation of findings

Three frameworks for feasibility studies were used in the interpretation of the triangulated findings (quantitative and qualitative). In terms of assessing feasibility, the primary framework used was Bowen's feasibility framework (Bowen *et al.*, 2009). Final triangulated findings are presented in four aspects of Bowen's feasibility framework (Shanyinde *et al.*, 2011; Bowen *et al.*, 2009; O'Cathain *et al.*, 2015). Bowen's feasibility framework was adopted as it guides design, evaluation, and interpretation and prioritizes interventions which are deemed feasible and likely to be efficacious (Bowen *et al.*, 2009); and is commonly adopted and followed to report feasibility of carrying out various studies (Hagen *et al.*, 2011; Parker *et al.*, 2013; Peddle-McIntyre *et al.*, 2012; Kamioka *et al.*, 2011).

Apart from the Bowen's feasibility framework, another two feasibility frameworks were adopted in reporting quantitative and qualitative research in feasibility (Table

3.4). Firstly, 12 of the 14 methodological dimensions of Shanyide et al's framework are reported, with the aim of ensuring rigor of reporting quantitative feasibility research; two items (randomisation procedure and blinding procedure) were excluded as they did not fit with the observational study design) (Shanyinde *et al.*, 2011). In addition, 19 qualitative dimensions of O'Cathain's framework were also used, to ensure credibility of reporting qualitative feasibility research (O'Cathain *et al.*, 2015). This combination of the three frameworks was used to cover the research objectives.

The four overarching aspects of feasibility (adapted from Bowen's framework) are:

1). Limited outcome testing

The limited outcome testing aspect (findings presented in Section 6.1) is used to determine whether the study has achieved its objective "to evaluate 'real world' clinical outcomes associated with integrative treatment for MSDs". It provides a general idea of what patients have received at the RLHIM, and potential changes in outcome.

2). Patients' acceptability in integrative treatments for MSDs

The issue of patients' acceptability of treatment provided (findings presented in Section 6.2) is used to frame findings that answer the research objective 'to explore patients' experiences of receiving integrative treatments for MSDs'. Patients' decision making process to seek CAM treatment and access CAM through the RLHIM, their referral pathway, and their acceptability of the integrative treatments for MSDs provided at the RLHIM during the 12 months follow up, are presented.

3). Patients' demands for integrative treatments for MSDs

The issue of patient demands for the treatment (findings presented in Section 6.3) also answers the research objective 'to explore patients' experiences of receiving integrative treatments for MSDs'. In addition, it frames the findings on another research objective 'to explore patients' expectations of receiving integrative treatments for MSDs'. In this section, patients' MSD characteristics and their previous experiences are presented and linked to their expectation, as well as participants' perception of the demand for the treatments they were receiving.

4). Feasibility of study design

In this section (findings presented in Section 6.4), the research objectives ‘to determine whether comprehensive and multilevel evaluations for IM in MSDs are justified’, and ‘to determine patients’ expectations and experiences in participating in the research study’ are answered. The feasibility of a number of specific methodological dimensions was explored, including: participant eligibility, research recruitment and retention, participants’ characteristics, patients’ acceptability in research procedures, ethical conduct, logistics of multicentre research, workability of the pre-set protocol, impact of research, patient involvement, and outcome measures. These provided detailed information on methodological issues in conducting the mixed methods feasibility study.

Table 3 5 Combination of the three feasibility frameworks

F*		QUAN Dimensions	QUAL Dimensions
LIMITED Limited E TESTING*	Intervention content and delivery	**1. Intervention development***** To what extent does the planned intervention need to be refined or adapted to make it more acceptable to users or more relevant or useful to the specific context in which it is delivered?	
		2. Intervention received	
		3. Cost and duration of intervention** Was it possible to calculate intervention costs and duration?	
	Outcome	**4. Sample size calculation**** Did the feasibility/pilot study allow a sample size calculation for the main trial?	**Breadth of outcomes***** Do some trial participants feel that they have experienced or noticed improvements in some outcomes that need to be included in the full trial?
ACCEPTABILITY	Decision	**1. Decision to seek RLHIM treatment**	
	Referral	**2. Acceptability of referral pathway**	
	Intervention	**3. Adherence to intervention**** Did participants adhere to the intervention?	
		4. Acceptability of intervention** Was the intervention acceptable to the participants?	**Perceived value, benefits, harms or unintended consequences of the intervention***** What value do service providers and intervention users place on the intervention and the outcomes it plans to deliver? What benefits and harms do they feel they have experienced from the intervention so that these can be measured in the full trial?
			Acceptability of intervention in principle*** Are service users or health care providers unhappy with any aspect of the content or delivery of the intervention?
			Feasibility and acceptability of intervention in practice*** What are service users or health care providers' views of the implementation of the intervention? Has implementation varied by setting? Are there any important intervention-context interactions? Should implementation be tailored by setting?
DEMAND FOR INTERVENTION*		**MSDs characteristics**	
		Previous MSDs or healthcare experiences	
		Expectations and hopes	
		Imbalance in supply and demand	**Dose of intervention***** Is the right amount of the intervention getting to the right recipients in the right way?
FEASIBILITY OF RESEARCH DESIGN*	STUDY DESIGN, CONDUCT AND PROCESSES	**1. Eligibility**** What factors influenced eligibility and what proportion of those approached were eligible?	
		2. Recruitment** Was recruitment successful?	**Recruitment***** How do the planned recruitment practices work in the field? Do recruitment practices need to be improved to increase recruitment rates and levels of informed consent? If so, how? Are the trial participants willing to be randomised? Are clinicians willing to recruit patients, or are they uncomfortable?
		3. Retention** Was retention to the study good?	**Retention***** Are there ways in which trial procedures could be improved to increase retention rates?
		4. Participants' characteristics	**Diversity of participants***** Are the planned recruitment practices likely to result in recruitment of the desired range of participants for the trial? If not, how might recruitment practices be improved?

		5. Impact of research	**Trial participation***** How is the planned trial communication implemented by recruiters and received by participants? How can trial communication be improved to ensure recruiters understand patients' views about participating in the trial?
			Acceptability of the research study in practice*** Is the trial design acceptable to patients, recruiters and service providers in practice, or are there ways in which participants try to alter the procedures?
			Acceptability of the research study in principle*** Is the trial design acceptable to patients, recruiters and service providers in principle?
		6. Consent** Did eligible participants consent?	**Ethical conduct***** Are the informed consent procedures appropriate and acceptable to likely trial participants?
		7. Logistics of multicenter** Were the logistics of running a multicenter trial assessed?	
		8. All components of the protocol work together** Did all components of the protocol work together?	**Fidelity and reach of intervention***** Do those delivering the intervention and/or receiving it adhere to the **planned** intervention? If not, what are the reasons for this? What are the limits of acceptable tailoring of the intervention?
			Adaptation of research study conduct to local context*** Will the planned trial procedures allow the trial to operate effectively in the proposed context? Do any changes need to be made to these procedures?
		9. Impact of research	**Impact of trial on staff, researchers, participants and the health system***** Does this trial have any unanticipated negative impacts on recruiters, participants, other stakeholders and the health system? How can these impacts be minimised (e.g. workload involved in recruitment, numbers of measures undertaken)?
		10. Patient and public involvement*** How is patient and public involvement best achieved in the trial?	
	MEASURES	**11. Selection of most appropriate outcomes**** Were outcomes measured those that were the most appropriate outcomes?	**Selection of outcomes***** Are outcomes important to service users selected for measurement in the full trial—both primary and secondary?
		12. Outcome assessment** Were outcome assessments completed?	**Accuracy of measures***** Are the process and outcome measures valid for this participant group?
			Completion of measures*** Can completion rates of measures be improved?
			Development of measures*** If validated measures do not exist for all the outcomes to be measured in the full trial, can they be developed in preparation for the trial?

*indicates the four general areas in feasibility (Bowen *et al.*, 2009); ** indicates methodological items suggested for reporting quantitative feasibility study (Shanyinde *et al.*, 2011); *** indicated dimensions suggested for reporting qualitative feasibility study (O'Cathain *et al.*, 2015).

3.7 Interpreting and reporting mixed methods results

As discussed in Section 3.1.1, quantitative and qualitative data were collected and analysed separately and concurrently, until the interpretation stage, when the quantitative and qualitative designs interacted (Pluye *et al.*, 2009). Both strands answered research questions that focused on three concepts: expectation, outcome (experience/effects), and feasibility. There were unequal sample sizes in the two strands (patients who participated in the pre-treatment and follow-up interviews are a subset of approximately half the sample size of patients who participated in the observational study). Results from each strand were merged and interpreted. This section explains the decisions on how to merge the results of the two strands. The final results of this MMR are presented in Chapter 6.

Interpretation and triangulation of quantitative and qualitative results used side-by-side comparison in a summary table, with evidence provided for each dimension. The overall feasibility of this research study was reported in terms of limited outcome testing, acceptability and demand for the intervention, and the feasibility of the study design, four aspects which follow Bowen's feasibility framework (Bowen *et al.*, 2009).

In addition, the following questions were also explored: to what extent do the quantitative and qualitative results converge; are the qualitative findings related to the quantitative results; to what extent do the qualitative process findings enhance the understanding of the experimental outcomes; and in what ways do the qualitative themes and the quantitative results converge and diverge to suggest change. These will be presented in Chapter 6. In contradictory cases, results from both strands were reported and summarised with equal priority.

Merging the two strands allowed an in-depth qualitative exploration and a rigorous quantitative examination of the integrative treatment provided for MSDs at the RLHIM, with quantitative analysis enabling generalisations to a population and qualitative analysis seeking in-depth understanding from a few participants.

3.8 Ethical Considerations

Patient involvement is recommended to inform good practice and allows patients to be actively involved in organising or facilitating research (Gooberman-Hill *et al.*, 2013). In this research study, a patient representative (RP) contributed to study design, which included giving ideas on when/how to contact patients, and giving suggestions on acceptability and the design of questionnaires. This was taken as 'participating', which is ranked comparably high in the involvement ladder (Burston *et al.*, 2014). RP also contributed to agenda setting, development of patient information and consent procedures, and identification of outcomes (Gooberman-Hill *et al.*, 2013).

Ethical approval was sought from NHS ethics. The research team applied for a "proportionate review" at the beginning as the research study was going to evaluate a package of existing integrative treatments for MSDs already given at the RLHIM (NHS Health Research Authority, 2014), but this was refused. A full review application was then carried out, in which the research team was asked to add the word 'feasibility' or 'pilot' given that the study was perceived as being fairly unique for research in an NHS hospital and that no pilot data were available to guide the research study.

Ethical approval for the study was obtained from City and East London Research Ethics Committee on 24th Oct 2013 [REC reference number: 12/LO/1341]; UCLH R&D on 8th Jan 2013 [reference number: 12/0472]; LSBU ethical approval on 21st Jan 2013 [UREC 1280]. Anonymous data were held securely and transferred only between the research team members.

Two substantial amendments were submitted to the ethics committee, based on changes to the study protocol to improve recruitment. They were approved on 7th May 2013. The annual reports to the ethics committee were submitted each year after receiving ethical approval and were approved. Challenges in ethical application are presented in Section 7.3.6.

The principles of confidentiality, privacy and safety were preserved. Patients volunteered to participate in the study and no coercion took place. At the research student's first point of contact with patients, detailed verbal and written information was provided and they had the opportunity to ask questions. They were given at least

24 hours to consider participating in the study. They were also encouraged to talk about the study to independent parties, (e.g. their GPs or friends/family) and if they agreed to participate they signed a consent form. Patients who consented to take part in the observational study were also asked to indicate their willingness to take part in qualitative interviews/focus groups, but could just take part in the observational study if they preferred not to participate in the interviews/focus groups.

All participants were sent an information sheet (Appendix 3.1) within one week of recruitment. They were asked to complete three copies of a consent form (Appendix 3.2), countersigned by the research student (one copy for the research file, one copy for the patient, and one copy to leave in their medical notes). Patients who withdrew from the study or withdrew from the treatment were also invited to the follow-up interview. This enabled both positive and negative experiences of treatment to be captured. Those who returned the consent form and indicated willingness to take part in an interview or focus group were contacted by the research student. The research student verbally provided aims and procedures of interview, and the rights of participants again.

Participants were informed that if they observed any serious adverse effect from their hospital treatment, they could immediately withdraw from the study. However, no major adverse events were reported from the participants. While risks are minimal (if any), patients can be benefit from a better management of their condition, they could also benefit from the higher level of attention they would receive as being part of the study. For the participants who withdrew from the study, data already collected with consent were retained and used in the study, with no future data collected nor any research procedures carried out on or in relation to the patient.

Potential benefit of participating in this research study include: Patients may benefit from a better integrated management of their musculoskeletal disorder if the particular packages of routine NHS treatment they receive at the RLHIM are proved effective. Attention to the patient's condition may also help indirectly in helping patients to cope better with their conditions. Participants who were interviewed may also benefit from discussing their expectations and/of experiences of receiving treatment.

The research student had access to participants' personal addresses, phone numbers to post questionnaires, remind participants, and to arrange qualitative interviews. The research student could also get access to their clinical data if necessary, e.g. in the case of any major adverse events; or when collecting data on what treatments were given. Study questionnaires only contained the patient's unique code number. For those who were interviewed, participants' details were omitted from the transcript. Direct quotations from respondents were anonymised so that they were not be identifiable and only anonymised data were transferred between the research team. All participants' personal data and their consent forms were stored in locked filling cabinets in the research student's office within the University and could only be accessed by the research student and will be shredded on university premises 5 years after the completion of the study. The digital audio tape recording of patient interviews and focus groups were destroyed once the study was completed.

3.9 Chapter Conclusion

This chapter provides details of the methodology and methods, which is situated under the research student's pragmatic epistemological stance and the MRC framework of developing complex intervention. It should help readers to understand the study procedure and how the research student conducted each step. This also allows readers to assess the quality of this research study.

Due to a lack of previous research evaluating integrative treatment for MSDs in a secondary care in the UK and the complexity of IM care, a feasibility study was designed following the MRC framework. Mixed methods and a pragmatic observational quantitative approach and interviews were used in order to understand the phenomenon of the integrative treatments and patients' perceptions.

Newly referred MSDs patients at the RLHIM were recruited for a period of 15 months and each consented participant was followed up for 12 months. PROMs including VAS, sfBPI, and SF36 were assessed at four, eight, and 12 month post initial treatment appointment. Pre-treatment interviews and follow-up interviews and focus groups were carried out prior to participants' initial appointment and 12 months after the initial appointment respectively. Data collection and data analysis was conducted independently, with quantitative outcome measures targeted at evaluating the research process and the feasibility of assessing effectiveness; and

qualitative questions targeted at exploring participants' expectations and experiences of receiving treatment at the RLHIM. Quantitative and qualitative data were collected and analysed separately, with the main changes in PROMs assessed by repeated measures ANOVA, and interview data analysed using framework analysis. Mixed methods findings are reported with findings from both strands triangulated in the interpretation stage under the guide of three feasibility frameworks. Full NHS ethical approval was obtained with two minor revision made to improve recruitment.

Chapter 4 Quantitative Results

Aims and Structure

This chapter answers the research question on the feasibility of researching IM for MSDs using the quantitative findings. It reports on recruitment and retention to the study and the analysis of data collected from the 60 MSDs participants who consented to take part during the 27 month period (Jan 2013 – April 2015). Quantitative results are triangulated and interpreted with qualitative data in Chapter 6.

This chapter details the recruitment, response and completion rates of participants (Section 4.1), followed by a description of participants' baseline characteristics (sociodemographics and their MSDs) (Section 4.2). Other baseline characteristics including referral characteristics and participants' GPs' locations, and the characteristics of the integrative treatment received are provided in Section 4.3 and 4.4. In Section 4.5 and Section 4.6, changes in participants' expectations and pre-specified outcome measures are given, followed by predictors of responses (Section 4.7), sensitivity analysis (Section 4.8), and further subgroup analysis (Section 4.9). At the end of this chapter, a summary of the quantitative results are given.

Results on costs are not reported in this thesis for reasons given in Section 7.5.5. The two sets of baseline characteristics for interviewed participants are reported separately in Section 5.1. The statistical reporting in this chapter follows the SAMPL Guidelines (Lang and Altmanb, 2013), in combination with the strengthening the reporting of observational studies in epidemiology (STROBE for reporting the observational study results (von Elm *et al.*, 2014).

4.1 Response and study completion rates

Figure 4.1 shows the overall flow of participants through the study. During the recruitment period (Jan 2013 – April 2014), a total of 181 eligible patients identified

by a hospital musculoskeletal physician using the inclusion criteria (Section 3.2.2) were contacted by the research student (first screening). Several issues were challenging in identifying and recruiting eligible patients. The reasons for these issues are presented as a limitation to the feasibility of the study (Section 6.4) and are discussed in depth in Chapter 7 (Section 7.5). Twenty of the 181 patients were excluded at the second screening as they did not fit the inclusion criteria. Of the remaining patients, 101 refused to participate, the most common reason being having no time or no interest (n=49), three patients stated that they had no faith in CAM and were referred to the hospital for conventional interventions (see Figure 4.1). A final total of sixty patients (37%) were included in this research study. The results of the analysis in this chapter are based on these 60 participants.

All 60 participants completed the first baseline questionnaires. Of these, seven had previously had treatment at the RLHIM but had now been referred for a new episode of MSD treatment. Eighteen of the participants (30%) were on a waiting list, 16 of whom completed second baseline measurements prior to their treatment. Some inevitable issues specific to hospital arrangements restricted the recruitment, for example, nine participants' initial appointments were cancelled or changed. During the study, six participants were lost to follow-up at T1 (four months, n=54), four additional participants at T2 (eight months, n=50), and three additional at T3 (12 months, n=47), leading to a completion rate of 78% at 12 months follow-up (Figure 4.1). Table 4.1 showed a detailed information on questionnaire completion and those who were interviewed and drop outs into the study.

All participants completed the VAS, SF36, and sfBPI over the 12 months follow up, but the completion of the mCSRI was 85% (46 participants/54) at four months, 74% (37/50) at eight months, and 77% (36/47) at 12 months. Completion of treatment log was poor, with only 22 (37%) logs (count as one if the log for one patient was filled

only once) filled in and none of these reflected all the treatments patients received etc in the 12 months' follow-up period.

Table 4 1 Study participants' (n=60) basic information and questionnaire completion during the 12 months' period and their attendance in pre-and-follow-up interviews

ID	Age	Gender	QUAN				QUAL		
			0	4m	8m	12	Pre interview 1-1	Follow-up 1-1	Follow-up FG
1	41	F	√	√	√	√	x	x	x
2	85	F	√	√	√	√	√	x	x
3	57	F	√	√	√	√	√	x	x
4	25	F	√	√	√	√	√	x	x
5	74	F	√	√	√	√	√	√	x
6	52	M	√	√	√	√	√	x	√
7	31	M	√	√	√	√	√	x	√
8	50	M	√	√	√	√	√	x	x
9	67	M	√	√	√	√	√	√	x
10*	46	F	√	√	√	√	√	√	√
11	55	M	√	√	√	x	√	x	x
12	38	M	√	√	√	√	√	√	x
13	36	F	√	√	√	√	√	√	x
14	78	F	√	√	√	√	x	x	√
15	50	F	√	√	√	√	√	x	√
16	38	F	√	x	x	x	x	x	x
17	63	F	√	√	√	√	x	x	x
18	70	F	√	√	√	√	x	x	x
19	37	F	√	√	√	√	√	x	x
20	60	F	√	√	√	√	√	√	x
21	44	F	√	√	√	√	√	√	x
22	47	F	√	√	√	√	x	√	x
23	53	F	√	√	x	x	√	x	x
24	67	F	√	√	√	√	x	x	x
25	52	F	√	√	√	√	x	x	x
26	48	M	√	√	√	√	√	√	x
27	57	F	√	√	√	√	√	x	√
28	55	M	√	x	x	x	x	x	√
29	45	F	√	x	x	x	x	x	x
30	30	F	√	√	√	x	x	x	x
31*	69	F	√	√	√	√	√	√	√
32	45	F	√	√	x	x	√	x	x
33	64	F	√	√	√	√	√	x	x
34	58	F	√	x	x	x	x	√	x

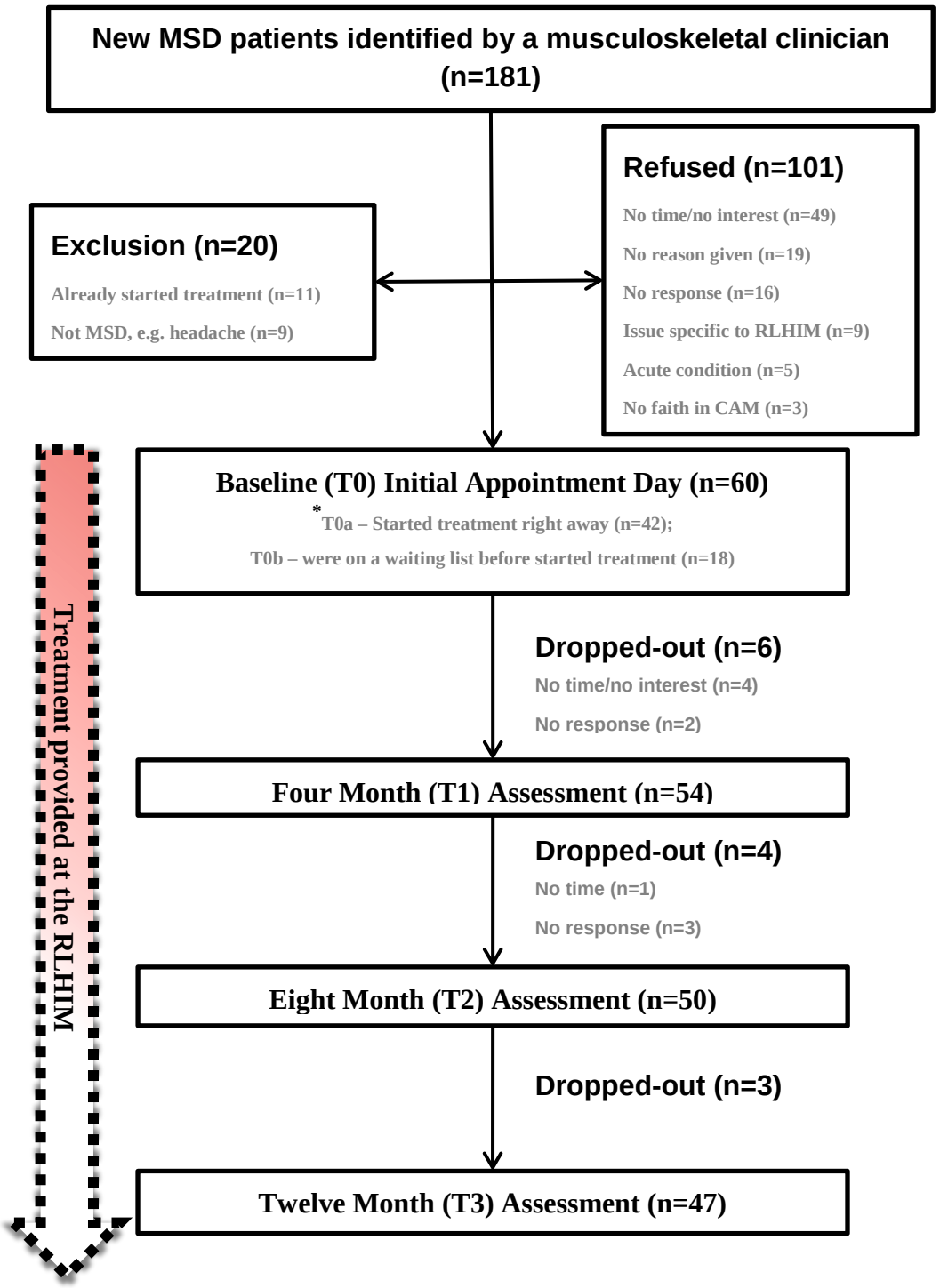
ID	Age	Gender	QUAN				QUAL		
			0	4m	8m	12	Pre interview 1-1	Follow-up 1-1	Follow-up FG
35	45	M	√	√	√	√	x	x	√
36	45	F	√	√	√	√	√	x	x
37	48	M	√	x	x	x	x	x	x
38	29	F	√	√	√	√	√	x	x
39	27	M	√	√	√	√	√	x	x
40	32	F	√	√	√	√	√	√	x
41*	51	F	√	√	√	√	x	√	√
42	59	F	√	√	√	√	x	x	x
43	52	M	√	√	x	√	√	x	x
44	45	M	√	√	√	√	x	√	x
45	32	M	√	√	√	√	x	x	x
46	63	F	√	x	√	√	√	x	√
47	77	F	√	√	√	√	√	x	√
48	66	F	√	√	√	√	x	√	x
49	62	F	√	√	√	√	x	x	x
50	38	F	√	√	√	√	x	x	x
51	69	F	√	√	√	√	x	√	x
52	41	F	√	√	√	√	x	x	x
53	61	F	√	√	√	√	x	x	x
54	62	F	√	√	x	x	√	x	√
55	43	F	√	√	√	√	x	√	x
56	45	F	√	√	√	√	x	x	x
57	67	F	√	√	x	x	x	x	x
58	55	M	√	x	x	x	x	x	√
59	65	F	√	√	√	x	x	x	x
60	60	M	√	√	√	√	x	x	x
**	52	F:73%	60	53	49	47	30	28	

Key: F: female, M: male

*Participants who were interviewed in both one-to-one interview and focus group at follow-up

** Mean/percentage/counts

Figure 4 1 Flowchart of study recruitment and follow up assessment



MSD=musculoskeletal disorders;

$^{\Delta}$ Questionnaires include the SF-36^{TM} health survey, short form brief pain inventory, visual analogue scale, and modified client service receipt inventory

4.2 Baseline characteristics of the participants

4.2.1 Sociodemographics and lifestyle characteristics

All participants' sociodemographic characteristics were collected from the initial questionnaire, with no missing data (n=60, Table 4.2). Participants' education level was grouped into two categories: college education and above, and below college education level; occupational status was grouped into retired, not working due to ill health, employed (full time), employed (part time) and other; Occupational groups professional/technical/skilled manual and unskilled or not applicable.

Most of the participants were female (n=44, 73%), had an average age of 52, were married or living with partner (n=28, 47%), and the more common education level was college/ diploma level or above (n=49, 82%). One quarter of the participants were retired, with most (n=47, 78%) participants' occupational group coded as professional/technical/skilled. Most of the participants (n=46, 77%) were native English speakers, the majority were white British (n=40, 67%), and the most common stated religious affiliation was Christian (n=27, 45%).

Data on smoking and alcohol consumption were also recorded at baseline with no missing data (n=60). Most participants were non-smokers (n=46, 77%) and did not drink alcohol (n=41, 68%). For those who did, the average weekly number of cigarettes was 53.36±11.434 (n=14) and the average units of alcohol consumed was 11.89±2.879 units (n=19).

Table 4 2 Participants' sociodemographic characteristics

Sociodemographic Characteristics, n=60		Number (Percentage)
Age (yrs), mean (SD)		52.1 (13.798)
Female		44 (73%)
Marital Status	Married or Living with partner	28 (47%)
	Single/Divorced/Separated/Widowed	32 (53%)
Educational Level	College/Diploma and above	39 (65%)
	Below college level	21 (35%)
Occupational Status	Not Working/Employed Part-time Due To Ill Health/Retired	41 (68%)
	Employed (Full-Time) or other	19 (32%)
Occupational Group	Professional/technical/skilled	47 (78%)
	Unskilled or not applicable	13 (22%)
Mother Tongue, English as First Language		46 (77%)
Ethnic Origin	White British or White other	47 (78%)
	Others	13 (22%)
Religious Affiliation	Christian	27 (45%)
	No Beliefs/Prefer Not to Say/Others	33 (55%)

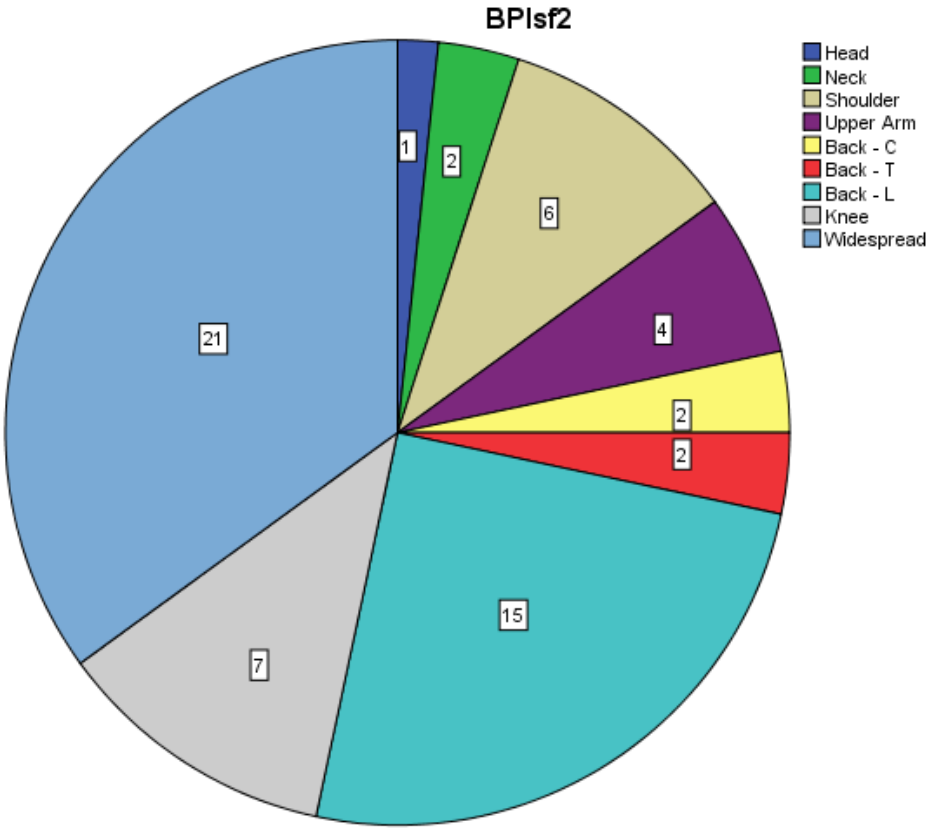
SD=Standard Deviation, yrs=years

4.2.2 MSDs characteristics

Participants' MSD characteristics were evaluated using ICD codes and the location of pain were documented using the sfBPI. Though it was intended to collect both participants' primary and secondary ICD codes, the primary ICD codes of only 42 participants (70%) were available; no secondary ICD codes were available. Among the 42 available primary ICD codes, 37 (88%) of participants' primary ICD code was diseases of musculoskeletal system and connective tissues (M00-M99), with the most common codes being M54 (dorsalgia; n=13, 22%) and M79 (Other and unspecified soft tissue disorders, not elsewhere classified; n=13, 22%).

Participants were required to put one ‘x’ on a body figure to show the location of the most painful area. However, 21 participants (35%) put ‘x’ in more than three places; these participants were categorised as ‘complex’. This was the most commonly reported location of pain, followed by LBP (N=15, 25%), and knee pain (n=7, 12%). Figure 4.3 shows the locations of the most painful area reported by the participants.

Figure 4 2 Locations of the most painful area as shown in sfBPI



Key: Complex: pain in more than three places on the body figure; Back-C: Cervical region back pain; Back-T: Thoracic region back pain; Back-L: Lumbar region back pain

4.3 Referrals and participants’ GPs’ location

In this section, data on participants’ referrals collected from the hospital CDR system is reported. Just over a third of the participants’ initial appointments were cancelled or changed (n=21, 35%). Eighteen (30%) did not start their treatment immediately

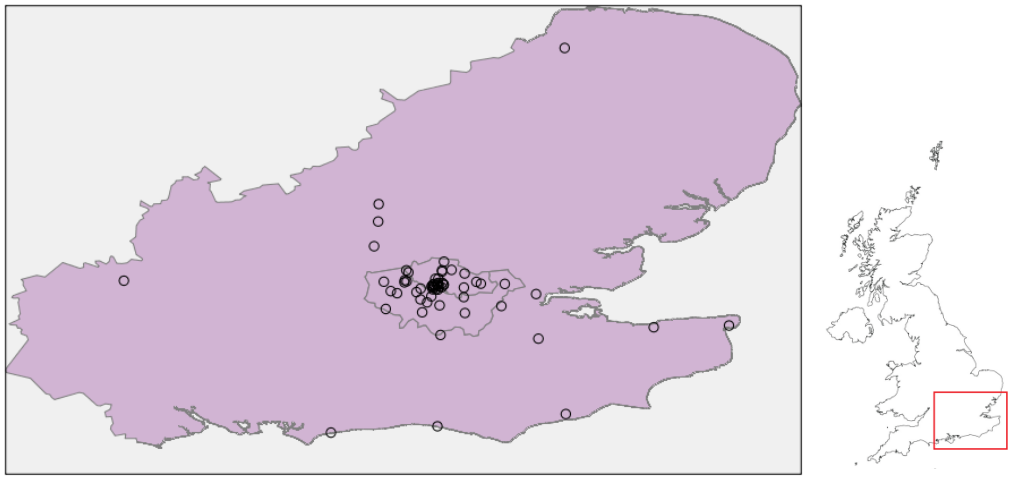
after their first appointment at the RLHIM. The mean length of time between participants receiving their referral letter and their initial appointment (n=60) and the length of time they were on a waiting list (n=18) are reported (Table 4.3). Figure 4.3 shows participants' GPs' practice location. The inner circle represents the broad line of greater London.

Table 4 3 Referral, appointment and waiting time

Referral Characteristics (n=60)		**No. (%)**
Cancelled/changed appointments, No. (%)		21 (35%)
Waiting list, No (%)		18 (30%)
Time interval between referral & 1st appointment, days		Mean (SD): 44.0 (24.9)
Time on waiting list, mean (SD), days		9.63 (16.79)
GPs' Location	North East London	22 (37%)
	Non-North East London	16 (27%)
	Outside greater London	22 (37%)

SD=Standard Deviation

Figure 4 3 Sixty participants GPs' location on map of South East England



The inner circle depicts greater London

4.4 Integrative treatments for MSDs at the RLHIM

This section reports the characteristics of integrative treatments for MSDs the 60 participants received during the period January 2014 to April 2015. Participants received complex integrative treatment with various packages of treatment or single

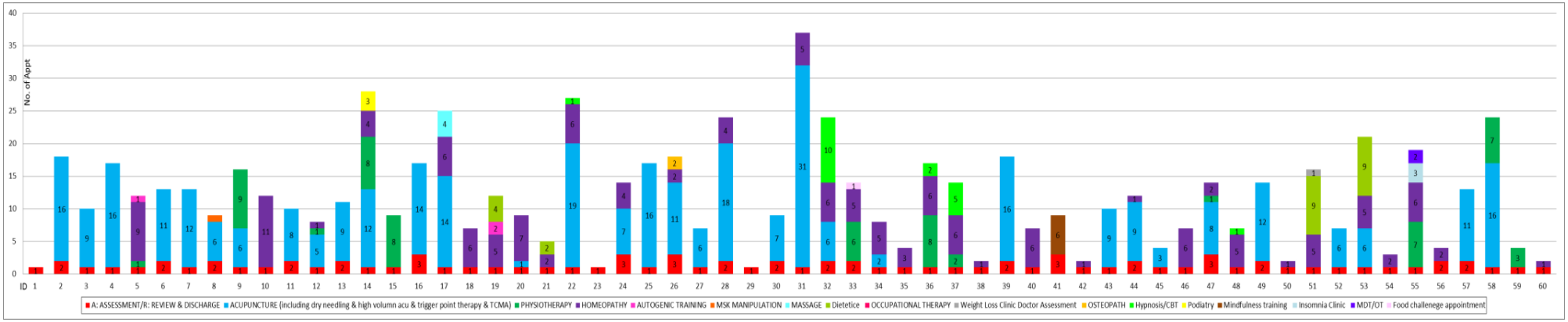
treatments of different lengths, frequencies, and types. These data were converted to length (days) of treatment and was categorised into four categories: finished treatment within 4 months; stopped treatment between 4-8 months; stopped treatment between 8-12 months; and still continuing treatment at 12 month follow up. All 60 participants received a musculoskeletal clinical assessment within their initial appointment and a musculoskeletal review before being discharged. Type of treatment received was grouped into those receiving a single CAM treatment, or those receiving multiple CAM treatments, and analysed using SPSS.

Most participants received one modality plus assessment (n=32, 53%): most commonly received were acupuncture (n=18, 51%) and homeopathy (n=12, 34%). Ten (17%) participants received two modalities plus assessment; thirteen (22%) received three modalities plus assessment; two (3%) received four modalities plus assessment. In three cases (5%), participants only received an assessment without any intervention. Figure 4.4 shows the various types of integrative treatments participants received.

The highest number of appointments/sessions of treatments (plus assessment) was 37 sessions during the year, while the lowest, apart from the three cases who only received assessment, was 2 sessions (median: 11.5 sessions). Overall, acupuncture (n=33), homeopathy (n=31), and physiotherapy (n=12) were the three most commonly received treatments at RLHIM for the participants during the follow-up period, followed by dietetics (n=5), hypnosis/CBT (n=5), occupational therapy (n=2), musculoskeletal manipulation (n=1), insomnia clinic (n=1), podiatry (n=1), weight loss clinic (n=1), autogenic training (n=1), massage (n=1), osteopathy (n=1), and mindfulness training (n=1). The complexity of the treatments participants' received and frequency of treatment are given in Appendix 4.1.

As the most commonly provided intervention at the hospital during the study period, acupuncture at RLHIM may be provided in the high volume acupuncture clinic (group acupuncture), or as individual sessions of acupuncture, electroacupuncture, dry needling, TCM acupuncture, and trigger point therapy, dependent on participant individuals' needs. The acupuncture treatment is provided by doctors, nurses, or physiotherapists and it normally lasts 15-30 minutes. Choice of points may vary and change depending on the progress of patients' conditions.

Figure 4 4 Types of integrative treatments received by individual participants for MSDs at the RLHIM over 12 months



4.5 Sensitivity Analysis

In order to explore the robustness of the results and to understand the relationships between dependent and outcome variables, several sensitivity analyses were performed to determine potential differences between participants who completed questionnaires at all four time points (n=47), and the ones who did not (n=13). Table 4.4 shows that there was no significant difference between the baseline characteristics for the completers and non-completers, which suggests there was no particular reason that the thirteen participants dropped out during the one-year follow-up related to these baseline characteristics. Therefore, casewise deletion was adopted, with subsequent results presented only for the completers (n=47). There was no missing data in VAS, sfBPI, or SF36 at all-time points.

Table 4 4 Comparison of baseline characteristics of participants who did or did not complete outcome measures for all four time points

Baseline characteristics	Completers (n=47)	Non-completers (n=13)	*P*
Age	52.13 (14.656)	52.00 (10.614)	0.977
Female	74.5%	69.2%	0.705
Married/living with partner	48.9%	38.5%	0.503
College/diploma & above	68.1%	53.8%	0.341
Not working/employed part-time due to ill health/retired	76.6%	61.5%	0.277
Professional/technical/skilled	80.9%	69.2%	0.368
English as 1st language	76.6%	76.9%	0.980
White British/white other	74.5%	69.2%	0.705
Christian	40.4%	61.5%	0.176
Non-smoker	74.5%	84.6%	0.444
Non-drinker	66.0%	76.9%	0.452
PEQ RLHIM	7.17 (1.579)	7.92 (1.706)	0.140
PEQ CAM	7.21 (1.628)	7.92 (1.656)	0.171
NEL CCG	38.3%	30.8%	0.871
Received treatment for ⩾12m	51.1%	50%	0.859
Multiple treatments	44.7%	30.8%	0.368
VAS	70.72 (19.935)	68.38 (18.478)	0.705
sfBPI Pain Severity	6.42 (1.805)	6.02 (1.935)	0.488
sfBPI Pain Interference	6.37 (2.279)	6.36 (1.984)	0.987
SF36 Physical	26.809 (15.682)	22.981 (15.388)	0.437
SF36 Emotional	35.632 (18.043)	35.141 (16.416)	0.930

PEQ: patient expectation questionnaire, VAS: visual analogue scale, NEL: North East London,

CCG: clinical commissioning group, BPI: brief pain inventory
Values shown are means (SD), or n (%); *p* calculated from independent t test for continuous data and chi- square for categorical data

4.6 Changes in participants' expectations

Two scores of participants' expectations were assessed at all-time points: one was to evaluate their faith in the treatment provided at the RLHIM; the other was to evaluate their faith in CAM treatment in general. Descriptions of how their expectations were measured are available in Section 3.4.2. Higher score means a higher expectation. Participants had a mean expectation score over 7 (out of 10) on both the treatment at the RLHIM and CAM in general before their initial appointment at the RLHIM (with a mean of 7.17 and 7.21 respectively, p>0.05) (Table 4.5).

Table 4 5 Participants' mean expectation scores at four time points

PEQ Score (n=47)	Baseline, mean (SD)	4m, mean (SD)	8m, mean (SD)	12m, mean (SD)
PEQ RLHIM	7.17 (1.579)	6.74 (2.336)	6.66 (2.209)	6.60 (2.209)
PEQ CAM	7.21 (1.628)	7.36 (1.607)	7.51 (1.692)	7.49 (1.999)

SD=Standard Deviation

Changes in participants' expectations were compared over 12 month follow-up period using repeated measures ANOVA. The mean scores for participants' expectations for treatment at the RLHIM or for CAM in general were not statistically significantly different over the 12 months follow-up, $F(3, 138) = 1.647$, $p=0.181$; $F(3, 138) = 0.641$, $p=0.590$.

4.7 Changes in outcome measures

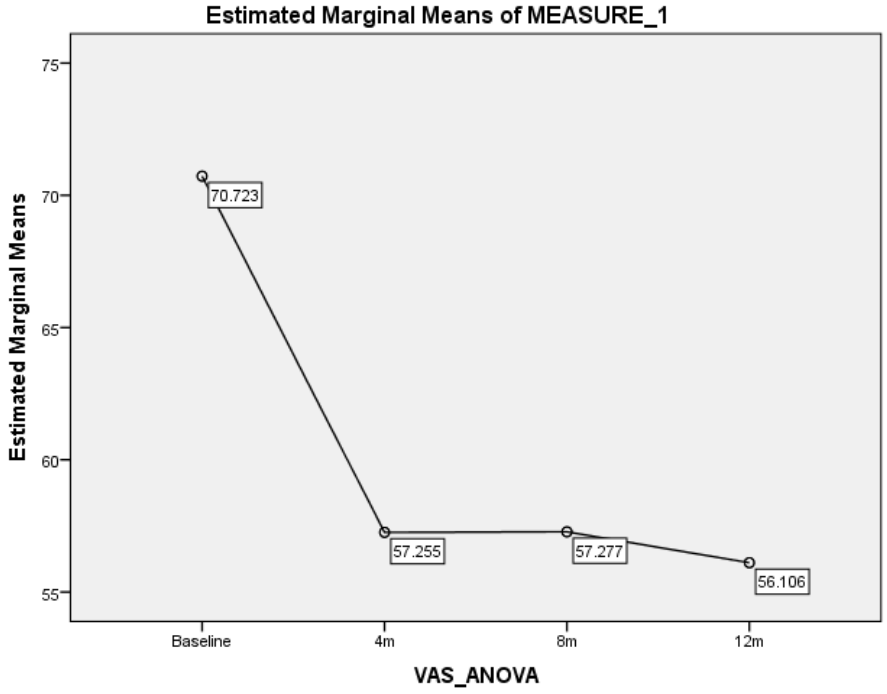
Patient reported outcome measures in VAS, SF36, and sfBPI were evaluated at baseline, for some participants also at the second baseline (for those who were on a waiting list, n=18, results in Section 4.9). In addition to the raw data collected from

the completed questionnaires at baseline, 4, 8 and 12 months, the variables on SF36 and sfBPI were computed and transformed as described in Section 3.6.1. The results presented are for the sample of n=47.

4.7.1 Changes in primary outcome measures

The level of pain dropped during the first four months and this lower level was sustained over 12 months as measured by VAS (Figure 4.5). A lower score in the VAS indicates less pain.

Figure 4 5 Changes in pain over one year follow up as measured by the VAS



As the mean changes in VAS were approximately normally distributed (Appendix 4.2), and there were no outliers identified, one-way repeated measures ANOVA was conducted to compare the changes in VAS over four time points. It showed that the mean scores of VAS were statistically significantly different over the 12 months' period, $F(3, 138) = 10.674$, $p < 0.0005$. Paired sample T tests were carried out to assess the difference between each pair of time points: they showed significant improvements with a moderate to large effect size in improvements in pain as

measured by VAS at four months (effect size SE=0.615), a small to moderate effect at eight months (effect size =0.490), and moderate to large effect at twelve months (effect size =0.574). Comparing to VAS at four months, it slightly increased at the eight month, following a minor drop at the twelve months. But these changes were not significant (Table 4.6).

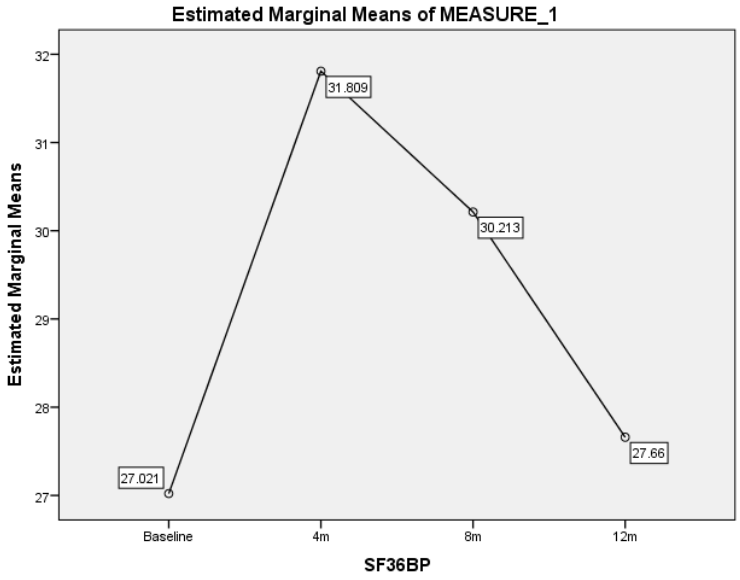
Table 4 6 Changes in VAS (pain) between baseline, four, eight and twelve months follow-up

Compare Groups (n=47)	**Changes in Mean (SD)**	**95% CI**	**P Value**
Baseline vs 4m	13.468 (21.907)	(7.036, 19.000)	**<0.0005**
Baseline vs 8m	13.447 (27.452)	(5.387, 21.507)	**0.002**
Baseline vs 12m	14.617 (25.450)	(7.145, 22.090)	**<0.0005**
4m vs 8m	-0.021 (16.640)	(-4.907, 4.864)	0.993
4m vs 12m	1.149 (17.195)	(-3.900, 6.197)	0.649
8m vs 12m	1.170 (9.687)	(-1.674, 4.014)	0.412

SD=standard deviation, CI=confidence interval of the difference

However, there was no statistically significant improvement in pain as measured by SF36 bodily pain dimension (Figure 4.6). A higher score in SF36 bodily pain indicates improvement in pain.

Figure 4 6 Changes in pain over one year follow up as measured by SF36 bodily pain



One-way repeated measures ANOVA was conducted to compare the changes in SF36 bodily pain over four time points. Repeated measures ANOVA showed that mean scores of SF36 BP were not statistically significantly different, F (3, 138) =1.233, p=0.300. There was a non-significant but minor improvement in pain at 4 months, 8 and 12 months. A summary of overall changes in pain as measured by SF36 bodily pain are presented in Table 4.7.

Table 4 7 Changes in SF36 bodily pain between baseline and four, eight, twelve months follow-up

Compare Groups (n=47)	Changes in Mean (SD)	95% CI	P Value
Baseline vs 4m	-4.787 (22.673)	(-11.444, 1.870)	0.155
Baseline vs 8m	-3.191 (21.211)	(-9.419, 3.036)	0.308
Baseline vs 12m	-0.638 (23.368)	(-7.499, 6.223)	0.852
4m vs 8m	1.596 (16.636)	(-3.289, 6.480)	0.514
4m vs 12m	1.149 (17.195)	(-3.900, 6.197)	0.123
8m vs 12m	2.553 (12.806)	(-1.207, 6.313)	0.178

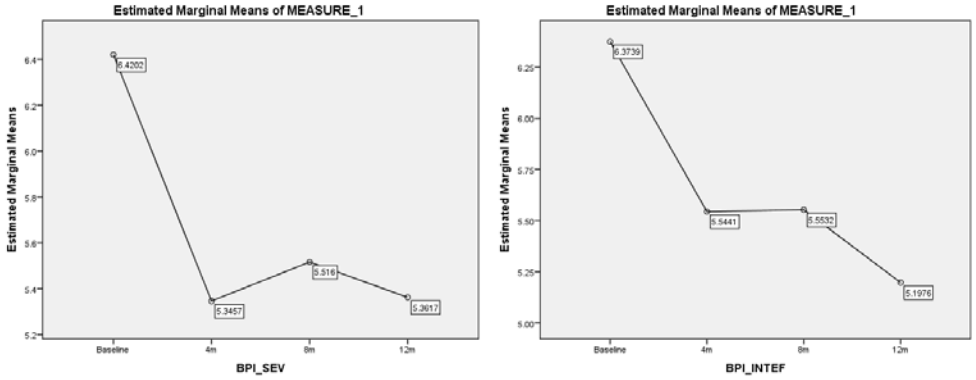
4.7.2 Changes in secondary outcome measures

Changes in the sfBPI (2 sub-outcome variables: pain severity and pain interference) and SF36 (2 sub-outcome variables: physical and emotional dimensions) were evaluated through the same approach. Internal reliability among sub-scales of sfBPI

and SF36 were high: Cronbach's Alpha were 0.731 at baseline, 0.916 at four month, 0.912 at eight month, and 0.919 at 12 months for sfBPI; and 0.758 at baseline, 0.875 at four months, 0.907 at eight months, and 0.899 at 12 months for SF36.

There were significant improvements in pain intensity: F (3, 138)=7.742, p<0.0005, and pain interference: F (3, 138)=5.522, p=0.001 as measured by the sfBPI at four, eight, and 12 months (Figure 4.7).

Figure 4 7 Changes in pain over 12 months follow up as measured by sfBPI (left: pain severity subscale, right: pain interference subscale)



As assessed by paired t test, comparisons between baseline and four, eight, and 12 months are available for each subscale (Table 4.8). It shows that there were significant improvements with a moderate to large effect size in pain as measured by sfBPI pain severity subscale at four months (effect size =0.628), a small to moderate effect at eight months (effect size =0.499), and moderate to large effect at twelve months (effect size =0.523). Similar improvements in pain were observed as measured by sfBPI pain interference, with small to moderate effects at four and eight months (effect size SE=0.400 and 0.440 respectively, and moderate to large effect at twelve months (effect size SE=0.546). There was no significant change between four and eight months, four and 12 months, nor between eight and 12 months.

Table 4 8 Means of 13 secondary outcome variables at four time points and changes in means comparing different time points

Compare Groups (n=47)	Mean difference, SD, p value

	sfBPI Pain Severity	sfBPI Pain Inteference
Baseline vs 4m	1.259 (2.005), p<0.0005	1.024 (2.557), p=0.005
Baseline vs 8m	0.925 (1.853), P=0.001	1.009 (2.292), p=0.003
Baseline vs 12m	1.059 (2.024), p=0.001	1.176 (2.154), p=0.001
4m vs 8m	-0.195 (1.597), p=0.392	-0.106 (1.672), p=0.657
4m vs 12m	-0.016 (1.807), p=0.952	0.347 (2.38), p=0.311
8m vs 12m	0.154 (1.242), p=0.399	0.356 (1.989), p=0.227

SD=Standard Deviation

On the other hand, as measured by repeated measures ANOVA, it failed to show significant changes in participants' quality of life in terms of physical improvement: F (3, 138)=1.432, p=0.236 as measured by SF36 physical dimension, nor in terms of emotional improvement: F (3, 138)=2.565, p=0.057. Small to moderate improvement was only observed in physical functions comparing baseline to four months, with mean difference: -6.019 (SD=18.477), p=0.020, effect size=0.326; and in emotional function at four and 12 months: 4m mean difference: -8.306 (21.412), p=0.006, effect size=0.388 ; 12m mean difference: -6.148 (17.569), p=0.021, effect size=0.350.

4.8 Prediction of responses

As explained in Section 3.6.1, multiple linear regression analyses with forward selection method were performed to explore potential independent variables that influenced the changes in pain response as measured by VAS at four months (y_1=VAS $_{baseline}$ – VAS $_{4m}$); and potential independent variables that may influence participants' expectations in the treatment at the RLHIM (y_2= PEQ RLHIM $_{baseline}$ – PEQ RLHIM $_{4m}$). As this was an exploratory analysis to explore which factors might influence participants' pain outcome and their expectations, no correction was made for multiplicity.

Predictor variables included in the model for exploring changes in VAS were: 1). Sociodemographics: age, gender, marital status, educational level, occupational status/group, mother tongue, ethnic origin, and religious affiliation; 2). Lifestyle: smoker or not, drinker or not; 3) Expectations in treatments at the RLHIM; 4).

Referral pathway; 5). Integrative treatment characteristics: length of treatment, complexity of treatment; and 6). Pain at baseline as measured by VAS.

Assumptions of performing multiple regressions specified in Section 3.6.1.4 were assessed. Approximate normality was achieved. There was independence of residuals, as assessed by a Durbin-Watson statistic of 1.813, therefore meeting the assumption of collinearity. There were potential outliers as all cases had a LEV more than 0.2; No Cook's distance value above 1 was detected. All outliers were kept as they are in the analysis.

The overall changes in VAS at four months might be partially predicted by adding two dependent variables: baseline VAS, and being a smoker. Those participants who were non-smokers and those who had greater pain at baseline had a better improvement in pain at four months, F (2, 44)=7.914, p=0.001, R^2=0.265. Regression coefficients and SEs are presented in Table 4.9.

Table 4 9 Correlation of variables for changes in VAS and PEQ RLHIM at four month (n=47)

Dependent variable	*B*	Unstandardised coefficients SE	R^2adjusted	β	p value
Intercept	-7.009	10.812	-	-	-
Smoker or not	-18.095	6.471	0.143	-0.364	0.008
Baseline VAS	0.355	0.143	0.231	0.323	0.017

B: unstandardised regression coefficient; SE: standard error; β: standard coefficient

Predictor variables included in the model for exploring changes in participants' expectations in the treatment at the RLHIM included all the independent variables used in exploring correlation with changes in the VAS mentioned above. Two additional variables: on waiting list or not, and the length of waiting time were also added. Overall changes in PEQ RLHIM at four months were partially predicted by participants' baseline expectation in treatment at RLHIM, with a higher expectation at baseline having greater decrease in expectation at four months, F (1, 45)=9.218, p=0.004, R^2=0.170.

4.9 Subgroup analysis

4.9.1 Baseline one vs. baseline two

As pre-specified in Section 3.5, participants who were put on a waiting list after their initial appointment at the RLHIM completed a second baseline before their first treatment (n=18). Two participants on the waiting list refused to complete the second baseline questionnaire as they believed there had been no change in their condition since baseline. With an average time on the waiting list of 10 days, it is understandable that these patients refused to complete the second questionnaire, particularly as one of the patients also had pain in her fingers, and the other had severe neck pain.

Clinical outcome measures were compared between the two baselines. Apart from participants' educational level, no significant differences were observed between the two baselines (Table 4.10). This indicated that the participants who were on the waiting list were representative for self-control comparison. However, considering the small sample size of 16 patients, self-comparison evaluation was not used as the final finding for limited effectiveness testing.

Table 4.10 Comparison of baseline characteristics of participants who were on waiting list and those who were not

Baseline characteristic	Waiting list (n=16)	No waiting list (n=44)	*p*
Age, mean (SD)	50.94 (17.479)	52.52 (12.409)	0.697
Female	62.5%	77.3%	0.253
Married/living with partner	43.8%	47.7%	0.785
College/diploma & above	43.8%	72.7%	**0.037**
Not working/employed part-time due to ill health/retired	75.0%	72.7%	0.860
Professional/technical/skilled	75.0%	79.5%	0.705
English as 1st language	12.5%	27.3%	0.232
White British/white other	75.0%	72.7%	0.860
Christian	43.8%	45.5%	0.907
Non-smoker	75.0%	77.3%	0.854
Non-drinker	75.0%	65.9%	0.503
PEQ RLHIM, mean (SD)	7.81 (1.759)	7.16 (1.554)	0.170
PEQ CAM, mean (SD)	7.25 (2.324)	7.41 (1.352)	0.799

NEL CCG	37.5%	36.4%	0.839
Received treatment for ⩾12m	43.8%	50.0%	0.668
Multiple treatments	37.5%	43.2%	0.693
VAS, mean (SD)	68.00 (17.937)	71.02 (20.174)	0.600
sfBPI Pain Severity, mean (SD)	6.27 (1.566)	6.36 (1.926)	0.964
sfBPI Pain Interference, mean (SD)	6.34 (1.924)	6.38 (2.316)	0.946
SF36 Physical, mean (SD)	30.55 (10.728)	24.32 (16.790)	0.173
SF36 Emotional, mean (SD)	36.56 (15.349)	35.22 (18.466)	0.827

4.9.2 Outcomes of patients receiving different integrative treatments

Subgroup analyses were performed for participants who received a single treatment (n=32), and the ones who received complex interventions (e.g. more than one type of treatment) at the RLHIM (n=28); and also for participants who received treatment for different lengths of time (less than 12 months, or ⩾ 12 months). Independent t tests showed that different complexity or different lengths of treatment did not affect the improvement in pain at four months ($p_{complexity}$ =0.616 and p_{length}=0.780).

4.10 Chapter Summary

This chapter presented quantitative results on the feasibility of carrying out this research study. Issues were identified from recruiting eligible patients but follow-up responses and retention at 12 months were acceptable. Apart from the mCSRI, completion rate in the three selected PROMs were very good. Most participants were middle age, female Caucasians, with higher educational background and most of them were not working or working part time due to ill health or retired. Most participants had widespread pain in various locations, and low back pain and knee pain were the top two common location of pain identified. 37% participants were referred from NEL CCG, while 37% were referred outside greater London. The integrative treatments they received at the RLHIM during the follow-up period varied in terms of types, combinations, frequencies and amounts. Combination of treatments participants received ranged from one to four, with most of them only receiving one type of intervention apart from their assessment appointments (53%),

followed by receiving three types of treatments (22%). Acupuncture, homeopathy, and physiotherapy were the three most commonly received treatments. Participants' expectations in treatment at the RLHIM and their expectations in CAM in general were assessed over the 12 month follow-up, with no significant difference detected.

Improvements in pain severity were observed, with a moderate to large effect size as measured by VAS and sfBPI at 4 months, and this improvement was maintained between 4 and 12 months. Improvements were also observed in pain interference, physical function, and mental function, with a small to moderate effect size as measured by sfBPI and SF36. The results suggested that VAS and sfBPI appear sensitive to changes observed in integrative treatment for MSDs.

Those participants who were non-smokers and those who had greater pain at baseline showed significantly better improvement in pain at four months; a higher expectation at baseline was associated with greater decrease in expectation at four months. However, analysis of potential predictors is exploratory due to limited sample size; these data should therefore be interpreted with caution.

Chapter 5: Patients' Expectations and Experiences

Aims and Structure

This chapter addresses the research questions concerning participants' expectations prior to integrative treatment and taking part in the research study; their experiences of receiving integrative treatment at 12 month follow up and their experiences in participating research study (pre-specified in Section 1.6). For participants to have a clear memory regarding their experiences in completing the PROMs, they completed the first questionnaire pack right before being interviewed for the pre-treatment interviews, and they were asked to complete the last questionnaire pack in the few days before they were interviewed or on the day prior to the follow-up interviews.

The sociodemographic details and clinical characteristics of patients who were interviewed were compared with those who were not interviewed, in order to ensure that the participants interviewed were representative of all study participants (Section 5.1). The first research question was assessed by pre-treatment interviews, with 30 one–to-one, face-to-face interviews with MSD participants before their initial appointment for a new episode of MSD treatment at the RLHIM (Sections 5.2 -5.8). The second research question was answered by the results from the follow-up interview: 15 one-to-one interviews and four focus groups (n=15 participants), 12 months after their initial appointment at the RLHIM (Sections 5.9-5.15).

Since the pre-treatment and follow-up interviews took place over different periods of time and were largely aiming to answer different research questions, these were analysed separately (details in Section 3.6). Regarding the follow-up interviews, one-to-one interviews and focus groups were analysed together, but with 'FG' marked for those who took part in a focus group. In order to keep the results consistent, and to best show the changes over the one year, the framework developed for the follow-up interviews was based on the framework developed for the pre-treatment

interview. This means that the naming of categories and themes were as much the same as for those in the pre-treatment framework as possible.

In accordance with a framework analysis approach, most themes identified (Sections 5.2-5.9, 5.13-5.15) directly reflected the questions the research student asked in the interviews, with new themes emerged under each category. Three themes (Sections 5.10-5.12): self-awareness and reflection, self-directed integrative approach, and imbalance in supply and demand emerged from analysing the follow-up interview data analysis. These emergent themes are given first, after providing the general picture of how participants lived with MSDs (Section 5.9). This was because emergent themes were considered higher value as they were not directly asked about, were generated from multiple questions; and indicated topics the participants were interested in talking about. Apart from those emerging categories, all categories for both pre-treatment and follow-up interviews are presented as two sets of stories, in a sequential and logical order, to guide the audience.

Rather than using a weighted rubric, the themes and sub-themes are presented in order of importance as determined by the number of participants who commented or quoted on that theme. A summary of results on themes and sub-themes generated from the two qualitative studies are presented after each theme. Table 5.1 shows the symbols used in presenting the results in this chapter.

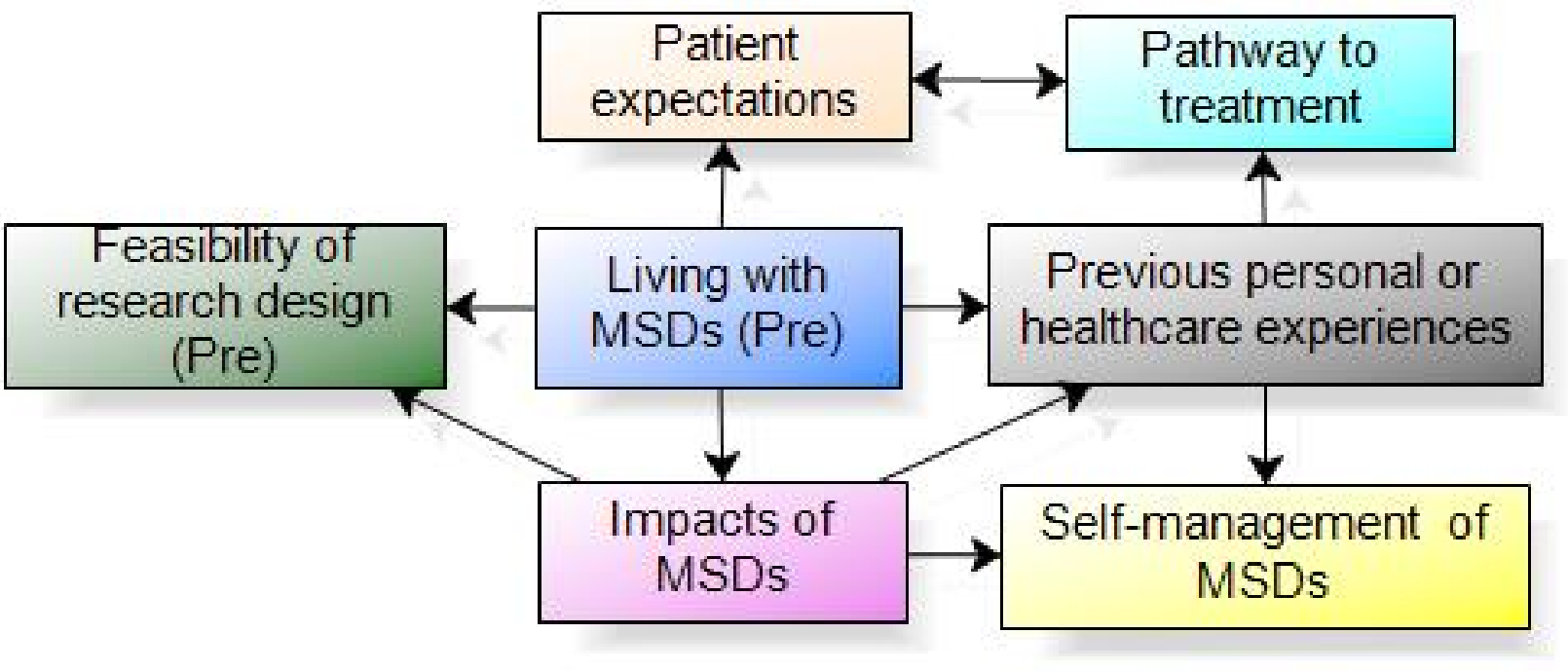
Table 5 1 Symbols used in presentation of qualitative results

Symbol	Explanation
…	Omissions of quotes
[ ]	Research student's interpretation or observational data
‘’	Participants' own words
Capital letters	Shouting or emphasising
Identification	Pre-treatment: 1st: participant ID Follow-up interviews or focus groups: 1st: (FG=focus group) participant ID; 2nd: treatment(s) received at the RLHIM for MSDs during Jan 2014-April 2015, e.g. FG28, Acu+Homeopathy

Figure 5.1 and 5.2 shows the connections of the themes generated from pre-treatment and follow-up interviews. Details of how and why they are connected are available

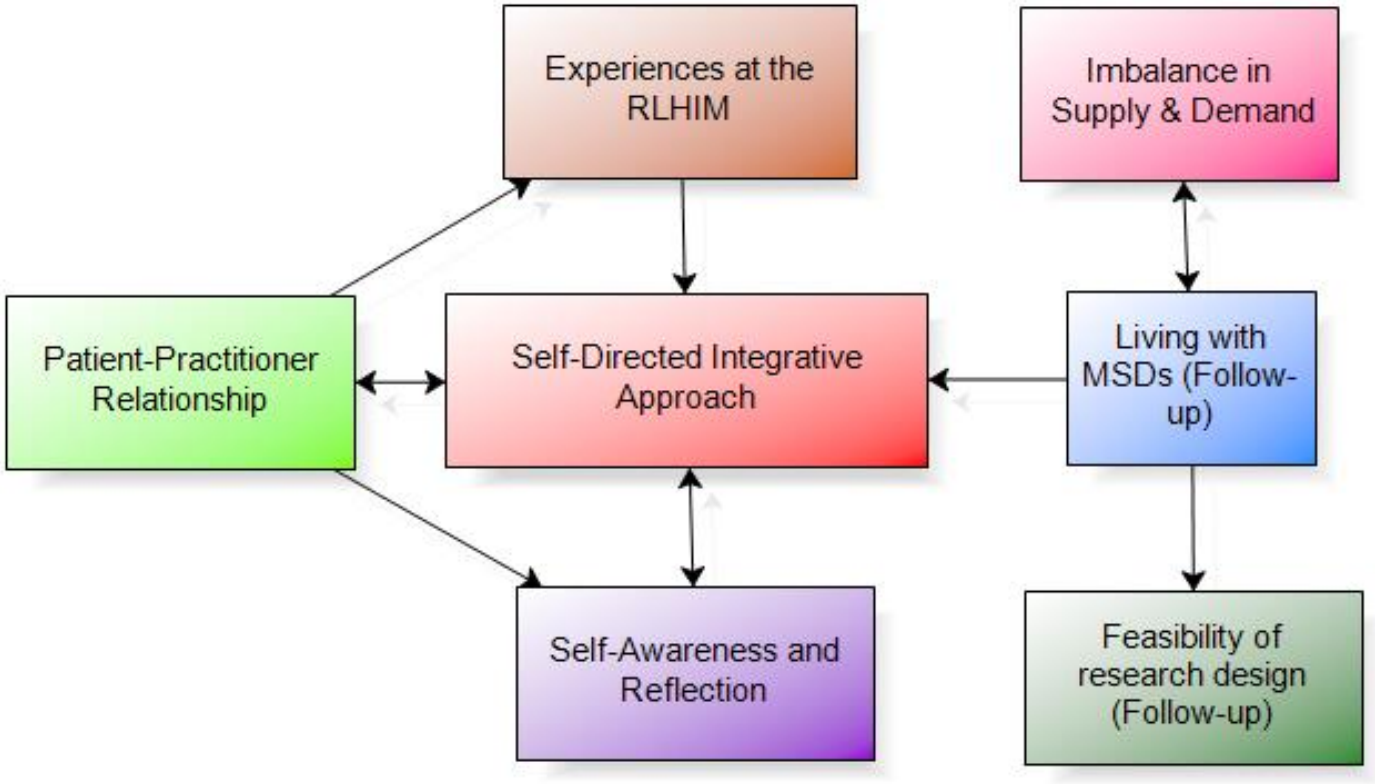
in the introduction of each theme in the subsequent sections. Comparisons and combinations between the pre-and-follow-up interviews are reported at the end of this chapter (Section 5.16). A summary of the findings from the two parts of the qualitative study are presented in section 5.17, with the main findings of patients' decision making, expectation, and experiences presented first, followed by the findings on feasibility in terms of participating in the research study.

Figure 5 1 Connections between categories (Pre-treatment)



'Pre' indicates categories with same titles in follow-up interviews identified from pre-treatment interviews

Figure 5 2 Connections between categories (12 month Follow-up)



'Follow-up' indicates categories with same titles in pre-treatment interviews identified from follow-up interviews

5.1 Baseline characteristics of interview participants

Although initially the plan was to purposively select 30 participants for both pre-treatment and follow-up interviews, ethical approval and recruitment took longer than expected. In addition, insufficient numbers of patients appeared available to attend an interview and for completing questionnaires one and a half hours before their first appointment. Therefore, patients were invited sequentially until 30 were interviewed for the pre-treatment interviews. Similarly, for follow-up interviews, seventeen participants were sequentially interviewed one-to-one; and fourteen were interviewed in four focus groups. Altogether 28 participants were interviewed, as three participants also requested to attend a focus group after being interviewed individually. Five participants who dropped out from the quantitative study were interviewed at the 12 months (Table 4.1).

Among those participants who were interviewed, 19 individuals were interviewed in both pre-treatment and follow-up interviews; and 40 were interviewed in either pre-treatment or at follow-up interviews. In order to check whether participants interviewed in either pre or follow-up interviews were no different to those who were not interviewed, differences in baseline characteristics between those who were interviewed and those who were not interviewed were evaluated. All continuous data are presented as means (standard deviations); and all categorical data are presented as numbers (percentages).

Drinkers were more likely not to have been interviewed than those who were non-drinkers, $x^2(1)=4.660$, $p=0.032$; and mean pain severity as measured by sfBPI (was significantly higher in those who were interviewed), mean difference 1.156 (95% CI, 0.194 to 2.118), $t(58)=2.406$, $p=0.019$. There may be a variety of explanations for this; either because participants who were drinkers were less likely to have healthy lifestyles and may be less open to health advice or face to face communication with

the researcher, or alternatively those participants who were drinkers were more sociable, able to get out more and therefore were less willing to participate in research. This association could have created some bias. There was no difference in other baseline characteristics between interviewed participants and non-interviewees (Table 5.2).

Table 5 2 Comparison of baseline characteristics of interviewed and non-interviewed participants

Baseline characteristics	Interviewed (n=40)	Not interviewed (n=20)	*p*
Age	52.43 (14.489)	51.45 (12.634)	0.799
Female	70.0%	80.0%	0.308
Married/living with partner	45.0%	50.0%	0.463
College/diploma & above	60.0%	75.0%	0.196
Not working/employed part-time due to ill health/retired	67.5%	85.0%	0.127
Professional/technical/skilled job	77.5%	80.0%	0.552
English as 1st language	77.5%	75.0%	0.535
White British/white other	77.5%	65.0%	0.233
Christian	37.5%	60.0%	0.084
Non-smoker	77.5%	75.0%	0.535
Non-drinker	77.5%	50.0%	**0.032***
PEQ RLHIM	7.60 (1.630)	6.80 (1.508)	0.071
PEQ CAM	7.60 (1.766)	6.90 (1.294)	0.121
NEL CCG	42.5%	25.0%	0.149
Received treatment for ⩾12m	52.5%	40.0%	0.262
Multiple treatments	50.0%	25.0%	0.056
VAS	72.63 (18.999)	65.40 (20.080)	0.178
sfBPI Pain Severity	6.72 (1.660)	5.56 (1.935)	**0.019***
sfBPI Pain Interference	6.51 (2.143)	6.09 (2.347)	0.482
SF36 Physical	24.39 (14.288)	29.16 (17.827)	0.267
SF36 Emotional	32.84 (16.801)	40.89 (18.265)	0.095

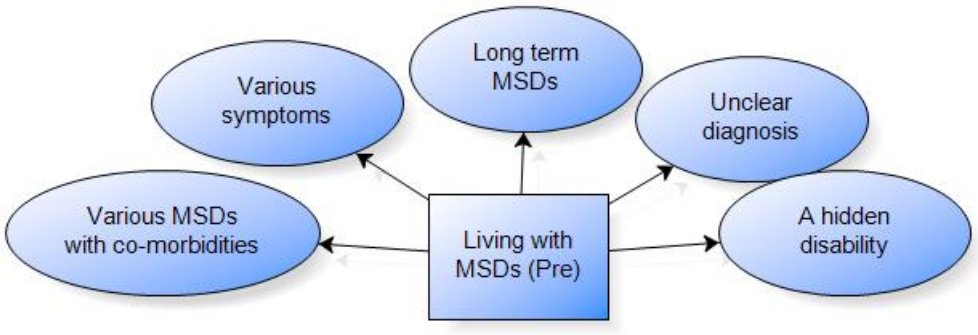
*Bold indicates statistically significant differences between interviewed and not interviewed participants

5.2 Living with musculoskeletal disorders (Pre-treatment)

The theme 'living with MSDs' contains information generated when participants were asked the following question: "Can you tell me about the condition for which you have been referred to the hospital?" Relevant data when answering other questions were also coded under this theme. This section provides an overall picture of how participants perceived living and adapting their life as a result of having an

MSD and other existing conditions. In most of the interviews, participants were keen to share their history, symptoms, the impact on their life, and the strategies they used. This information was offered spontaneously to the research student. Figure 5.3 shows the themes under ***living with MSDs (Pre)*.**

Figure 5 3 Sub-themes under the theme living with MSDs (Pre)



5.2.1 Various musculoskeletal disorders with co-morbidity

All participants shared their MSDs history. Although participants were not purposively sampled, they were relatively representative as their baseline characteristics were similar to those who were not interviewed (Section 5.1, Table 5.2).

Most participants (n=23) had widespread pain over the body, including osteoarthritis (OA) or rheumatoid arthritis (RA) in multiple joints (n=11), fibromyalgia (n=7), scoliosis (2), complex regional pain syndrome (n=1), myalgic encephalopathy (ME) (n=1), and joint hypermobility syndrome (JHS) (n=1). Seven participants had primarily localised pain in their back (n=5), shoulder (n=1), and face (n=1). Most participants' MSD(s) were with varying levels of degeneration (n=23, 77%), some were caused by accidents (n=6, 20%).

Nine participants stated that they had other health issues which were unrelated to MSDs such as headaches and digestion problems, or had 'a lot of things wrong'.

5.2.2 Various symptoms

Apart from one participant who stated having stiffness with no pain, all participants (n=29) expressed varying levels of pain in joints, muscles or ligaments, with 'good days' and 'bad days' and pain fluctuating or appearing unexpectedly.

> *It's got better and then it's got worse. Some days I have good days, some days I don't (11).*
>
> *I mean sometime it's okay you know, it's just, you're aware that it's not as settled as it used to be. Other time it really hurts. Other times it's like there is glass in you, you know, it's changeable (20).*

Participants also reported restriction and limitations in movement caused by stiffness, muscle weakness, or joint degeneration (n=18).

> *For example my wrists are completely melted together. So I cannot move them at all. And I have some limitations on my hips and this also for example if I don't lift it [left leg]… I'm very limited because I have limited movement. My joints don't have the normal range of movement that other people do (19).*
>
> *Stiffness in my neck. Sometimes stiff neck, and interferes daily routine (03).*

Some participants (n=6) reported feeling tired or exhausted because of the pain or feeling uncomfortable, which sometimes resulted in psychological change.

> *I've suffered a lot with the fatigue, and the weakness. But you know, it's like I have pains here, and with headache, joint pain and I'm just, you know, just feeling fatigue. So I haven't got the energy, you know, to go (23).*
>
> *I think it is the exhaustion that perhaps affects me the most. It is such an effort to remain upright and cheerful when the whole of my body is aching really severely with nothing able to relieve the ache. Even if I am perfectly relaxed the pains are very much present (05).*

In two unusual cases, the participants experienced joint dislocation, one of whom also experienced poor proprioception.

5.2.3 Long term musculoskeletal disorders

Most participants (n=25) had at least one MSD for more than two years. They came to the hospital for treatment because they suffered and wanted to find some relief from the symptoms.

> *Because I can have quite a flare up in my symptoms, which I found really really hard to manage by myself… I mean on a daily basis, probably the worst problem, or the things affect me the most now, but, you know, I will suffer quite a lot of kind of acute problems, although it's a chronic condition (10).*

Many participants (n=15) expressed that long term conditions (LTCs) can result in the use of many prescribed medicines and poorer health, which could have been related to the severity of their conditions.

> *Three years is different from having it for 15 years! And there is difference as they [patients who] have been given less medicines. They had less medicine, less drugs, so they are still a bit healthier than me (19).*

5.2.4 Unclear diagnosis

Some participants (n=10) had difficulties getting a diagnosis for their MSDs. They spent a long time, and often trying many kinds of tests before receiving a proper diagnosis. One lady had been actively involved in research studies, trying to identify what condition she had, but was still waiting to get an answer.

> *And he did all sorts of tests. Oh I used to go to conferences and saw lots of consultants from all over the world, and they questioned me, but no one ever sorted anything out. And he thought, in the end, maybe I have some sort of new disease. They thought I might have had Crohn's disease, and then he said we might have a Fabry disease by the end we finished. But they never really got it sorted…. And I was assured, every time, I used to go to [hospital], every 4 months, every 6 months, and I was assured every time I went, they say 'oh it's just it, this is what it is, and just deal with it like that', and they did, and I was assured next time will be the time. And I'm still waiting 43 years, for that, to sort that out (05).*

In one case, the participant suddenly became severely disabled. It was suggested that he either had an acute treatable disease, Lyme disease, or stiff person syndrome (SPS), which currently has no cure.

> *Because my concern is that – what I hope is misdiagnosis. And hopefully, this Lyme disease, which is very different to SPS [stiff person syndrome]. I'm hoping it's a[n insect] bite and it might be Lyme disease. That's what I'm hoping for. Because that is very treatable. If it's this SPS, then I'm not sure about what they can do for me. As far as I see relief in pain - well not pain, discomfort, to relax my muscles (06).*

In another case, the participant was diagnosed as having one condition which was subsequently changed to a different diagnosis.

> *I went to the GP, she said it is carpal tunnel, which is why I went to the orthopaedic. … the consultant, and he said he thought it's complex pain, hmm, and referred me to the other hospital, down the road here. And I went to see the specialist physiotherapy and he said yes, he thought all the symptoms seems to stress that it's complex pain, complex regional pain syndromes (47).*

5.2.5 A hidden disability

A common perception was their condition is a 'hidden disability, as it is not understood or recognised by other people because they 'look very well', their 'grip strength [is] perfectly normal', or they have a 'normal range of movement'. Eight participants experienced difficulties in explaining and proving how they feel, both physically and emotionally.

> *It's kind of mad because if you see me walking around, you'd think "Oh, it doesn't look so bad." But it's -- well, it's the stopping, you know? And I walk for a little bit and then the pain comes on and have a little bit of rest. And then straightaway you get the pain from sitting because I stop at bus shelters or things like that (08).*
>
> *Another thing is – people don't understand you. For example, if you chop off an arm, they see you don't have an arm, it's something obvious. What I've got is not something visible, something obvious. It's difficult for them to understand that THIS ARM DOES NOT MOVE! I cannot lift things, I can't get things from the*

> *shelves because I can't lift my both arms, I can't take it just with one. And it's just hmm, very difficult. Because they say, 'you look so healthy!' [laugh] (19).*

An example was given by a lady with JHS where she was abused/challenged while on public transport. Because JHS is not widely understood by the public, she did not expect everyone to understand her condition, but wished she could 'let others know how you feel'.

> *When I asked to sit down [on the London underground], a lot of people would be quite abusive, verbally aggressive. And I will get challenged, and get told 'I look fine, they had a hard day at work', or 'about to have a hard day at work', what's wrong with me. Hmm, if I tell them [that I have JHS] and they ask for evidence…. And, I think, just in general level, I think some people think I'm being kind of precious about myself, they think you're kind of asking special favours, because they can't see anything wrong, hmmm… I don't even think that it's just lack of understanding. I don't expect every person in the street to understand about hypermobility (10).*

Inadequate awareness at work or by the public was reported by five participants.

> *In theory, your employer is supposed to let you move. But in practice this didn't happen… Actually I have to struggle [to get support]. I asked them to get me an ergonomic mouse, to support my wrist. And it took months and months, and my boss never bought it. So I ended up buying it for myself. So it's, it's, in theory, they SHOULD because this, hmm, I even spoke with this person who is responsible for the workers, you know, for the wellbeing of the workers… Those are the things make big difference for me (19).*

Summary of living with MSDs (Pre)

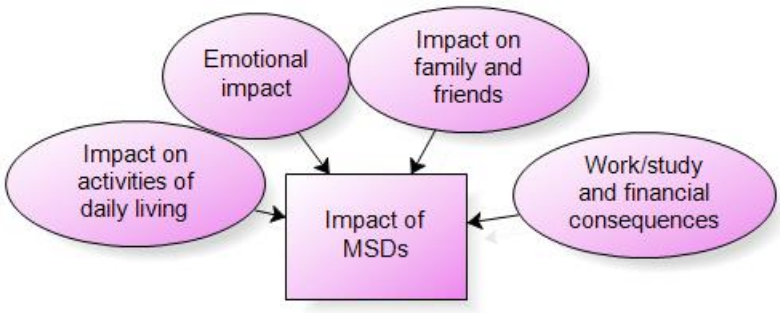
- Participants had a variety of MSDs with most of them having widespread pain all over their body caused by degeneration, with additional other non-MSD health issues;
- Participants experienced various physical and emotional symptoms including fluctuating pain, stiffness and restrictions in movement, fatigue and exhaustion;

- Participants suffering from chronic MSDs was described as being associated with polypharmacy and poor health;
- Some participants had an unclear or a changing MSD diagnosis ;
- Participants felt MSDs were often hidden disabilities as they 'looked normal', or had difficulties explaining how they felt. They felt there was a lack of public awareness about their disability.

5.3 Impact of musculoskeletal disorders (Pre-treatment)

Information generated when asking participants the following question: "How does your condition affect your daily life?" explored the impact of MSDs. Participants reported that MSDs affected their life in various ways, including their activities of daily living, emotional impact, impact on relationships with their families and friends, and impact on their work and study which also impacted on their cost of living. This was closely associated with the theme living with MSDs (Pre) (Section 5.2) as MSD symptoms affected quality of life; and was associated with physical, emotional, work or income. Figure 5.4 shows themes under ***impact of MSDs***.

Figure 5 4 Sub-themes under the theme 'impact of MSDs'



5.3.1 Impact on activities of daily living

All participants reported that their MSDs in some way affected various aspects of daily life, from simple tasks like running a bath, completing housework, to major choices like not having a baby. Participants felt they achieved less than

they wanted to; or reported they used to be very active and now had to compromise their activities, subsequently lowering their quality of life. *It's all simple things like eating, talking, these little things are much more difficult. … And simple things like jumping into the van, going down to the coast, being by the sea for a few days. It's simple pleasure. But now, none of those is possible (06).*

It's not easy, you know, hoovering, or even washing up because if I stand still for too long, I have to take the pressure off one leg, so. I'm used to it. I make allowances now but it's still not normal… If I didn't have this pain and there're a lot of things I'd love to do, you know (38).

I've just had a wet room [installed] so I can shower myself now, but up until then, he'll [46's husband] have to wash me. Do you know what that's like? I'll be down in the bathroom to wash myself and have your independence. And that had – that was going on for probably about two years. It's had a big effect (46).

But it's actually diminishing the quality of many people's life really severely. But that doesn't seem to count. Well I'm getting in the late in my age - it's too late for kids, but I wouldn't really want it [JHS] on them… It's ruined my life, it really has, it makes thing incredibly tough (10).

Thirteen participants reported difficulties in sleeping because of the pain.

I can't sleep even when I take a sleeping tablet. I took one last night. I only got four hours of sleep. I used the hammer one day and next thing I hurt my arm, I couldn't sleep, I couldn't move and I can't pick nothing up in the morning. … You know, basically when you knock yourself out and then you have a few beers, you know you're comatose, you'll be zonked out. You know in that way you can get some sleep (08).

5.3.2 Emotional impact

Almost every participant (n=29) described the psychological effects of their MSD such as being frustrated, upset, anxious, sad, angry, or depressed. These emotional changes were perceived as being linked with each other.

Frustration was the most common emotional response reported by the participants (n=19). These emotional responses emerged when patients experienced restrictions and limitations due to their MSDs as they were less able to achieve things, or when they were tired of explaining their conditions to friends or families.

> *You feel very frustrated, you know, very alone, and it can actually cos you mental disturbances which can make your condition even worse… At the moment, I'm actually hmm, because I isolated myself a lot. So at the moment, I'm in, hmm, in an institution or whatever you call it, where people are helping me to deal with these problems, emotional problems. But I still believe that everything is linked (43).*

> *I'm in pain, yeah. Yet, I want to cook. That's my job. I've done it for so many years, 40 years. You're not doing it right. I get frustrated, you know… And then, you lose things in my kitchen because he [046's husband] needs to move them, and I get angry. It's MY kitchen. Do you understand? (46).*

> *So yeah, it's frustrating, because it's, you know, people said 'what's wrong with you?', and I said, and then I go 'okay'. I just thought I was going crazy, you know. I thought perhaps it is in my head. Perhaps I am making it up [laugh] (47).*

Stress and anxiety particularly developed when patients felt they were isolated especially from their social contacts (n=11).

> *When I came out from the hospital, obviously it's a big drop. It's not so scary from hospital to get back home. But to not be well, and to not be looking like I'm going to get better, there's only way that I can get worse. Suddenly I become independent. That's huge.. …But when you are on your own, sadness comes back, that's all what you can do (06).*

Participants got emotional and sometimes depressed because of their difficult life with MSDs (n=11). This may be because their MSDs evoked a mixture of different emotional reactions so that they were not able to cope with.

> *When you're not able to do the simplest of tasks, it gets you down. And you feel you cannot enjoy your life anymore because you're stuck inside and not being able to live a life as normal as you'd like to be. So, it does get you very depressed. The brain sometimes takes over everything. It doesn't allow you to be the person you are (15).*

> *I was a bit desperate, so the physical took over the emotional. So I was feeling very low and very depressed (43).*

In rare cases, fear (n=3) and anger (n=2) not necessarily directly due to their MSDs were less frequently expressed as an emotion, usually as a response to challenge.

> *I can tell you I'm petrified to be in a car, petrified. I have a car, but I wouldn't drive in London, and I won't drive more than 2 miles down the road. I'm petrified. I'm shaking all the time. If a car gets too close to the back of me, I'm in a very bad state mentally, I mean just absolutely traumatised me the car because if anyone hits me again, what would happen next? What damage would happen? It changed my life there in the car…. I'm strong in mind until the pain gets to the point where I just want to look at him [046's husband] and say "put a knife to my head just get rid of the pain". When the pain gets to that 10 plus, they always say, "What's your pain level, 1 to 10?" I've gone about in the 20s now. Now, I get a gun and pull ahead because there's nothing to stop the pain. I guess that's how it affected my life (46).*

> *But what I do resent is being quizzed and challenged about having a health issue if I asked to sit down in the tube, and so it could be really personal upsetting, and it can make me quite angry at times (10).*

One participant refused to talk about the emotional impact of MSD.

> *Don't ask me that time. I don't want to go that far, but it did affect me a lot. I really do have a hard time. I don't even want to talk about it. It was a hard time for me to go through, my health and my relationship. I don't want to hurt my children either, but there was only me for them. It was a hard time, anyway (33).*

5.3.3 Impact on family and friends

Most participants (n=26) reported their MSDs had affected their relationship with friends or family. This was caused by various reasons, both physically when patients were unable to go out to meet people or because they were too tired to communicate, and mentally when they were dealing/coping with so much pain that they had no energy left to talk to others or were unable to concentrate on conversations.

> *When I got the pain, I don't go out. I CAN'T, because I'll be all over the place, you know, wondering what I was doing [laugh]. I don't sort of, umm, now and again I can get uptight with people when I'm out shopping and someone stands in me way and I wanna do it quickly, you know. It aggravates me to get home because; the sooner I get home the better. But if I'm okay, I'll stay out all day. I would. … And you are just not interested in, you're not listening what they [friends] say, and you're answering wrong (20).*

> *I've noticed I've fallen out of touch, or not in touch with friends as much as I previously was, and that needs to change, but, you know, it's harder when I'm*

> *trying to work full-time. So, when I'm done with my day at work, I'm not always feeling like I would be able to, say, get in the train to central London to see some friends for a few hours and then come home. I feel like I need to, kind of, go home, and I'm working home a lot now, and so, I don't have that interaction as much. …You'll feel that you don't want to keep talking about it with your family and friends because you always - it's kind of a constant state (39).*

Some participants (n=7) explained that when they were in pain, their relationship with friends, partner, or family was affected as it affected their mood.

> *You know, I'd scream at him [her husband]. It's affected obviously our marriage in that sense, although we've got a long marriage. We're old. He's not going to leave me. No way. We've been married too long, but it's still not nice to him, so it's affected him very badly, the way I treat him. I can't be helpful. I can't do all the things that a woman does (46,).*

> *I had the closest relationship, and romantic or sexual and loving relationship or intimate relationship, because I think the role is getting confused, you know, are you partners or are you caring and carer for, and I think, you know, that's not a very good role to bring in, and I certainly think it caused a lot complications to my current relationship (10).*

In a rare case, one participant stated they had an unsupportive family, which made her life even harder. A second participant stated that she would only like to talk with people who have the same experiences.

> *If you haven't got a supportive daughter, you haven't got a supportive husband, or, you know, then – and he is quite violent, on and off, you know, and hmm, it's like walking on egg shells, you know (54).*

> *A lot of people I don't speak to anymore, but the ones that are obviously my real friends and – and, I know it's not lucky, but it is unlucky for her, but we've got -- one of my friends has got the same condition. She's had it a lot longer than me. It was her that actually said that, "You know I think that you might have this," you know? So she helps. She helps because she does the same. She doesn't want to go out. She can't be bothered it. So we sort of -- you know, we sort of cheer each other up to go out (36).*

5.3.4 Work/study and financial consequences

Most participants (n=24) reported that their MSDs affected their ability to work. Some participants (n=13) were working part time because of ill health, or working full time but struggling with the available facilities or work environment.

> *It's like desk based, having to be sitting constantly, in the same position, for example, this is the right shoulder, and there are some connection between me standing there and doing the mouse, with my hands afterwards (19).*

Among these participants, some reported (n=11) not working due to ill health. They felt it was vitally important to be able to work as it provides meaning and structure to their life, which produces feelings of achievement.

> *It would be good to get back to some kind of job. That's what I'm trying to do in my life, to work really. …. So structure is always providing by work. I'm thinking to interact with other people would be good (06).*

Some reported a lack of interaction with colleagues (n=5), which may be due to having unexpected pain during working hours. This affected their work efficiency as well as their communication with colleagues.

> *I mean, I was working in Switzerland in March, and after the day of work, the restaurant was like 15 minutes' walk. But I couldn't go, because I couldn't walk. So, you know, that was fine. I just sat in the bar, had a bar meal. But it affects … because when you are doing that, you are meeting people and it's networking. So it does actually affect the work because that's how you find out what's going on, and what happened. So everybody thinks that you're just having a nice meal but actually you're still working in reality, but in fact I end up sitting on my own in the bar because no way I could walk for 15 minutes (20).*

Participants explained that it is a vicious circle as patients with MSDs could not work due to their pain, and thus could not afford treatment to improve their conditions. Five participants reported that MSDs affected their income, which affected their quality of life and the availability of being able to afford CAM treatment privately.

My wife and I lost our whole wage. It gets difficult, in a very basic boring way. But it's still reality (06,).

I'm not sure if they have any idea of what it's like trying to survive on an incredibly low income when you're ill and disabled (10).I used to earn a thousand, two thousand pounds a week. Life was a dream, and you have an accident, and then you argue over money with your wife and your kids because they want stuff and you can't afford stuff. … I just had to cut out a lot what I used to do. I used to travel a lot; I used to go out a lot. Now I don't go out at all; I don't drink anymore; I don't smoke anymore. These are not health things but, that's part of socialising in this country. Nothing [long silence] (11).

There were participants (n=2) who felt that their career progression and ambitions regarding work had been compromised by MSDs in what they could achieve.

I was quite ambitious. I was so high achieving. I worked long hours, you know, I was planning on being much more advanced in my career than I am now. But because I was set back so hard, and how I struggled doing a day at work and concentrating on my work because I can't… If I have two more days off work in the next six months or so, then I get disciplinary problem, you know, and eventually if I keep having to take a bit of time off, which is what has been happening periodically, I have to take a little bit of time off, then I'll get into trouble and it can lead much over that, that's kind of a main, the main reason for trying to sort things out really (39).

So it certainly had affected my work. Because I can't do – I was sort of progressing in my career, and I have to kind of pull back, and get rid of all of that, and just be a teacher. I'm hoping that I'm doing a good job. Hmm, sometimes I'm incredibly tired, and then, it's hard. But I am really trying hard, you know, that it doesn't affect my work. So, I just have to see how it goes really. We can't really afford me to go part time, at the moment [laugh]. … I've given up all responsibility at work. So I was a deputy head. So I've given up, I'm literally a teacher, given up everything that I could (47).

Summary of impact of MSDs (Pre)

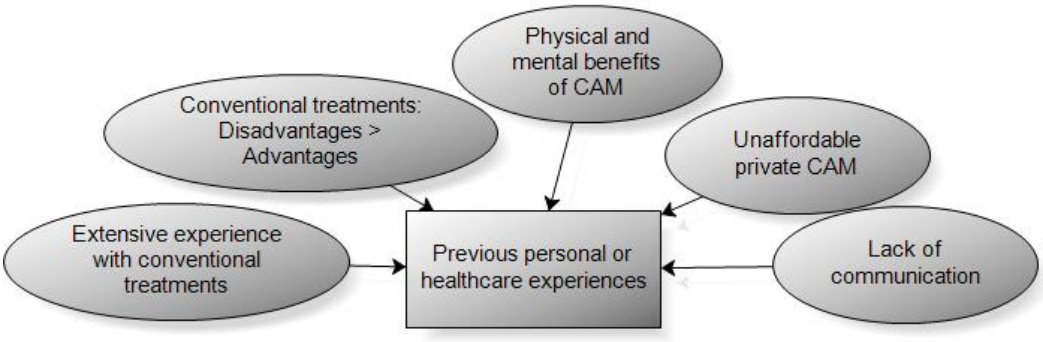
- MSDs affected a wide range of physical aspects of life and quality of life, and interfered with sleep;
- The psychological impact of MSDs included feelings of being frustrated, stressed, anxious, sad, angry, depressed and fearful;

- MSDs affected participants' relationships with their friends and family, both physically and mentally;
- MSDs affected participants' ability to work and work efficiently; being able to work was considered vitally important as it provided a meaning and structure to their life, which produced feelings of achievement;
- Being unable to work caused financial insecurity and ability to pay, which affected participants' quality of life.

5.4 Previous personal or healthcare experiences

The theme 'previous personal or healthcare experiences' contains information generated from the following question: "What treatments have you used to try to improve your condition?" Relevant data when answering other questions were also coded under this theme. This theme contains two parts: the first part (Sections 5.4.1 & 5.4.2) presents participants' previous experiences with conventional treatments; the second part (Sections 5.4.3 – 5.4.5) presents participants' previous experiences of CAM. At the end of this section, a lack of communication with healthcare providers is discussed (Section 5.4.6). This theme is closely associated with participants' MSDs as all their experiences were around finding appropriate treatments for their MSD. Figure 5.5 shows sub-themes under the theme ***previous personal or healthcare experiences***.

Figure 5 5 Sub-themes under the theme 'previous personal or healthcare experiences'



5.4.1 Extensive experience with conventional treatments

Most participants (n=22) had extensive experience of and had used several types of conventional treatments either in the past or currently. Oral pain killers (n=21) included: 1). non-steroidal anti-inflammatory drugs (NSAIDS) (n=13): ibuprofen, naproxen; 2). (Semi-synthetic) opioids (n=8): codeine, oxycodone, hydrocodone, morphy, oxycontin; 3). Anti-depressants (n=7): nortriptyline, amitriptyline; 4) paracetamol and compound analgesics (n=2): co-codamol, Co-proxamol. Other forms of medications included steroid injection (n=8), pain plasters/cream/patches/gel (n=7).

Although only two participants specifically stated that they took more than six types of medications, which is commonly defined as polypharmacy (Fialova Daniela *et al.*, 2005), many participants (n=13) had two or more medications for treating the same MSD. The definition of polypharmacy is complex and individualised, and prescribing may involve; duplication of medication, drug/drug interactions, possible side effects/toxicity signs, and two or more medications to treat the same condition (Bushardt *et al.*, 2008).

Physiotherapy was the second most common treatment reported by participants (n=18). This included exercises, hydrotherapy, and some manipulation. Six participants had previously had psychological treatments including: diazepam, psychologist consultation, counsellor consultation; eye movement desensitization and reprocessing (EMDR), cognitive behavioural therapy (CBT), and mirror therapy. Four participants had taken supplements, including vitamin D, vitamin B12, vitamin D, vitamin B compound, vitamin C, zinc, and folic acid. Immunomodulating drugs (antimalarials and steroid treatment for rheumatoid conditions, methotrexate) were stated by three participants who were referred for rheumatoid conditions. Three had experiences of a pain management clinic. Other participants received metabolic

treatment, arthroscopy for knee, laminectomy, plasma exchange, and plastic surgery (all single cases).

A few participants who had other health issues stated they were having conventional treatments for their underlying circulatory system diseases (blood pressure tablets, defibrillator), or diabetes (medications) (n=4).

5.4.2 Conventional treatments: Disadvantages more than advantages

Although many participants (n=16) had previously benefited from various conventional treatments, including medications (n=11), injections (n=4), hydrotherapy/swimming (n=3), physiotherapy (n=3), and surgery (n=1), a lot of them felt they were associated with side effects, or the effects did not last long.

Fourteen participants (88%) stated that they were trying to avoid medications or (frequent) injections as they believed that these were closely linked to side effects. They 'numb your brain', 'make you drowsy/dizzy', 'destroy your stomach, guts, busted the intestines', 'weight gain', 'antibiotic allergy', or lead to medication resistance or kidney/liver problems, especially when taking for long period of time.

> *I think I've been dependent on tramadol for so long. I found it hard to wean off - made me shaky and cold… My liver, I think, has been affected due to the long term that I have been taking the medications (15).*
>
> *It [anti-malarial] has basically helps or not helps basically it lets me lose quite a lot of weight, stomach cramps, vomit, nausea, headaches (23).*
>
> *Conventional medicine has always kept the symptoms largely at bay, and the side effects are horrendous (21).*
>
> *It [anti-depressant]can make you drowsy and you need it all the time, you know you take it and then your body gets used to it and then you take tablets, and anti-depressants are not very healthy (12).*
>
> *I'm going to have to ask my husband to tell you exactly because my memory with the tablets and everything isn't very good… My kidneys and my liver, they did nearly fail Christmas before last because of all the medications (46).*

> *Especially since I started taking my pills, I'm much more sensitive with it than I was before, and my girlfriend used to hate it when I was out of things in the evening, you know. She would be able to tell I wasn't there (39).*

This is particularly obvious when participants had co-morbidities and were taking many medications for their health issues at the same time (n=3).

> *So all these [medications] work, but it feels false, feels not good for you. It's not good for you especially for a long period of time… These are serious anti-depressants I suppose. There're several different varieties of problems around me, some with stroke, some with diabetes, and with complications. So it's worst with these complications. So I don't have the habits, with drinking habits etc. It's a combination of life issues and people doing what they could fit in (06).*

Apart from three participants who found physiotherapy helped in strengthening muscles or helped in "realising postures", 10 out of 13 participants found no benefit from physiotherapy or even made pain worse, especially with the non-guided physiotherapy (when only one instruction was given, then patient left to practice himself at home) as the participant was not sure if he had done it properly.

> *I went to physio and it was rubbish, a lot of rubbish and they didn't know…They gave me exercises and then I went back next time they said, "You're doing too many exercises." And I said, "But last time, you said I wasn't doing enough, and now I'm doing too much." And then again we less and you know -- and anyway. And so, they didn't ask me to go back so I felt good because it was like a waste, a waste of time (08).*

Four participants, who stated injections were helpful, all felt it was excellent in relieving pain. Injections helped them for different lengths of time ranging from 5 weeks to one year. However, they all reported that after a while the injection started to wear off.

5.4.3 Physical and mental benefits of CAM

Thirteen participants had no previous experience of CAM therapies before their RLHIM appointments, for those who had previously experienced CAM, 12

participants (71%) experienced CAM in a private setting, 11 (65%) received CAM treatment previously in an NHS setting, and four participants received both. Acupuncture and massage were the most commonly received CAM therapies reported by participants.

Acupuncture was the most popular or valued treatment stated by the participants who experienced benefits of using it. Of the 15 participants who had previously received acupuncture for their MSD, 13 (88%) perceived acupuncture to have been beneficial. Other helpful CAM treatments which participants reported were Pilates, osteopathy, massage, herbal medicine, Alexander technique, reflexology, and tuina. Acupuncture (n=11/15, 73%), Pilates (n=3/4), and homeopathy (n=2/17) helped in reducing pain; acupuncture (n=5/15) and osteopathy (n=2/4) helped in improving movement; Pilates helped to strengthen muscles (n=3/4) while acupuncture was reported in "softening the muscle" (n=1/15); and one (out of three) participants felt reflexology had helped with sleep and appetite. Three out of 15 participants also reported that acupuncture helped in reducing the conventional medications, and one participant found acupuncture especially helped during winter.

> *But with the acupuncture, they tend to soften it [the pain] a little bit… Acupuncture will cut that pain down quite well. It won't get off it [pain] altogether. But it makes it a lot more manageable (11).*

> *I just started Pilates as well. I've only done one Pilates session and I want to continue, because that makes your tummy strong, but in a gentle way. It's quite kind to your back, you know… I know some Pilates moves like turning in chairs just slowly and just breathing, and that's helped me as well (38).*

In terms of mental health, participants reported benefits from acupuncture (n=4/15), mindful breathing (n=1/2), yoga (n=1/3), and massage (n=1/6) made them feel relaxed or helped with fatigue. One participant felt tai chi made her more aware.

> *It [auricular acupuncture] just makes you feel good in yourself in the world (06).*

Five participants reported benefits of receiving integrative treatment packages in pain management courses, and acupuncture in addition to aqua fit or other exercises.

> *I'm seen by the doctor plus the dietician, physio, and everything - acupuncture. It's more than I was expecting and it helped me a lot. I mean I'm really happy…Like I said, everything is helped, not only with one thing. Everything is helped… plus talking to them as well, they help further (33).*

However, in a few cases, participants reported that CAM helped, but the effects tended to wear off (acupuncture n=3, Pilates n=1).

5.4.4 Unaffordable private CAM

Many (n=12) believed that private CAM clinics were too expensive and that they could not afford them.

> *For me, personally, I believe they helped me a lot. It's just the fact if I'm not working, I cannot afford to do it privately (23).*
>
> *How can you afford alternative therapy? You can't really. It's only if you're lucky (38).*
>
> *That was the most expensive thing I've done because the sessions were so long… It was £90 to £100 each, so I did about three. … Basically, in the first year, I was doing mixtures of those [NHS and private acupuncture], but it was too expensive to carry on doing it (39).*

Among those participants who felt that private CAM clinics were unaffordable, three reported this was due to their lack of ability to work as a result of their MSDs.

> *So if I wanted to do stuff like that [acupuncture], I have to be privately funded, which, when I only get disability money, it's just not, it's not physically possible to afford things like that (40).*

Some participants (n=4) who reported benefit from CAM by receiving treatment within the NHS argued that they needed to finance further private treatments themselves after they had finished a course of NHS CAM, which was a burden for them.

> *Because in that [hospital], the physiotherapist there does six sessions of acupuncture, and it helped me a lot, it did. And they said to me that 'you can have it regular', but I couldn't afford to pay (03).*

5.4.5 Lack of communication

Four participants thought there was insufficient communication or explanation from the practitioners they had seen previously outside the RLHIM. Two stated that medications were always the first option GPs considered for pain under any circumstances; one participant stated that limited time was given in consultations.

> *If I see my GP, they give me medicine, see me in five minutes, and give me the medicine, and that's it (33).*

More details on participants' communication with their GPs regarding their RLHIM referral are discussed in 5.6.4.

Summary of previous personal or healthcare experiences

- Participants tried various types of conventional treatments, including various painkillers, and multiple medication use, physiotherapy, psychological treatment, supplements, and pain management. Some of them were taking additional conventional treatments for other health issues;
- More disadvantages than advantages were identified by participants who took conventional treatments, particularly medications and injections, which were believed to be closely associated with various side effects, especially in the long term. These side effects have made their health worse, especially when they had other co-morbidities and polypharmacy. Most participants stated physiotherapy was not helpful; injection was helpful but effects were not sustained;
- Nearly half of participants had no previous experience of CAM. For those who did, acupuncture and massage were the most common received CAM treatment in participants' previous experiences;

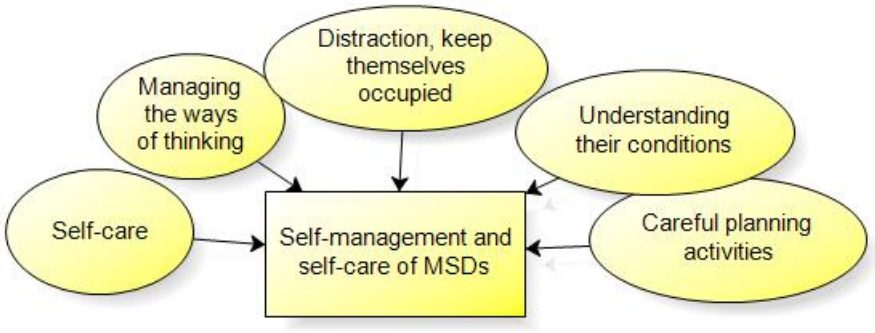
- Participants who had used CAM treatments previously experienced physical benefits in reducing pain, improving movement, strengthening or softening muscles, and improving sleep and appetite; and mental benefits in relaxing and fatigue, and being self-aware. Another benefit reported was reducing medications taken. Integrative packages of treatments were perceived beneficial for some participants. A few participants reported these benefits tended to wear off;
- Participants reported private CAM clinics were unaffordable, particularly given participants were exacerbated by a lack of ability to work due to their MSDs. Some participants, who had previously had CAM via the NHS, had to go privately after several treatments, and typically found this an economic burden;
- Negative experiences of CAM included perceived lack of effect, make pain worse, and restrictions in movement during the treatment;
- A small amount of participants felt there was a lack of communication with practitioners about their previous experiences.

5.5 Self-management and self-care of musculoskeletal disorders

This section contains information mainly generated when asking participants the following question: "What self -help measures have you used to try to improve your condition?" Participants touched on relevant data when answering other questions and these were also coded within sub-themes under this theme. Participants reported various strategies to cope or to treat themselves. These included self-care strategies for their MSDs, managing their thinking about their MSDs, and making changes in their lifestyles to adapt. Sub-themes under this theme are closely linked to participants' MSDs and their previous personal or healthcare experiences (Sections

5.2-5.4). Figure 5.6 shows the sub-themes under ***self-management and self-care of MSDs***.

Figure 5 6 Sub-themes under the theme 'self-management and self-care of MSDs'



5.5.1 Self-care

Half of participants (n=15) reported they used self-treatments at home, to help manage their MSDs. Similarly half (n=14) experienced benefits from doing physical exercises. The intensity of exercises depended on their conditions. Participants in comparably better health were able to do more exercises and more likely to benefit. Reported exercises included: walking, dancing, stretches and strengthening exercises, deep breathing, tai chi and Qigong, yoga, swimming (and aqua fit), use of a Wobble board, and Pilates.

> *I'm trying to do the exercises that I got from that course [pain management course] most days. I'm at least doing the warm-up and these exercises. I'm mainly trying to do all the stretches and the strengthening exercise as well. … I think, I mean, all the pain management making the change yourself and doing the exercises and modifying your lifestyle, but I don't know. Just look at the problem from a different direction, and I thought that was a good thing (39).*
>
> *It's [tai chi] very gentle stretches and you know, all the time, his voice was saying 'think about your breathing', you know, are you sort of going like this and on his phone he recorded himself going through the breathing technique. So any time I can, just plug into my phone, just listen, and relax (47).*
>
> *I think there were six sections [of pain management, including exercise, mindful breathing, understanding of the pain] to start with, and that was really really helpful because they explained, you know, how to sort of rearrange your life*

really, to trying cope with this ongoing pain... We did exercises, hmm, so mindful exercises, you know, all the time, kind of thinking, 'how's that feel, how's my breathing'. We did mindful breathing... And he actually managed to make us a DVD with exercises on, so we can do [at home] (47).

Well, it's [physiotherapy] brilliant. You sort of inflate it yourself, this thing [wobble board], and lift your legs a little all over the place, and of course, it makes you keep still to keep your balance. You know you're doing all the exercises without realising, because you've got to sit like that. So I went and bought one [Wobble board]. We looked at it and she told me what to do and I've been doing that regularly. And to me, that's doing something (31).

During the interviews, two participants reported benefits in having healthy diet (one was in a macrobiotics programme). However, it may be the case that some participants felt they already had a healthy diet so felt no need to change it or to mention it as this was not asked in interview.

5.5.2 Managing the ways of thinking

Some participants (n=9) recognised that part of the progression of MSD symptoms is also part of their life. They tried to be positive and cheerful, to carry on with daily life.

When I said about my life, I don't mean I'm giving up. What I mean is, I was married, I had my son, I looked after my mom when she was ill, and I looked after my brother when he was ill, and now it was my time of life (02).

I've learned now, you know, as the years going back, that you have to be positive and stay optimistic because if you don't maybe take control over the situation, the actual disease will take control of your life and then you will be very sad (23).

I just -- a part of the depression was -- with me, was though I couldn't accept that I couldn't do what I used to do. But now, I just -- I don't put pressure on myself now. I just get up and I have breakfast and I have a coffee you know, and then I'll think, "Well yeah, I can do that today." And I don't force myself to do anything because when I force myself to do anything, it sets off my anxiety which stresses me out and makes me ill, like my stomach starts to play up then (36).

5.5.3 Distraction, keep themselves occupied

Eight participants were actively involved in various activities as it helped distracting them from their MSDs and keeping them occupied. These activities included: reading and studying, knitting, arts and crafts, jigsaws, gardening, having 'chill' time (watching a film, having a bath), going shopping, and joining different clubs (reading, language, rugby).

> *I keep myself busy at all times, either mentally or physically, doing a variety of things, but I am spending more and more time reading. I don't feel I can do more to distract myself. … When it became obvious that I was not going to be able to return to nursing I decided I had to keep my brain active so I enrolled at my local college for Spanish classes. I have gone on from there to learn French, German and Russian, plus a year of Greek and Latin (05).*

> *When I'm doing something, reading, I can't read, that's the problem, cos when you are reading, you're conscious of your pain as well. Because when I'm active and you are doing things, your mind is completely different and you're moving. When you are stationary, and you read, suddenly, you feel 'oh dear!' You know what I mean? When you've done what you're doing, physically, and you're concentrating on that. When you do eventually stop, you thought 'oh it hurts!' But it didn't hurt at first. So you just, rest a bit, and then carry on (09).*

5.5.4 Understanding their conditions

A few participants (n=6) were trying to keep updated with information about their conditions. They felt that being knowledgeable could help them understand the condition, explain their symptoms, and identify possible treatments and how they might work.

> *I do reading to understand what would benefit me. So, like things like reflexology and acupuncture I like to do a lot of self-knowledge. So it's not, it's not, you know, only maybe the hospitals and GPs that … told you what to do. Maybe you … also need to understand yourself (23).*

5.5.5 Careful planning of activities

Some participants (n=5) reported that since having MSDs, they have had to carefully plan their activities, schedule or arrange how they do things to adapt to their MSDs.

> *My strategy for coping has always been to plan each day well ahead of time and then no matter how I feel, I do what I have decided for that day. I never ask myself how I'm feeling today (05).*
>
> *If I'm running a bath, you know I have to lean on the bath. If I put some trousers on, pick up one leg but I can't pick up the other. You know everything I do, it affects it. It isn't the same. It absolutely affects everything (38).*
>
> *I'm very conscious that I need to try and better plan out and manage what I do and, you know, things like carrying shopping bags from the supermarket is not a good idea. You know, …[I] break up my shopping into smaller ones, going with my girlfriend or friend (39).*

In one case, a participant stated having MSDs affected her decision making and the choices she made in her daily life.

> *Hmm, so I sort of, have to make new decisions. To start, I need to make new decisions, you know, when I had this pain, it was fatigue, I was really tired. I couldn't, I couldn't, I didn't go out. I couldn't drive, you know. It took a while for me, just to sort of, build up, gradually (47).*

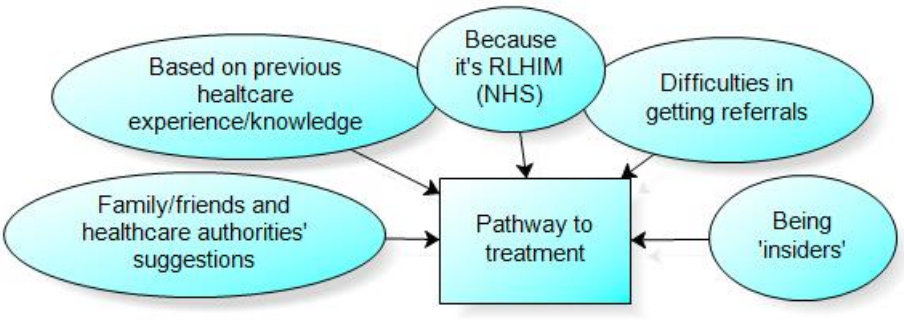
Summary of self-management and self-care of MSDs

- Self-care of MSDs included various types of conventional physical exercises such as walking and stretches, and CAM exercises such as Tai chi, yoga, and Pilates; and healthy diet;
- Self-management strategies included distraction from their MSDs, self-learning and understanding the MSDs, and carefully planning daily activities to suit their life with MSDs.

5.6 Pathway to treatment

The theme 'pathway to treatment' contains information generated when asking participants the following question: "Can you tell me how you came to be referred to the Royal London Hospital for Integrated Medicine?" Participants who touched on relevant data when answering other questions were also coded within sub-themes under this theme. This theme contains two sections: the first section (5.6.1 – 5.6.3) presents participants' decision making process of coming to the RLHIM, which is closely linked with participants' previous personal or healthcare experiences; the second section (5.6.4 & 5.6.5) presents participants' experiences in getting access to the treatment at the RLHIM. Figure 5.7 shows sub-themes under the theme ***pathway to treatment***.

Figure 5 7 Sub-themes under the theme 'pathway to treatment'



5.6.1 Family/friends and healthcare authorities' suggestions

Many participants (n=10) decided to try CAM therapies as their friends or families had previously benefited from these therapies.

> *My wife totally agrees with acupuncture and what most people class as witchcraft we class as normal healing like herbal medicine, and stuff because they all work. We know they work. What's that, what they call it? Homeopathy! Yes. My wife went and had a course of it (11).*

Or they were recommended by their GPs or consultants (n=4).

> *I've had injections, and he [GP] said he's been trying to help me get acupuncture, as it goes between, to trying help with, in between when I get the pain, cos I don't want too many injections. I think twice a year is quite enough (02).*

> *My doctor, Dr [GP], believes in it [acupuncture]. He's actually trained in acupuncture. So he said 'you get as many as you can, if it can get you back on your feet' (11).*

5.6.2 Based on previous healthcare experiences or knowledge

Some participants (n=8) had tried many different types of treatment but found nothing helped, so they were open minded to try any available therapies for their MSD.

> *I think if you get to the stage where I am, that all these conventional therapies couldn't help you at all, then you'll try whatever comes along (05).*

> *For patients who have a problem like I have, in short periods you're using these medicines [conventional medications]… Because I've had it for 15 years, and I destroyed myself with medicines. Maybe it would work much better for me if I used nature medicine, for me to recover, for me to have any benefit. I want to try it. I don't mind if I don't see any benefit. I wish I could get rid of all these [conventional] medicines… I have beliefs in nutrition (19).*

> *It was because nothing had worked so maybe taking another route would be better (32).*

> *I've seen, you know, even it's only just TINY TINY benefit, I've seen the benefit for it [acupuncture] so, you know, I'm quite open. I'll give anything a go (40).*

Participants' personal interests may also influence their decision making in using CAM: two participants worked in the CAM field (one studied homeopathy, the other was a Reiki healer); and one participant was fascinated about the use of herbs since the 13th century and were having beliefs in them.

5.6.3 Because it is Royal London Hospital for Integrated Medicine (NHS)

When asking participants why they were referred to the RLHIM, some participants (n=6) expressed the feeling that they trusted RLHIM and believed that the healthcare

professionals at the RLHIM are well qualified and knowledgeable in the field, and would provide a high level, professional job.

> *They're all doctors and they know what they are doing. I know in the private clinics, basically as long as someone has the ability to practice, no matter qualified or whatever, you can take a separate course in it, and still practise it, so yeah. But I know that here is actually full on medical acupuncturist and so on (04).*

> *It's one of the leading homeopathy hospitals in the country… And as such, he [RLHIM Dr] will do professional job (20).*

> *I mentioned to him [RLHIM Dr] about this prolotherapy. And he knew what exactly it is … And the doctor said 'oh yes I'm involved in that study' (38).*

5.6.4 Difficulties in getting referrals

Most participants (n=27) were pleased with the length of time they had to wait once their GPs agreed to refer them to RLHIM. However, many (n=22) had issues communicating with their GPs in order to get a referral to the RLHIM.

> *My GP is absolutely useless. He's no good at all. I had difficulty with my GP, cos my GP, you see, the hospital consultant couldn't refer me direct, he wasn't allowed to do that. So I have to go through my GP. So I went to my GP, he said 'I can't refer you to the hospital, it isn't an NHS', but I know it is cos I was under UCH anyway. My GP is very difficult. He told me all sorts I can't believe it! He told me in alternative medicine, no doctors are fully trained. It was UNBELIEVABLE! My GP is absolutely against it. ... I think all of it is because his practice has to pay for me to come here, and he's always concerned about his money (05).*

> *Hmm, it is to do with NHS funding. So, for - there is a whole protocol. With shoulder things, they can do it if you've tried a lot of stuff (27).*

Many participants (n=13) found there was inadequate access to CAM treatments as they were not available in their local GP practices. Some (n=5) interpreted it as due to a lack of NHS funding for CAM treatments.

> *The thing is you don't get offered anything like that [CAM treatments] do we at home? It's part of the fibromyalgia thing. My consultant, as I said, my pain consultant, who's Chinese, believes in all that kind of stuff, but he can't get any*

> *funding on anything to refer any of his patients to things like that. So if I wanted to do stuff like that, I have to be privately funded (40).*

5.6.5 Being 'insiders'

Some participants (n=9) were referred to RLHIM through a referral letter from specialists in UCH and the group of hospitals associated with UCH, such as the National Hospital for Neurology and Neurosurgery (NHNN).

Some participants (n=6) believed that whether they are referred to RLHIM or not, and for how long, was a 'postcode lottery', based on different referral schemes in different boroughs and on which conditions they had.

> *I'm not sure why, but if I do want something [CAM treatment], they'll say, "Oh, it's out of the borough. It's not in our borough. Why do you need to go there? You should go here." Then, I'll have to explain to them the problems with them, and then, eventually I did get the referral. And then, that's when I started to get treatment and diagnosis as well (15).*
>
> *So, I'm extremely lucky. It is in my patch. In my borough [Camden] (27).*
>
> *It's the postcode lottery. It [referral to RLHIM] depends on where you live. How good your services are and whether you are in this part (38).*

In one case, the participant who had experience dealing with CAM services suggested that people can 'no longer get homeopathy' at the RLHIM and the best way to get homeopathy treatment is to get referred to rheumatologists (who is also a homeopath therapist), under a specialist in the RLHIM.

> *I said to him [GP] that they [CCGs] may, probably won't fund it [homeopathy], if you do it to the RLHIM. So I suggested he write to [RLHIM doctor], as a rheumatologist, consultant of rheumatologist, at UCLH, but put this address, which is what he did. And that's how I got through. Because the rheumatology doesn't come under the sort of like, easy access (20).*

Summary of pathway to treatment

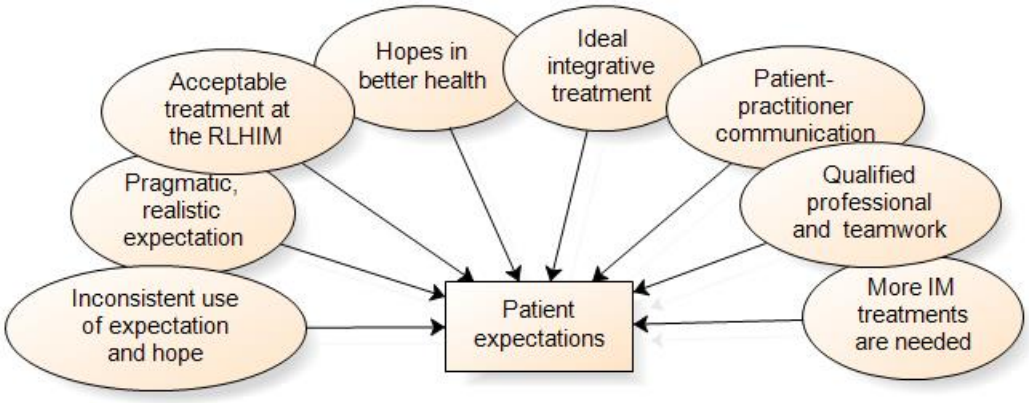
- Participants decided to try CAM treatment as their families and friends had previous positive experiences, or it was suggested by healthcare professionals;

- The decision for using CAM was also influenced by those who seldom had any positive impact from conventional treatment, or their personal knowledge or interests;
- Having qualified, knowledgeable professionals was one reason participants came to the RLHIM;
- Most participants were pleased with the time they waited to get referred, but experienced difficulties in persuading their GPs to refer them to the RLHIM. They believed lack of access to CAM services may be caused by a lack of funding;
- Participants felt two aspects affected whether they could get referred: which borough they were in, whether they were referred from another doctor in the same group (e.g. UCH or NHNN).

5.7 Patient expectations

The theme 'patient expectations' contains information generated when asking participants the following question: "Can you tell me what your expectations are for your treatment at the hospital?" Relevant data obtained when answering other questions were also coded within sub-themes under this theme. The issue in participants using the terms expectation and hope inconsistently is discussed below (5.7.1). Their expectation and acceptability of the treatment at the RLHIM are also discussed (5.7.2 -5.7.8). Content in this theme was closely linked with participants' MSDs and their decision making process, discussed in Section 5.6. Figure 5.8 shows the sub-themes under the theme ***patient expectations***.

Figure 5 8 Sub-themes under the theme patient expectations



5.7.1 Inconsistent use of expectation and hope

When asking about their expectations of the upcoming treatment at the RLHIM, most participants (n=26) talked about their hope, and the terms "expect", "hope", "want", "think", and "believe" were used interchangeably. Expectation refers to 'a strong belief that something will happen or be the case'; while hope refers to 'want something to happen or be the case' (Oxford Dictionaries, 2014).

> *I have great expectations [laugh] that they'll be able to cure me from my pains [laugh] (02).*
>
> *My expectation? I hope I could be pain free and I could hold my head up for long, longer than now (03).*

Though participants inconsistently used the words expectation and hope, some (n=6) of them were aware of the clear differences between the two.

> *I don't have any expectation apart from hope that I feel better, that it works but that's because I've been to so many people and they all said, "Oh, we can't help you (36).*
>
> *I am, [long hesitation], there's a hope. There's a hope, is one thing, and expectation is another. I have high hope, but my expectation is umm, pragmatic. It will or it won't. You know, it doesn't always work. It doesn't work on everybody (20).*

5.7.2 Pragmatic, realistic expectation

A lot of participants (n=18) stated having pragmatic, realistic, or neutral expectations for the upcoming treatment at the RLHIM as they had long term experiences with their MSDs. Some (n=7) also shared their experiences in how to manage their expectations.

> *It's being realistic, that my expectations are day to day, not look into the future. I can't look into the future. Today is the future. Although tomorrow is the future, I don't want to know how I feel tomorrow. I want to know how I feel now, today. So I live today and I don't worry about tomorrow, where some people would worry 'what's going to happen to me in ten years' time'. Oh my god I don't think that far. Cos I've travelled since 1983, with this pain. I'm still here, and I'm living, I'm doing most things, not everything I can do (09).*

> *Hmm, I try not to build my hope up so much now, cos up till then, every time I saw a new person, I thought, 'this is gonna be it'. And then at the end, 2 months, nothing happened and you get, oh dear, I'm really dying for a day or two, then I say no it's no good. So I try not to raise my hope so much now. Whatever I get will be a bonus (05).*

5.7.3 Acceptable treatment at the RLHIM

When asked were they expecting any issue with the treatment at the RLHIM, most participants (n=18) had no concerns about coming to the RLHIM for their treatment at all as they believed the CAM/IM treatments are mostly non-invasive, or they did not state any concerns in the interview.

> *M: do you think there will be any side effects?*

> *Not that I've ever hear, no. hmm, I found it really strange that people ... Actually I'm very interested in it [acupuncture]. It's funny because I don't like needles. But with this, because that's [the needle] so thin, I don't see why it's a problem (04).*

> *I've seen it [acupuncture] on television, you know. I think because I had so many different kinds of tests and you know, blood tests, millions of blood tests, so it's [blood test needle is] bigger [laughs]. I'm quite open to anything really. If somebody said, 'right, this is going to help', [I would try it] (47).*

Some participants (n=7, all living outside London) stated that the journey from their home to the hospital was quite time consuming and that was one of their concerns. There was one participant who was concerned about perceived inadequate evidence behind treatment provided at the RLHIM.

> *There is evidence for acupuncture, but there's no evidence for homeopathic and there's no evidence for herbal medicine, like these teas and there's no evidence for Chinese herbal medicine. They do studies, trials. They have to do trials (12).*

Several participants (n=4) were worried about whether they would get re-referred after this episode of treatment.

> *They [doctor in previous experience] said, you know every -- if we can do it every 12 weeks, 12 sessions I got and just keep getting yourself re-referred. And as long as it can be funded (31).*

5.7.4 Hopes for better health

Participants hoped that the treatment at the RLHIM could help improve their health status, particularly including symptom relief (n=30), improving functional ability (n=17), and to minimise the amount of medications they were taking (n=9).

All participants hoped to have some degree of symptom relief. Pain relief was the outcome expectation most frequently stated. Other symptoms such as stiffness, stress related to the MSD and sleeping disorders were also discussed.

> *To get at least be able to manage my pain, if not completely cured. I know some things like arthritis, they'll never go away, but at least [to] be able to manage myself and manage to take care of myself or look after myself and manage the level of pain. Even that would be a big bonus for me (15).*

> *I'll be okay as long as I get some help. If I can get 20 percent or 30 percent less pain, I'll be a happy lady. I can put up with pain. I've got pain most of my life. I can put up with pain. But if I can get rid of just that bit [of pain] to help me get through the bit [of pain] that I got. I'll be okay (46).*

> *I had [acupuncture] once before and it helped with getting my movement back. I was in a lot less pain… I was getting aggravated, stressed. It cut down stress a lot because there wasn't so much pain (11).*

In association with pain and other symptoms caused by MSDs, functional ability is closely linked to quality and enjoyment of life. Their functional ability was often focused around work, hobbies, social life, or daily living activities.

> *Well, I hope the treatment here will provide me with a better health, better standards of living for me personally where I was not in so much pain (43).*
>
> *But you know, if I would go back to swimming, I'm able to do all my strokes, with actually, actually no pain. … But if they can get me in the right movement and reduce the pain. I do know people who have, you know, really good success with acupuncture. So I am very open and I am up to it (27).*

A few participants (n=2) stated that they needed some meaningful activities, such as getting back to work, which would enable them to interact more with people and also build their self-worth.

> *There are a lot of things to do, and distractions. But purpose has gone. If you see the distinction. It would be good to get back to some kind of job. That's what I'm trying to do in my life, as being work, really. And now, just money, but just structure, and I'm very disciplined, otherwise – don't drink too much. So structure is always providing by work. I'm thinking to interact with other people would be good (06).*

5.7.5 Ideal integrative treatment

Nineteen participants (63%) had something in their mind before receiving treatment at the RLHIM, among which thirteen were aware of which treatment they could be expected to receive before their initial appointment at the hospital: acupuncture (n=10; one specified Western acupuncture, one eastern acupuncture); homeopathy (n=1); physiotherapy (n=1); one patient was on the waiting list for a combination of CBT, mindfulness and acupuncture. Five participants had no idea what they would receive but had a clear idea of what they hoped for: acupuncture (n=3); homeopathy

(n=1); pain management (n=1); assessment (n=2: one specified they 'desperately' wanted a CT/CAT scan). One participant was referred for joint injection but was looking forward to trying reflexology if available.

The remaining eleven participants (37%) stated that they had no idea of what treatment they were expecting or hoping for. Some had an open mind to any treatment as long as it was not medication; some placed their trust in the practitioner and believed they would be offered the most appropriate treatment for their conditions. Participants expressed what kind of treatments they hoped to receive at the RLHIM.

Many participants (n=10) hoped to have ***individualised*** treatment and wanted their whole situation to be considered by the practitioner. They believed that the treatment protocol that works for one patient may not work for another.

> *Basically what I do expect is that first, you know, for my case history to be taken into account and something devised that is going to be beneficial for ME. That's my only expectation of the treatment and such, but other than that, you know, I have no expectations (21).*
>
> *Because I do believe that herbalism is a very individual thing. You know, it's from patients. It's not - what works one, might not works for another (43).*

Some participants (n=7) hoped to have 'natural', 'organic', and '**non-invasive treatment'**.

> *This way to me is non-invasive, it's natural. And that's how I would like to be treated, you know. I don't want to feel sick, or things like that, you know (54).*

Some participants (n=6) believed that both CAM and conventional treatments have a place for MSDs and the practitioner should use the **optimum treatment(s)** for their conditions and also gave examples to illustrate their ideas.

> *I don't know what I'm going to get. Because this is a hospital for integrated medicines, and what will happen is they would assess my condition, and decide what they think is appropriate for me. And if it is homeopathy, or diet, or acupuncture, or physio, or a bit of one two three things. That's what they will do. … That's not to say that I'm anti-conventional medicine. Because I'm not, I think it has a place. I think they ALL have a place…. They WILL give you what you need. That's why when you say are you getting homeopathy, well I hope I do. But at the same token, they will only give it to me if they think it's appropriate treatment to have and they may give me something that I would prefer not to have but at least I know they are conventionally trained, and they will assess it accordingly. Because they are also trained in complementary and they'll know whether something will work or not. And if they don't think it will work, then they're not going to waste my time (20).*

> *I mean, I am not an idiot. If I fall or do something to myself, I will immediately take an ibuprofen. I'll take an anti-inflammatory, so I'm not stupid. But you know for chronic condition, I'd rather try work them out with complementary….THAT [a combination of CAM and conventional treatments] is the sensible approach into integrated medicine. It is not seeing them as two different things. My son lived in [an Asian country] for a little while. And we were talking on Skype one day and he'd been to a doctor. I think he had a stomach upset. And he said, 'look what they gave me!' He held up a load of like little blister packs, four pills each pack and it's like that was his dose. … And two of them were conventional medicines, and the other two pills were complementary, to deal with the side effects. You see, so to me, that is really integrated medicine (27).*

A few participants (n=4) hoped that the treatment could help them get rid of the condition **from the root**, to solve the pain completely, rather than suppress it.

> *And I realised that the medicines, you become dependent on them. You've got side effects on them, and after, I've got to try something alternative, which is not just medication, but something that can get to the root of the problem and solve the pain rather than just suppress it (15).*

5.7.6 Patient-practitioner communication

Many participants (n=9) hoped to have better communication with the practitioners they were going to see at the RLHIM, in terms of receiving more up to date medical information or professional advice (n=5).

> *But you know, really I just want up to date information and knowledge about treatments, which was initially why I asked to go and be referred to the hypermobility clinic at UCH because I was coming up against situations where, particularly physios, might say, "Well, we don't recommend that now for hypermobility." But that's what I've been told as kind of an article of faith in my pain management course, and I thought "Well, I actually need to find out now what I should be doing then, what the latest research suggests." (10).*

> *It's nice to have the words of an expert, you know, somebody is knowledgeable in that field to guide me, more than just the internet (43).*

A few participants (n=6) stated the importance of patient engagement in treatments, which they believed could help the treatment. They wanted to be listened to and they cared whether the practitioner is a good listener or not. They hoped to have more understanding and mental support from the practitioners.

> *I don't want to be shut up. I just want to be listened to, I don't want some doctors to go and shove a fistful of pills in my mouth. I want somebody to hear what's coming out of my mouth (21).*

> *If patients were engaged in it [treatment], they felt better as a result, as just being involved in it, you know. And that is a holistic thing. You feel better, if you've been spoken to, as a human being, and you've been involved and you feel sort of empowered…. And made her feel relaxed and made her feel somebody cared about her actually. Basic caring, which is all the NHS supposed to be about, isn't it? You know, people caring for you, and doing their best, you know (54).*

5.7.7 Qualified professionals and teamwork

The contents in this sub-theme overlapped with participants' decision making process of coming to the RLHIM (Section 5.6.3), but this was also an emergent new

sub-theme in the patient expectation theme. It was a sub-theme as participants firmly clarified these beliefs.

Many participants (n=8) stated that they trusted medically qualified doctors more than CAM practitioners in private clinics, where the practitioner may start practising after simply attending a short course.

> *They're all doctors [at RLHIM] and they know what they are doing. I know in the private clinics, basically as long as someone has the ability to practise, no matter qualified or whatever, you can take a separate course in it, and still practise it, so yeah. But I know that here is actually full on medical acupuncturist and so on (04).*

A few participants (n=3) emphasised the importance of teamwork and multidisciplinary team work together to help resolve their health conditions.

> *The people here will work in conjunction with the other professionals that see me, so they won't do anything that's going to and they won't say, "Stop the steroids and have this herb or whatever." (21).*

5.7.8 More integrative treatments are needed

Some participants (n=9/17) who had previously experienced CAM treatment felt the CAM treatment available in the NHS is not enough and they would like to receive more. They wish to experience long term effects and continue to receive treatment at the RLHIM to maintain their symptoms at a bearable level.

> *They [physiotherapists in UCH] only provided six sessions [of acupuncture], in physiotherapy, for free. So they referred me, they said to me 'go back to your GP, and she'll refer you'. Cos I was benefited from the acupuncture, the pain relief was quite good. I was in pain in a way, but I could move my neck, stretch my neck. It was a lot better. So my GP referred me to this homeopathy hospital, to see if I could have it, on a long term, with the NHS, so that I could have good quality of life (3).*
>
> *But the problem is this – you can only have six treatments [acupuncture in an NHS setting]. They won't give you any more because it's obvious they must see other patients. So the only way I can get treatment is if I'm referred to different hospitals, and that's why, I'm hoping I can get it done here. … I*

> *think, I think, this is what I want to check with the doctor, when you have 6 treatments, you can be referred back again. You see, if I've got chronic pain, I don't know if I can get regular, maybe once a week, or once a month (9).*

Participants (n=7) who had previous experiences in CAM treatments also argued that they were only allowed a certain number of sessions in their previous treatment at the RLHIM. They were hoping to have more long term, regular treatment.

> *Well, it looks like I'm getting in this particular referral, six sessions of acupuncture, which for the time period that I have them, which would be over about 12 weeks. … So anyway -- but no, it will help. Oh, I'm sure it will help. It has in the past but -- and I'll just have to see at the end of it if I've got any money to pay privately to keep it going until possibly I can get another referral peeking in (10).*

Three participants expressed their wish to have CAM treatment as 'in-between' treatments to complement conventional treatment, to help with their MSDs. Among these, one participant mentioned the need for "hands on manipulation". One participant thought that more practitioners are needed in order to meet the demand for IM treatment.

Summary of Patient Expectations

- The terms expectation, hope, and want were used loosely and inconsistently by most participants;
- Majority of participants had pragmatic and realistic expectations towards the treatment provided at the RLHIM as they believed that the hospital was experienced in treating MSDs, which involved actively managing their expectations;
- Most participants had no concern about their impending treatments at the RLHIM as they believed the treatments would be non-invasive. Living far away from the RLHIM and difficulties in getting re-referrals were the most common concerns;

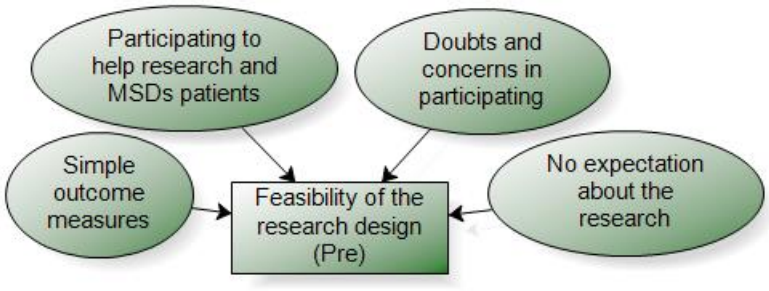
- Most participants were aware of the treatment they were expecting and hoping for. Acupuncture was the most common treatment they expected;
- Participants hoped to have better health in terms of symptom relief (pain, stiffness, related stress, sleeping disorder), improving functional ability (better quality of life, meaningful activities), and to be able to reduce medication;
- Participants hoped to receive individualised, non-invasive treatment through having optimum treatment, and treating their conditions from the root cause;
- Participants hoped to better communicate with RLHIM practitioners, and hoped to be engaged in the treatments;
- Participants expected RLHIM practitioners to be skillful professionals, who worked in conjunction with other healthcare professionals;
- Participants who had previously benefited from CAM treatment wanted to receive more; they hoped to have long term effects with more follow-up CAM treatments on a regular basis as a result of the RLHIM provision.

5.8 Feasibility of the research design (Pre-treatment)

The theme 'feasibility in research design' contains information generated when participants were asked the following two questions: "Can you tell me what do you feel about taking part in the study?", and "What are your expectations being involved in the study?". Relevant data when answering other questions were also coded within sub-themes under this theme. Participants demonstrated their level of acceptability of the process by their completion of the outcome measures (Section 5.8.1); and in the reasons for participating, their doubts and concerns, and their expectations regarding participating in the research study (Sections 5.8.2 - 5.8.4). The data were associated with the theme living with MSDs (Section 5.2) as participants experienced various symptoms with fluctuating pain and fatigue which affected their acceptability of

participating in this research study. Figure 5.9 shows the sub-themes under the theme ***feasibility in research design***.

Figure 5 9 Sub-themes under the theme feasibility in research design



5.8.1 Simple outcome measures

Most participants (n=20) found the questionnaires easy to follow and quick to complete and stated no difficulties in completing them. Pain scales (VAS and sfBPI) were the two most popular outcome measures as they were easy to follow and took minimal time to complete, though some participants (n=8) had difficulties deciding what score to put on the pain scales. This is mainly due to having fluctuating levels of pain which were affected by what they were doing and whether it was a 'good' or a 'bad' day.

> *I mean sometimes it's okay you know, it's just, you [are] aware that it's not as settled as it used to be. Other time it really hurts. Other times it's like there is a glass in you, you know, it's changeable. So it's not really. … It depends, if you asked me, say one day, then I might put higher scores, and on other day it would be lower (20).*

The least popular measure was the mCSRI which assessed the overall costs during the past three months. Participants (n=9) reported difficulties in remembering treatments received during the past three months, or felt that there were sensitive questions asked in the mCSRI (n=9). In two cases, the participants did not answer the questions asking about their insurance and national insurance benefits at the beginning but answered after the researcher explained why they were asked.

> *Well, apart from those 2 questions I told you that I was not sure what is the point of it [2 questions about patients' income and benefit], but then you did tell me about why you put them there, so that's fine. I'm happy with it (26).*

5.8.2 Participating to help research and MSDs patients

The main reason for patients to participate in this research study was to help research in CAM/IM for MSDs, and ultimately help patients who have similar conditions. Many participants (n=14) stated that they were taking part to help evaluate the practice provided at the RLHIM.

> *I actually feel that, this is my personal view, that through research, and asking different types of people then, I think there should be more research done in this field in order to have a clear and a better idea of what is the global, you know, a general idea (43).*

> *As much as you need me [for the research], and I trust that you will collate the information you take from me every day [study data] and, you know, do something proactive with it. I'm not sure that conventional medicine when they take these surveys do proactive things with it, you know because they're not looking for cures for anything (21).*

Participants (n=13) also took part in the study to help provide information in the field, to help other patients with MSDs to better understand how their life was with their condition.

> *I don't mind taking part in this study because I feel if you can help me [to understand my condition] and then if my experiment, whatever you do would help other people who go through similar pain, to help them (15).*

> *I am happy to help. Because mostly when I'm sick, I feel so down. I think other patient will feel the same as well (13).*

Some participants (n=6) expressed that they participated to help the research student as a person.

> *Well I don't know if I would benefit anything from you, but as you are a student, and you are learning, I just thought I come along and have a chat with you and if I can help in any way I will (02).*

Other reasons included: for clinicians to better understand their condition (n=5), to help themselves understand their conditions (n=3), to return to the RLHIM as they previously benefited from it (n=2), and to help them in getting more follow-up treatments at the RLHIM (n=2).

5.8.3 Doubts and concerns in participating

Many participants (n=12) claimed that they had no problems in participating in the research study because the study procedure was clearly described, the way of being contacted by the research student was acceptable, and it did not involve drugs. However, this was not supported by some observational data within the interviews. Participants' concerns were mainly due to their MSDs or other health issues, and due to a lack of time.

Ten participants experienced physical barriers in participating in the research study. These included a need to move and stretch during the interview (n=8); having difficulties in completing questionnaires due to hand deformities (n=2); and getting a headache during the interview (n=1). One participant had dyslexia. But they all completed the questionnaires themselves and completed the interview.

> *I can't hold my neck up high, I can't do housework, it starts, pain. I can't see too much TV, I can't see newspaper, find it hard to filling forms, because I have to bend my neck down. That's why I don't take [part in] research (3).*

Concerns associated with the study design (n=9) included: participants worried about time before their appointments (n=7, one was interviewed before completing questionnaires as participant requested); insisted being interviewed outside the clinic room in the corridor (n=3); and wanting to leave early as they had travelled from outside greater London therefore interview was shortened (n=3). One participant found the explanation in the patient information sheet unclear (reconfirmed study aim, did not understand what was a 'focus group').

In rare cases, emotional changes in participants were observed. Three participants cried during the interview when they were talking with the research student about their life and experiences with MSDs.

> *Sometimes – I know it sounds depressing but sometimes I just want to run away, you know, sort of – it IS very depressing. But I try not to depress other people with it, you know what I mean. [started crying] I don't want to depress you (54.*

One participant refused to answer a question.

> *M: Do you think this affects you emotionally?*
>
> *33: It did that time. Don't ask me that time. I don't want to go that far, but it did affect me a lot.*

One particular participant argued that patients' anecdotal experiences should be taken as evidence for CAM, rather than keep on conducting clinical trials.

> *It might be anecdotal, but if ten people have found it works for them, then I'd believe those ten people… And if it works, why do you need loads of evidence? Why do you need it? Why do you need to keep on doing clinical trials, clinical trials, when people had said it worked for them!… Just trust the patients, talk to the patients, if it's helping with them, why are you so bothered about it, for goodness sake, you know. You know, it's just ridiculous, isn't it? (54).*

5.8.4 No expectation about the research

When asked about their expectations in participating in this research study, most participants (n=25) gave very short answers claiming that they had no expectation, or were very 'open-minded' to this research. Answers to this question were very similar to reasons for participating in the research study that they were to help research and patients with similar experiences (Section 5.8.2)

Summary of acceptability in research design (Pre)

- VAS and sfBPI were the most acceptable outcome measures as they were simple to follow and quick to complete. Difficulties in completing them

included being unable to give a score due to fluctuating pain. mCSRI was the least acceptable outcome measure, with difficulties reported in remembering previous treatments, and finding some questions too sensitive

- Participants took part in the study mainly because they felt research is needed in the field and they wanted to help other patients like themselves;
- Though participants claimed that they had no concern participating in the research study, the research student noticed physical barriers to them completing questionnaires and interviews; concerns about time during the interviews; and unclear explanation in the patient information sheet; emotional changes were observed in some interviewees;
- Participants had no clear expectations for the research study; their expectations about taking part in the research study were associated with their decision made to participate.

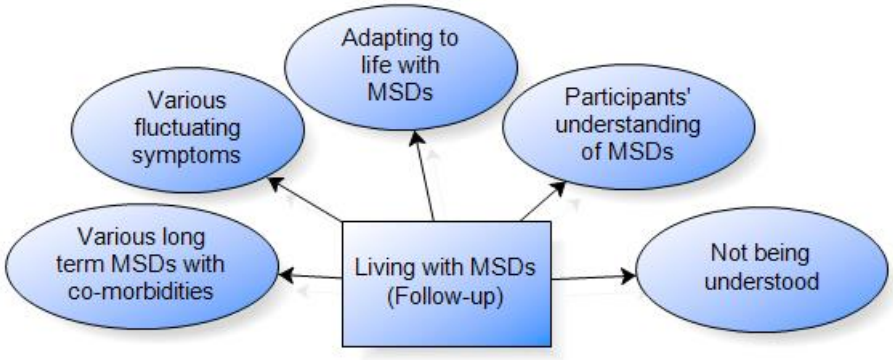
Sections 5.2-5.8 presented findings generated from the pre-treatment interviews immediately before patients received their initial appointments at the RLHIM. From Section 5.9 onwards (Sections 5.9-5.15), the results presented are generated from the follow-up interviews and focus groups, which took place 12 months after participants' initial appointments at the RLHIM, with a different sample of people to the pre-interviews. For the follow-up interviews, findings generated from the 15 one-to-one interviews and the four focus groups were similar, therefore used the same framework. Findings were presented together, except in Section 5.11.4 (self-care), Section 5.14.3 (empathy and shared decision making), and Section 5.15.2 (engagement and benefits in participating) where particular findings were presented on focus groups. At the end of this chapter, a comparison of pre-treatment and follow-up interviews is presented where there were overlaps in the two frameworks (Section 5.16).

5.9 Living with musculoskeletal disorders (follow-up)

Though the research student did not ask questions directly related to participants' experiences of living with MSDs, all participants shared their experiences of living with MSDs when being asked the following question: "Has the treatment changed your symptoms, wellbeing and quality of daily life? If so, how?" Relevant data when answering other questions were also coded within sub-themes under this theme. The changes attributed by participants to treatment are detailed later in 5.13.2 (theme 'experiences at the RLHIM' – sub-theme 'effects of treatment at RLHIM').

This section starts by introducing participants' MSD symptoms, their long term complex health experiences, and how MSDs were affecting their life (Sections 5.9.1 – 5.9.3); following their understanding of MSDs and how their MSD pain was not understood by others (5.9.4 & 5.9.5). Figure 5.10 shows the sub-themes under ***living with MSDs (Follow-up)***.

Figure 5 10 Sub-themes under the theme living with MSDs (Follow-up)



5.9.1 Various long term musculoskeletal disorders with co-morbidities

All participants in this phase of the study (follow-up interview) had chronic MSDs lasting from 3 to 44 years, with most participants using the phrase 'many years' (n=15).

Among those participants, 13 participants stated that they had pain all over their body; eight stated they had rheumatoid conditions: joint hypermobility syndrome (n=4), rheumatoid arthritis (n=3), lupus and myasthenia (n=1); six stated they had fibromyalgia; three osteoporosis. There were also rare cases: one participant had a primary progressive multiple sclerosis, another had stiff person syndrome. Seven participants stated that their conditions were associated with degeneration; while three suggested problems due to a car accident, one was due to a bad fall.

Many participants had other health issues as well as their MSDs. Many participants (n=11) reported sleeping problems. Some participants (n=5) felt that they had a mental health problem but it was unclear whether this occurred before or was as a result of their MSDs. Other participants had conditions such as; thyroid problems, glaucoma, and hypersensitivity. These co-morbidities may or may not have been related to their MSDs.

> *When you're suffering from an auto immune you can't turn it off (55, Physio+Homeopathy+Insomnia clinic+MDT/OT).*

> *But I suppose I have quite bad memory. They said it's because of mental health related stress and depression and stuff like that (FG7, Acu).*

5.9.2 Various fluctuating symptoms

All participants in the one-to-one interviews and focus groups shared their symptoms of their MSDs. Most of them had experienced various levels of pain (93%) and restrictions in movement (75%). Some experienced stiffness (57%) and fatigue (21%).

Many participants (n=19) shared their experiences of fluctuating pain or immobility.

> *The pain is permanently there. And the severity of it depends on the weather, depends on what I've done, how I've been sitting, whether I've been travelling, all various things. So like today, for being on the train, cos obviously it was really rattily and jerky. So tomorrow, that will be really bad.*

> *My lower back and the hips will be really bad… Yeah, just – everything triggers different things (40, Homeopathy).*

5.9.3 Adapting to life with MSDs

Almost all participants (n=27) reported that their MSDs impacted on a wide range of aspects of life, both physically and emotionally. Among these participants, many (n=17) changed the way they do things, to adapt to life with MSDs. This is linked to the sub-theme ***lifestyle-management*** and ***awareness of self-help***, which were both categorised as ***self-directed integrative approach*** (Section 5.11).

> *Sit on the stool and vacuum with…. I just bend over and move the thing backwards and forwards, you know. And it – that's all I can do (F14, Acu+Homeopathy+Physio).*

> *[I am] eating properly and sleeping well, and making right choices and decisions (55, Physio+Homeopathy+Insomnia clinic+MDT/OT).*

Some participants (n=6) expressed feeling disabled or functionally restricted, which may lead to a feeling of lacking independence and relying on help from others.

> *Well, you see, I don't want my wife doing everything for me. She's done all the housework; she's taking care of me. It's just, everything is pushing you on (F7, Acu).*

> *Uhhm, and so when you get home, when you're on your own, and you collapse and you see your family is aware of how it is. So maybe it might be useful to bring my husband or my son here then they to tell you how it is at home (FG41, Mindfulness training).*

5.9.4 Patient understanding of musculoskeletal disorders

Some participants (n=8) shared their understanding of their MSDs, which included how they interpreted the conditions, and how they understood the mechanisms operating with MSDs.

> *Well, your whole body is made up of connective tissue... well, your muscles are tense even it's not physically – you know what, I mean, your muscles inside, when they are trying to hold you together (05, Homeopathy+Physio+AT).*

> *Your muscle…, wrong messages is going to your brain doing that, when it's painful, when it isn't because they've been bombarded which messages of pain. So it's just re-educating the muscle, the messages. Actually, that's a good movement, so do it repeatedly. So that's what I do. And that tends to work (FG41, Mindfulness training).*

In some cases (n=5), participants shared their understanding of the possible psychological associations with their MSDs.

> *If I'm in pain, I just don't have the mental facility for it [socialise] all the time... I think, like depression, for example, it's one of the symptoms of fibromyalgia; anxiety is a typical symptom of hypermobility. And I do get quite stressed out (FG10, Homeopathy).*

Some participants (n=5) believed that their way of thinking affects the progress of their conditions. One participant took her friend as a role model and explained that people's interpretations of pain vary.

> *I think you got to believe in it [acupuncture can help with the knee pain] as well, because if you have a negative mind, sometimes nothing works. You know, don't forget this. Things like 'oh, I got pain in my knee', it depends how you relieve the pain in your knee, or how you think about it (09, Physio+Acu).*

> *So I do think when you treat the physical symptoms, your emotional health improves as well (FG10, Homeopathy).*

> *I asked her [a friend as a role model of 41] – I did say to her, 'are you in pain?' She was like, 'oh no, no. hmm, it's more of an annoyance'. She won't say it's painful. And it's painful... So her relationship to pain is not like my relationship to pain. I realised it must be painful. But she calls it 'an annoyance', or 'it's restriction', or 'stiffness'. Hmm, I think her relation to pain will be like if you gash your hand open, or bang your head somewhere, that will probably be pain for her (41, Mindfulness training).*

5.9.5 Not being understood

A few participants (n=5) expressed the feeling that their MSDs were not understood by others because they found it difficult to explain their MSDs.

> *Uhhm, but [although some people will tell you,] you cannot mindfulness awareness your pain away. You cannot visualise it away. You cannot exercise it away. It's there. It's not in your imagination because they are physical things that are there (FG41, Mindfulness training).*

Summary of living with MSDs (follow-up)

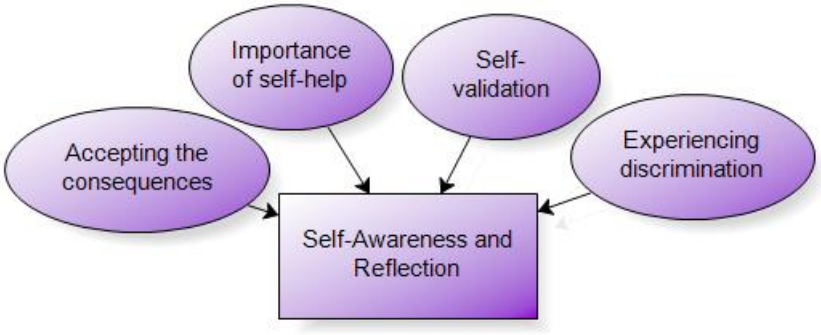
- Participants had various chronic MSDs and other co-morbidities;
- MSD symptoms included pain, restrictions in movement, stiffness, and fatigue. Participants experienced fluctuating pain and immobility;
- MSDs impacted on a wide range of physical aspects of life but participants changed the way they do things to adapt to their MSDs;
- For some participants physical and functional restrictions had an emotional effect, particularly being dependent on others;
- Participants shared their understandings of their MSDs, the psychological associations , and how their way of thinking may impact the progress of MSDs;
- Small numbers of participants felt their MSDs were not understood by the majority of people.

5.10 Self-awareness and reflection

Four sub-themes under the theme 'self-awareness and reflection' were emergent. No direct questions on these topics were asked. Sub-themes emerged mostly from participants' explanations of their experiences with MSDs and various interpretations due to different personalities and background characteristics. Participants' awareness of the progression of their MSDs and importance of themselves as their disease progressed (Sections 5.10.1 & 5.10.2) and validation in themselves when seeking consensus from practitioners (Section 5.10.3) are discussed. Participants'

experiences of 'discrimination' are included under this sub-theme as some participants felt they were being discriminated against (Section 5.10.4). This theme is associated with the theme self-directed integrative approach and the theme patient-practitioner relationship. Figure 5.11 is shown under the sub-themes of ***self-awareness and reflection***.

Figure 5 11 Sub-themes under the theme self-awareness and reflection



5.10.1 Accepting the consequences

Many participants (n=14), who had long term experiences of MSDs, expressed that they had to accept the fact of having an MSD and live with it.

> *I know my body's never going to be well again (55, Physio+Homeopathy+Insomnia clinic+MDT/OT).*

> *I know I'll never get cured… For 20 years on and off, and how that, kind of, almost, physical experience gets embedded in the, kind of, tissues in your body. To some extent, you, kind of, carry it with you (FG10, Homeopathy).*

A few participants (n=3) expressed positive thinking.

> *You got to keep your mind, uhmm, positive. You know, sometimes I think that I'm getting depressed and I'm going to cry or something. But, no, I mustn't. I fight against it. Uhmm, mind is very, very important (FG14, Acu+Homeopathy+Physio).*

One participant accepted she had to live with her MSD but needed help with it.

> *I am accepting defeat [laugh]... I'm not the kind of person to give in. But I'm not getting acknowledgement of that. Or I'm getting 'she can manage'. But I'm not managing and I don't want to be on the floor before I get the help. I want the help now! (41, Mindfulness training).*

5.10.2 Importance of self-help

Many participants (n=14) expressed an understanding of the importance of self-help.

> *If you are doing nothing, it's the worst thing in the world… But I think it is very important that, yes, people have to help themselves. It's no good having acupuncture, and then you don't help yourself. There's no point (09, Physio+Acu).*

> *I think it's more of a self-directed package of care. It was ME who insisted to get acupuncture, and physio, and some homeopathic remedies because I know three of them together are going to work. And I keep on reading, to be updated with new methods. I think that's very important (FG12, Acu+Homeopathy+Physio).*

> *The vitamin D level, that was affecting me physically as well. So now we've dealt with that. That's out the way. But again, that was ME recognising that. (41, Mindfulness training).*

Some other participants gave examples of what they had done to better manage their conditions.

> *Cos as a patient - a lot of patients don't help themselves. They do expect to come to these places or general hospitals and have a doctor or someone just fix them without helping themselves. And I think a lot of patients aren't informed enough and aren't willing to do the work themselves. You know, like eating properly and sleeping well, and making right choices and decisions. So- and when their health suffers they don't understand why. And they want a magic pill to fix it. So, you know it's a two way street. And I know a lot of patients aren't good patients, either. Which must frustrate the doctors as well I think (55, Physio+Homeopathy+Insomnia clinic+MDT/OT).*

In a few cases (n=4), participants expressed feeling that they had inadequate knowledge to help themselves. This potentially links 'awareness of self-help' to the sub-theme 'informative' under the sub-theme 'patient-practitioner relationship'.

I'm not aware of what I can or can't do. If I'm not having a twinge, 'oh, is that something to worry about', or, 'is that just a muscle' and I can just carry on. I've been carry on for years (41, Mindfulness training).

5.10.3 Self-validation

The sub-theme self-validation represents the use of other health professionals' or carers' words to confirm their health conditions, or to confirm what treatments would be beneficial to them.

In nine cases, participants quoted other health care professional's words, and carers (partner or family member, or friends) also attended the interview with the research student (n=5), to help provide a better picture of what the participants were going through. This was interpreted as a way of trying to validate what was happening to them.

But what I need to do is, go back to my GP and say, 'can you do me a, a sheet of paper, which tells me what you think I've got'… But it's validation that he said as well. Looking the piece of paper [laugh] (FG35, Homeopathy).

So she's [21] absolutely valid in her, you know, her assessment to Dr [RLHIM]. It's not personal. It's just something, you know, I've seen it as well. Cos we [21 and 21's mom] made a difference sometimes (21's mother) (21, Homeopathy+Diet).

And he said with these connective tissue disorders, and these muscle skeletal, things tense up very quickly and um, quite severely. And without that manipulation to get rid of them, and of course we can't exercise as well because we're just too tired and everything hurts (55, Physio+Homeopathy+Insomnia clinic+MDT/OT).

5.10.4 Experiencing discrimination

Some participants (n=6) felt that they were treated differently because of their prolonged unexplainable pain conditions and being elderly, for example being 'put in a group', with labels like 'old lady with chronic conditions' or feeling that their opinions are less valued.

They put me on cod liver tablets and that's all. I'm not seeing Dr [RLHIM] any more. It appears the older you are, you get the less you are valued. An old lady with chronic conditions [pooh] (FG54, Homeopath).

FG10: I think if I go to my GP now, they just think, 'she's middle aged and perimenopause'.

FG14: yeah, that's it! That's it!

FG10: when you get over certain age, it's like boom - we don't really give a damn.

FG14: yeah. All the GP seems to want to do is write up another prescription. They got too many patients. Get you out the door.

FG10: absolutely.

FG14: yeah, out the door. That's right.

(FG10, Homeopath; FG14, Acu+Homeopathy+Physio).

Summary of self-awareness and reflection

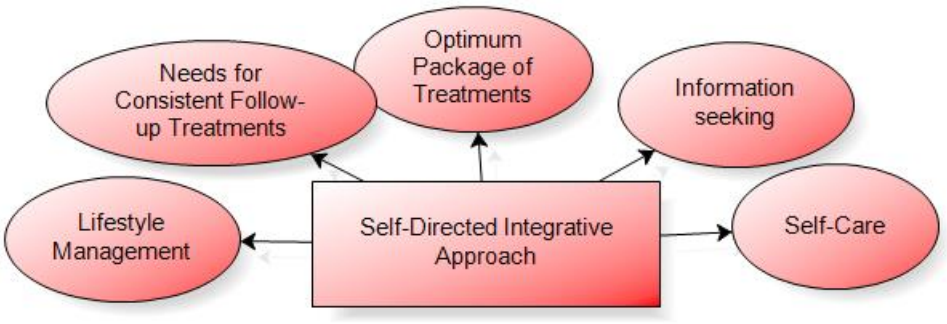
- Participants who had long term MSDs had generally accepted it and adapted their lifestyle to MSDs;
- Participants were aware of the importance of self-help;
- Participants felt more information on self-help was needed to guide them;
- Participants tended to used health professionals' or family members' words to confirm their statements regarding their MSDs;
- Some participants felt less valued as they were labelled as 'old ladies' with 'chronic conditions'.

5.11 Self-directed integrative approach

Participants were taking an important role in controlling their health. As their own 'health keeper', they often directed the ways that MSDs were managed and how they coped with things (Sections 5.11.1, 5.11.4, 5.11.5), as well as trying to understand how this interfered with the decision on when and what kind of treatments they required (Sections 5.11.2 & 5.11.3). Their understanding of the best treatments

presented in this section may have influenced their expectations on the treatments at the RLHIM as what they felt were the best options for them may not have met their expectations. Participants' self-directed integrative approach may also be associated with the patient-practitioner relationship, as potentially good informative communication may provide more guidance to self-management and self-awareness. Figure 5.12 shows the sub-themes under the theme ***self-directed integrative approach***.

Figure 5 12 Sub-themes under the theme self-directed integrative approach



5.11.1 Lifestyle management

Many participants (n=18) shared the way they managed their lifestyle to adapt to their MSDs. This included various strategies that helped them manage life with MSDs, which included healthy eating, planning schedules ahead of time, distraction from MSDs, and attending various social events.

> *Apricot juice is supposed to be great. I drink loads of apricot juice (FG10, Homeopathy).*
>
> *I sort of keep myself occupied, get distracted (05, Homeopathy+Physio+AT).*
>
> *I changed a lot of how I do things. I get the meat already ready, already skinned and cut. So I don't have to do that. I made changes to the home taps. And to make things easier, we changed the dish washer. So I'm doing my part at home. And I'm looking at new stuff that takes less time to do as well. Hmm, but if I want a curry, and I don't like – we do eat up, we do get takeaways but you can't live like that, you can't afford it (41, Mindfulness training).*

Some participants (n=4) shared their experiences of attending courses or clubs, which they found helpful.

> *I go away for a weekend and I go to all sorts of different courses, which I find fascinating (05, Homeopathy+Physio+AT).*

> *In fact last September I joined a "Singing for Fun" group at my local church. We started with just 12 people now we have more than 70 members. Isn't that amazing. We meet each Friday and every week I wish I wasn't going but once there am glad I made the effort. It's such a joyful group of people (FG12, Acu+Homeopathy+Physio).*

5.11.2 Optimum package of treatments

Some participants (n=12) shared their understanding of having an optimum package of treatments and the decisions they made in receiving those treatments. This included the situation where participants who were receiving a package of treatments and benefited from them, as well as those who had not necessarily received a package but pointed out the importance of having a package of treatments.

> *Having these three things [acupuncture, exercise, and medication] helps, you know, reduces pain. In other word, it affects you – medication on its own, yes, it reduces pain only for so what? And then you do medication and you exercise every day, it means a little bit more; and then when you have the acupuncture, and the medication, and the exercises, it reduces even more still (09, Physio+Acu).*

> *I can't just stop seeing all these other, you know, conventional medical doctors. Hmm, but I want something that could complement it and make me better, you know (21, Homeopathy+Diet).*

Twelve participants mentioned the treatment they would like to have. 'Hands-on' therapy was the most popular theme of treatments participants mentioned (n=9), including acupuncture, chiropractic, myofascial treatment, massage, and acupressure. Other treatments on participants' wish list included naturopathy and herbal medicine. Two participants stated they want to try 'something else', but 'no idea what'.

There were also cases (n=4) when certain treatments were unsuitable for them, so they made the decision to choose the 'right' treatment that suited them.

> *I mean, when I saw the physiotherapist she gave me exercises to take home and do at home, she gave me a sheet of paper with stuff to go and do at home, and whenever she would see me she would ask if I've done them and of course I'd say, 'not a lot,' because I don't know if they understand the pain and the exhaustion that you're in (55, Physio+Homeopathy+Insomnia clinic+MDT/OT).*

> *And that condition in the foot with the nerve is caused because of the joint hypermobility. My ankles are very lax so I go over on my feet a lot. So you do, you risk falling, you risk hurting yourself so exercise is difficult to keep the body loose and - you know keep things moving (FG10, Homeopathy).*

5.11.3 Information seeking

Some participants (n=9) stated they searched for information on their conditions and/or possible treatments. As this was not a target of questioning and the sub-theme emerged, most of the quotes were short statements without any further explanation of them.

> *I did some research on all the possible treatments (07, Acu).*

Among these participants, one gave an example of watching a medical TV programme, which indicated the importance of media to patients. This was linked with the sub-theme 'self-validation' (Section 5.10.3, under the theme 'self-awareness and reflection') and 'empathy' (Section 5.14.1, under the theme 'patient-practitioner relationship')

> *I watched a very interesting programme called 'Horizon'. It's all about placebo and I don't know if any of you have watched it. Did you watch it? That should be on a training programme for every trainee getting trained. Because at the end of it, the interesting thing is I found was how you got treated – whether you had a sort of empathic friendly type clinician, or whether you had one said, 'no, don't', you know, that sort of clinicians. And it made 20% better, just by the person being friendly and empathic and stuff (FG54, Homeopathy).*

5.11.4 Self-care

Some participants (n=6) shared their experiences of treating themselves. Different examples of treatments were given, including: yoga, TENS machine, acupressure, homeopathic tablets, and 'rubbing feet'.

> *I meant not to and only take them when pain was very bad. I tried a lot of stuff to avoid taking pain killers. I used ice packs for inflammation and it helped a bit (FG47, Acu+Homeopathy+Physio).*

A few participants (n=3) tried self-care at home themselves but had inadequate knowledge. This may link the sub-theme 'self-care' with the sub-theme 'informative' under the theme 'patient-practitioner relationship'.

> *I have a TENS machine at home and I have absolutely no idea where to put it. (FG46, Homeopath).*

> *I had come long ago for the physiotherapy. And I finished all sessions, which I all had. So I'm done with them. So I just have to practice which I do, occasionally [Laughter]. And the pain starts again, that's the time to [stop] (FG58, Acu+Physio).*

Summary of self-directed integrative approach

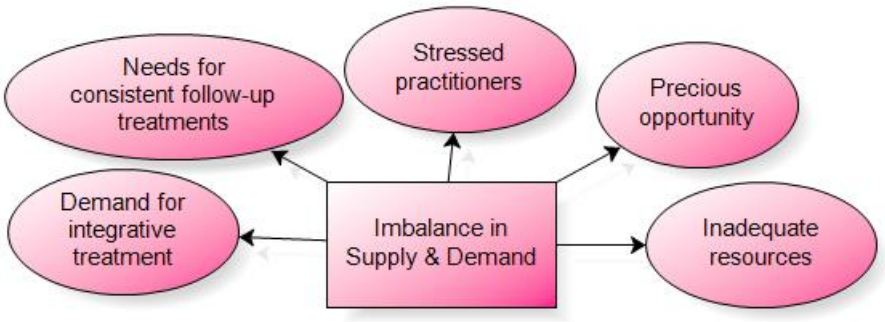
- Healthy eating, planning schedules ahead of time, distraction techniques, and attending social events were some of the strategies participants used to manage their lifestyle;
- Participants played an important role in deciding an optimum (package of) treatment(s) they receive. 'Hands-on' therapies were the most popular treatments;
- Participants actively read and learnt about their MSDs and the treatments available;
- Participants treated themselves using a range of CAM self-care options

including yoga, TENS, acupressure, homeopathic tablets, and massage, but found inadequate information available to guide them.

5.12 Imbalance in supply and demand

An imbalance in supply and demand is a sub-theme that emerged by cross reading the framework matrix. When discussing the treatment they received at the hospital or any treatment effects perceived, participants discussed their needs for integrative treatment and the perceived inadequate 'supply' of integrative treatment funded by the government. This imbalance was expressed in four main ways (Sections 5.12.1 & 5.12.2) and participants' attitudes towards this situation were revealed (Section 5.12.3). Possible reasons for that were suggested by a few participants (Section 5.12.4). This theme is associated with the theme living with MSDs as the nature of their MSDs required a prolonged treatment. Sub-themes under this theme are associated with the sub-theme RLHIM is unique (Section 5.13.6) under the theme experiences at the RLHIM. Figure 5.13 shows the sub-themes under the theme ***imbalance in supply and demand***.

Figure 5 13 Sub-themes under the theme imbalance in supply and demand



5.12.1 Demand for integrative treatment

Many participants (n=21) expressed feelings that there was inadequate treatment available at the RLHIM. This was closely associated with their chronic, ongoing conditions, therefore more frequent and prolonged treatments were needed. It was

also due to the unique position of RLHIM as an NHS hospital providing limited integrative treatments. The demands for the treatments at the RLHIM were reflected in several aspects:

Most participants (n=17) directly stated that there was inadequate treatment provided at the RLHIM. Some of them (n=6) felt that with a chronic condition, they need consistent follow-up treatments.

> *If you can have treatment every one or two weeks, it helps you... Having chronic pain for many many years, and when you found something that works, but you can't have, it doesn't make any sense, you know what I mean (9, Physio+Acu).*

> *I think it's easy to push into a private arena these things are readily available if here £50 or 60 an hour. The thing is you can only have a taster with 6 or 8 sessions or even less on the NHS. That's not enough to make a difference (FG6, Acu).*

> *But it's – when you get long term chronic condition, that's [getting re-referred] what you need. I need, I need acupuncture actually every month, would be brilliant. I felt much better when I had it... And [RLHIM 2] is right, she said, 'look, my service is in demand. Uhmm, you know, I can't see the same people being re-referred all the time' (FG10, Homeopathy).*

5.12.2 Need for consistent follow-up treatments

Many participants (n=16) expressed their needs or hope for treatments based on their understanding of their conditions and how treatments could work. Eight participants expressed their wish for consistent follow-up treatments for their ongoing conditions; five wished for more frequent treatment.

> *I have only managed to see Dr [RLHIM 2] 2 or 3 times a year, where ideally, it would be good to see him perhaps once a month, or once every couple of months, because, you know, if you are having ongoing – if you got long term chronic conditions, they are not going to get better. It's the case of management. And say if you are getting a course of acupuncture once every 2 or 3 years, in the interim you did quite badly (FG10, Homeopathy).*

Well, over a year, a period of a year of coming in here I don't know, four or five times, no I don't think that was enough (FG41, Mindfulness training). Some participants (n=5) experienced a long waiting time, either between sessions of treatments, or between re-referrals.

> *I think it was at least a three or four month wait list. Because it is one of the few holistic integrated insomnia clinics in the country I think (55, F, 43, Physio+Homeopathy+Insomnia clinic+MDT/OT).*
>
> *It was quite late and it took a long time to get referral to this hospital, cos you know, oversubscribed [laugh] (FG47, Acu+Homeopathy+Physio).*

Some participants felt that the length of the consultation was limited (n=4); or there was a need for more treatment options at the RLHIM (n=3).

> *They [treatment sessions] were very short. I know obviously there's only one of her [physio's patient in the clinic] but in- in all in all I would think within a half an hour session, you might have only got around fifteen minutes of actual treatment, and I felt like just as it was starting to work then it was time to go (55, Physio+Homeopathy+Insomnia clinic+MDT/OT).*

5.12.3 Stressed practitioners

Some participants (n=6) said that they felt the practitioners whom they saw were always under stress or under pressure.

> *Sometimes they've got lots of people to do acupuncture and they look very under pressure… So that's why sometimes I think when they are very busy and they've got lots of clients booked they don't give the proper attention, single - single time (22, Acu+Homeopathy+Hypnosis/CBT).*
>
> *The practitioner I'm seeing has to see several patients at one time in order to actually be able to deliver physical treatment. So he tends to be very stressed, which is difficult to cope with as a patient, though I don't blame him personally, but rather the hospital's administration or the clinical director (FG15, Physio).*

One participant expressed that more practitioners working in the field are needed as education takes time to turn around.

> *You see, the number of young physicians who work in the field is decreasing. They struggle with mainstream mindfulness and general wellbeing... But there are not enough trained people to do it. These people need the experiences and time to turn around (FG6, Acu).*

5.12.4 Precious opportunity

A few participants (n=4) expressed their gratitude at having CAM treatments at the RLHIM. By screening the framework matrix, these participants all had more than two years' history with MSDs and had already tried a variety of types of treatments.

> *But they were very kind enough to give me one [appointment] in 2 weeks. And I thought, 'I have to accept that. Maybe I have to make sure I get here on time. Leave earlier or whatever, anticipate train delays' (41, Mindfulness training).*

There was one particular participant who reacted badly to acupuncture during her menstrual period, but insisted going for the treatment as she had waited a long time to get it and did not want to cancel it.

> *I mean, the other thing I noticed is if I'm near my period, having acupuncture is hideous because my pain perception is really high. So if I realise, you know, I think 'oh god, I'm in my period and I got acupuncture', you know you are in for a bad one. It really gonna hurt. But you really can't cancel it because it needs wait MONTHS, you know (FG10, Homeopathy+Acu).*

5.12.5 Inadequate resources

A few participants (n=3) expressed worries about inadequate funding available for the treatment at the RLHIM.

> *And obviously with funding constraints over the years, it's got more and more difficult to get [referred] back in, you know (FG10, Homeopathy+Acu).*

In one focus group, two participants discussed their understanding of a 'patient led service' in the hospital.

> *NHS supposed to be patient led, so we can be given a budget. And if I would like that amount to be spent on massage, rather than medication, that's what they*

should follow. I would like to decide what treatment I have (FG54, Homeopathy).

If that happened, then there would be a really long waiting list for these kinds of manual therapies. I've been waiting for a long time to get acupuncture here. (FG7, Acu).

Summary of imbalance in supply and demand

- Integrative treatments at the RLHIM were in demand for chronic MSDs. Demand outweighed the availability of types and number of sessions of CAM treatments provided, and consultation time;
- Participants felt practitioners were under stress due to having too much work;
- Having integrative treatment at the RLHIM was seen as a precious opportunity;
- A few participants felt there was a lack of funding resources and that might be the reason in terms of limited number of treatments and long waiting time

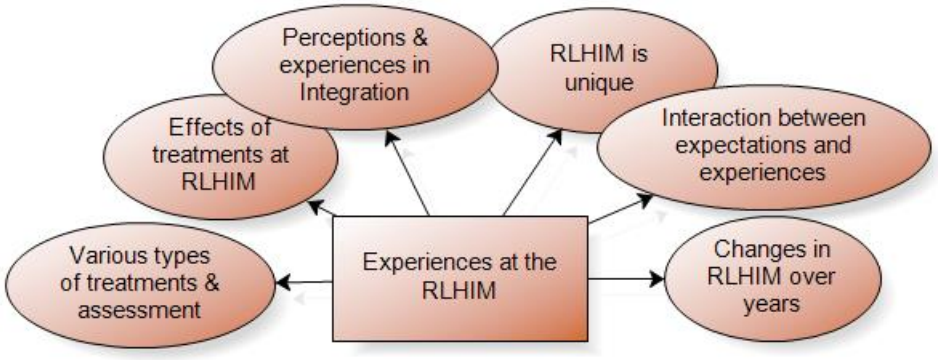
5.13 Experiences at the Royal London Hospital for Integrated Medicine

The theme 'pathway to treatment' contains the information generated when participants were asked: "Can you tell me about the treatment you received at the RLHIM and the experiences you have had during the treatment?". Relevant data when answering other questions were also coded within sub-themes under this theme.

The first three sub-themes (Section 5.13.1-5.13.3) presented in this section are related to direct questions, while sub-themes presented in Sections 5.13.4-5.13.7 are emergent sub-themes. The sub-themes under this theme are presented in a sequential order to provide a picture of what treatments participants received (Section 5.13.1) and the effects perceived (Section 5.13.2), followed by their experiences in integrative treatments for MSDs at the RLHIM (Sections 5.13.3-5.13.6).

Participants' experiences with the practitioners at the RLHIM are presented separately in the next section (Section 5.14) as it has a lot of content and can stand alone. This theme is associated with the theme self-directed integrative approach. Figure 5.14 shows the sub-themes under the theme ***experiences at the RLHIM***.

Figure 5 14 Sub-themes under the theme experiences at the RLHIM



5.13.1 Various types of treatments and assessments

Acupuncture, homeopathy, and physiotherapy were the most common treatments received for MSDs at the hospital. Most participants (n=18) who had had acupuncture stated that it was given weekly or biweekly or monthly for about 6 sessions. The treatment was approximately 15-30 minutes.

Homeopathic (n=16) treatment included prescriptions such as Arnica, Bryonia, Ignatia, Stramonium, Lachesis, and Cimicifuga (Actea Racemosa); as well as supplements such as phosphorus, fish oil, EPA [eicosapentaenoic acid], EFA [essential fatty acid], fish oil, cod liver oil, vitamin D, calcium. Supplements were also recommended by dieticians. Some participants (n=4) were asked to change their diet to include fish, milk, soy milk, and nuts; and supplements omega 3, and phosphorous.

Six participants had physiotherapy at the RLHIM. In the physiotherapy session, they had exercises to help strengthen the muscles, and some experienced short sessions of acupuncture or manipulation provided by the physiotherapist.

Participants also received other treatments; physical manipulation (n=5), osteopath (n=3), occupational therapy (n=2; one with inner soles made, the other received help in sleeping), cognitive behaviour training which includes education, awareness and mindfulness courses, and recommendation on books (6 sessions, n=1), transcranial magnetic stimulation (TMS) (n=1), insomnia clinic (6 weeks course) (n=1), marigold therapy (n=1), podiatry (n=1).

Some participants (n=9) stated that they received assessments at the RLHIM, which include blood test, x-rays, weight, blood pressure, MRI, and bone density testing.

5.13.2 Effects of treatments at RLHIM

Most participants (n=19) experienced benefits such as pain relief or functional improvements. They expressed that they were in less pain which they attributed to the treatments they received at the hospital, or they became more mobile and managed to do more exercises.

> *I'm moving up and down stairs without having to pull myself up… I went swimming, which I haven't been doing it for a long time, which is good… Well the cat can walk on me now without me feeling bruised, which is good. Uhhm, I can switch the indicate -- like you know, if I am driving flick it up the indicator and switch it with your finger, that would hurt. I mean just flicking a switch would hurt, which is crazy. Now, only sometimes…. Still, I mean it's not all gone but compared to how I was a year ago, you know, huge, huge difference (20, Homeopathy+Acu).*

Some participants (n=7) stated that they felt relaxed and experienced improved sleep.

> *The treatment has made me feel better in myself, although the pain in various places can still be quite intense (48, Homeopathy+Hypnosis/CBT).*

A few participants (n=3) stated that the treatments helped them reduce the medications they were taking, and felt better for themselves.

> *Do you know what, I've got to tell you this. I don't take all of these [medications] anymore. And I've been taking all of these tablets for many, many years but in the last six months I've managed to start not taking all of them tablets which is good. Yeah, very good. ….. Yeah I don't take all of them anymore. I'm better as a person (26, Acu+Homeopathy+Osteopathy).*

However, some participants (n=7) noticed changes in effects when they were receiving treatments at the RLHIM and felt the effects were associated with the length of treatment they had.

> *I definitely feel like I'm benefitting more lately than what I was before. Definitely... I used to have facet joint injections and I was under them for quite a long time and I had six courses of facet joint injections. Um, and I felt great afterwards for like a few weeks but then I felt back again whereas this time I actually feel like I'm- I'm improving, yeah… Consistently improving rather than improving and then going back to where I was. Yeah, so hopefully (26, Acu+Homeopath+Osteopath).*

> *But since I finished acupuncture a few weeks ago after my 6 sessions, I have had extremely vivid nightmares and night terrors (34, Homeopath).*

> *The problem is that given the chronic nature of my health conditions, my improvement does not persist without treatment, so that I relapse between treatment sessions has ceased (FG15, Physio).*

Sixteen participants responded when they were asked if they perceived any adverse events (AEs). Participants gave most feedback on acupuncture and homeopathy: pain when inserting the acupuncture needle was the most common AE (n=6). But they all felt it was fine and 'it's just the way it goes', apart from two participants: one received electroacupuncture and found it very painful when the adjustment was over what she could tolerate, the other reacted badly to western acupuncture as it made

the pain worse and therefore terminated the treatment. Other participants reported being sleepy, thirsty, and having nausea during their acupuncture. One participant stated that she experienced non-epileptic seizures which she felt was due to the homeopathic tablets she had taken. Eight participants reported no AE.

5.13.3 Perceptions and experiences of integration

When asking participants, "do you think you are receiving an integrative package of care at the RLHIM?", most participants explained in detail the treatment they currently have for their conditions, as well as whether they were currently waiting (treatments that had been referred for but have not received yet), not specific to RLHIM or MSDs. Several aspects emerged and are discussed. These include participants' experiences or understanding of integration.

Individualised treatment

The idea of receiving individualised treatment was mentioned by many participants (n=14). This included those who wished to have individualised treatment, those who felt already received integrative treatment at the RLHIM, and those who talked about their understanding of individualised care.

Many participants (n=9) expressed their wish to have individualised treatment.

> *And not all one's health conditions can be managed in one treatment and so one has to spread one's concerns and requests for treatment over the course of 2 to 3 appointments, taking 12 to 18 months to have them addressed (FG28, Acu+Homeopathy).*

> *But I have to insist that he hears me, and not treat me like the masses. I'm this patient. And this is what happens to me. And this is how I'm responding to this, or not responding to that. So I think he heard that. He's heard that now. But I'm tired of doing that. … And if you work in pain management, each person is different and you should be more, more aware or more sensitive to how you deal with that person (41, Mindfulness training).*

> *We need more integrated services with physicians who can see us as individuals, who can talk to us, explain to us (FG6, Acu).*

In a few cases (n=5), participants expressed feeling the treatments they received at the RLIHM were personalised and tailored to them.

> *I've got to know them [RLHIM doctors and nurses] all very well. And they're all extremely kind, each and every one of them. It is very individually tailored to me -- your needs. And anything – if you ask for anything extra, they're always happy do it. I find them extremely very pleasant and very caring and helpful (FG31, Acu+Homeopathy).*

A few participants (n=2) shared their understanding of the importance of individualised treatment.

> *But it [acupuncture] doesn't help everybody. You know, as I was saying, I know people who had acupuncture and say to me, '[09's name], it's [acupuncture is] a waste of time. It hasn't worked on me'. But you see, they don't help themselves afterwards, or it [acupuncture] doesn't help (09, Physio+Acu).*

Horizontal integration with multidisciplinary collaborative teamwork

Many participants (N=13) mentioned their experiences in UCLH and NHNN as they were referred from there, or they were receiving or previously received treatments or assessments in the above hospitals. The research student had difficulties trying to distinguish between treatments/assessments received at the RLHIM from those received in the other two hospitals as participants felt they are the same group of hospitals and should be of interest to the research student.

The research student found that for six individuals, their experiences of integrative treatment could not be separated from the treatments they had elsewhere for their MSDs and those for their other co-morbidities. This also led to more discussion on treatments they received elsewhere.

In one case, the use of the hospital CDR system was mentioned as the participant believed the research student could extract the information that was needed on her treatment from the hospital system.

> *But other than that, I would say, it's fine. And the only thing I didn't have or I don't have, is all the medications that Dr [RLHIM] has prescribed me. So, I'm sure you can get hold of that from the system (40, Homeopathy).*

Treating all aspects of life – whole person/holistic care

Some participants (n=5) stated that the practitioners at the RLHIM considered other aspects of their life apart from their MSDs.

> *Dr [RLHIM] mentioned that my liver function wasn't as good as it might be and I didn't think to ask him (FG12, Acu+Homeopathy+Physio).*

> *55: But what I find, perhaps even there a little bit, but more with the NHS doctors is that when you go to a consultant for a certain issue like the thyroid, they never really look at the body as a whole. They will isolate that body part and only give you treatment for that. Even if you say to them, 'I'm suffering with this', they very rarely connect the whole.*

> *M: Okay, and in this hospital?*

> *55: I- I will say that Dr. [RLHIM] does because he will ask me about my foot, he will ask me about my thyroid and he'll ask me, you know all the things, obviously and he knows my whole history (55, Physio+Homeopathy+Insomnia clinic+MDT/OT).*

Interestingly, in three cases, participants talked about who was taking care of their health: two felt that the practitioners at the RLHIM are taking care of their health, one felt that she was her own health keeper.

> *Dr. [RLHIM] is about the only one that obviously looks at it all (55, Physio+Homeopathy+Insomnia clinic+MDT/OT).*

5.13.4 RLHIM is unique

Some participants (n=8) expressed their feeling that RLHIM is unique and their understanding of differences between the RLHIM and other hospitals. This included different techniques of treatment:

> *Well, in the other hospitals, they pinpoint where you got the pain, so the needles go in where the pain is. Whereas in the integrated hospital, the needles were in certain lines, may not necessary be where the pain is. But it works. In other word, if I got pain in my knee, they can put it [needle] in my ear. Because they were explaining to me that there're so many thousands of meridians, what they call 'lines', where you can feel the sensation up or along the meridians. And to be honest with you [the research student's name], it was a completely different feeling to the acupuncture that I had before. So it was completely different, and I would say, better (09, Physio+Acu).*

It also included differences in general impression of the hospital:

> *But I have to say, generally, I think the standard of care within this group seems to me, is better on the whole than I had elsewhere (F10, Homeopathy+Acu).*

And that it is a NHS hospital that was providing integrative treatment:

> *I think the fact that it's been done by the NHS makes me very favourable. I don't fancy going into some acupuncturist in the high street, I really don't; and I wouldn't. No way where I'd go and see a chiropractor anyway. But I wouldn't if I could. Uhhm, and I think the fact that it is run by the NHS or orthodox medicine, gives it so much more credibility. That's my opinion (FG31, Acu+Homeopathy).*

5.13.5 Interaction between expectations and experiences

By cross checking the framework matrix, the research student noticed all the participants (n=7) who had some negative experiences at the hospital had high hopes to some extent, either in terms of high expectations for the hospital and the practitioners, or high expectations due to the efforts they made to come to the

hospital, or conversely that the treatments they received were not what they had expected.

> *40: For me to come all this way, and a consultant of his standing, I was kind of expecting him to do a little bit more [laugh]…*
>
> *M: you made a lot of effort to come in*
>
> *40: yeah. He kind of didn't put the same effort back, which you know, is disappointing… He [RLHIM practitioner] went to the board, for me. And basically said, 'we got this lady', bla bla bla, and the board said 'no'. And that's probably everybody has been promised. And he doesn't explain, you know? He just goes, 'oh you can't be inpatient because there's not enough funding, rahrahrahrahrah' (40, Homeopathy).*
>
> *I think it was raining that day when we left the hospital. Yeah, it was raining. We were sort of park across the way. And I must just stand there for about an hour. I don't think he even realised it had that effect on me. He didn't realise how desperate I was. He's obviously the wrong person to see (44, Acu+Homeopathy).*

There were also two cases where participants were not confident with what they were going to receive, but had positive experiences.

> *[Treatment] More than met my expectations because as I've said, I was very skeptical about the -- I don't believe in alternative medicine. I'm very orthodox medicine because I don't what it's done for me. It kept me up frightened. And so I was a bit skeptical. And having tried that therapy before that didn't help, uhhm, now it -- I have to say it's more than met my expectations. I'm pleasantly surprised really [Laughter]. I'm grateful (FG31, Acu+Homeopathy).*

5.13.6 Changes in RLHIM over years

Some participants (n=6) who had long term experience of receiving treatment at the RLHIM expressed their understanding of the changes in the hospital over the years, in terms of the referral pathway and funding restraints.

Referral pathway

Participants explained their long waiting time of getting re-referred to the RLHIM. Some participants (n=4) had noticed the change in procedures by not allowing internal referrals, so the only option was to ask their GP to go through the whole process again, which they found to be very time consuming.

> *Unless you are having an ongoing issue, it doesn't really work for it, by the time you get in there, you know, you need to be there 3 months before, which himself [RLHIM doctor] has acknowledged.…Uhmm, and I think, although I'm in the system now, I think my health authority doesn't have a contract here or something or I'm on some very old one. So if got kicked out now, I got to get a new referral in. I won't manage to get acupuncture. But I'm not sure how that would work. I think I might be in difficulty. And there's really no elsewhere to go, not in the NHS. Whether we've still got any NHS left which is another issue but, anyway [laugh] (FG10, Homeopathy+Acu).*

Funding restraints

There were also participants (n=3) who had noticed the cuts in funding in NHS over the years.

> *I know about the budget cuts of the NHS. And I know about the strain on resources and all of that (41, Mindfulness training).*

> *And it's been incredibly efficient you know. I sort of -- with the suggestion of one of the nurses who does the acupuncture, that I'd do it about after I get to session number six or number seven, I put the ball, you know, and start ball rolling so that it would run smoothly and I'd just keep hoping that the funding keeps going for as long as possible because it is certainly helping (FG31, Acu+Homeopathy).*

Summary of experiences at the RLHIM

- Participants received various types of treatments at the RLHIM, among which acupuncture, homeopathy, and physiotherapy were the most commonly received. A range of assessments were received at the RLHIM including blood

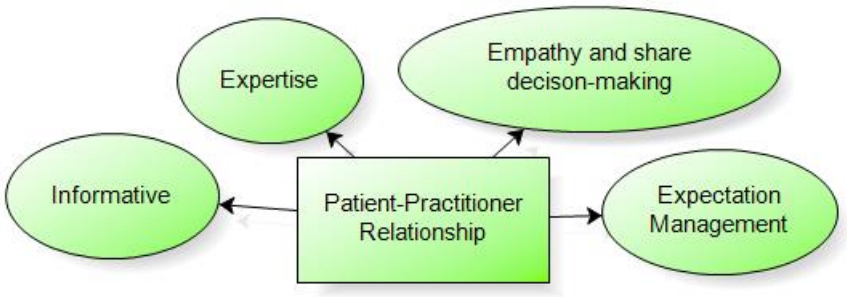
tests, x-rays, weight, blood pressure, MRI, and bone density testing;

- Most participants perceived more positive than negative changes in their MSDs. Frequently perceived improvements were pain relief, better functional movements, feeling relaxing, better sleep, or reducing the medication taken;
- Effects of treatments were reported to be in proportion to their length (longer treatment, better perceived effects);
- Most participants experienced no AEs during their treatments at the RLHIM. Most frequently adverse events occurred when having acupuncture was minor pain, and perceived by participants as "it's the way it goes";
- Individualised treatment was reported to be an important aspect of integrative treatment but small amount of participants felt they received individualised treatment at the RLHIM;
- Participants' experiences at RLHIM, UCL and NHNN could not be differentiated from each other. This might be related to the multidisciplinary teamwork and the integrative treatments for MSDs. Also, treatment for MSDs was not easily separated from that for co-morbidities;
- Some participants had positive experiences from the integrative treatments and believed that they had treatments that considered all aspects of life;
- Participants felt RLHIM was unique in terms of the professional treatments provided, their general impression of it, and that it is covered by the NHS;
- Participants' experiences at the RLHIM and their expectations were inversely related;
- Participants with extensive previous experience at the RLHIM observed changes in the referral pathway and funding restraints at the RLHIM.

5.14 Patient-practitioner relationship

This sub-theme is presented separately to patients' experiences at the RLHIM due to the large amount of time participants discussed and focused on it. There were no direct questions targeted at participants' interaction with practitioners at the RLHIM in the protocol; and this is a sub-theme that emerged in the early stage of this follow-up interview study, when asking about their experiences of the hospital. Therefore, a question was added (from the 8th participant) asking about their interaction with practitioners during treatments and consultations in thereafter. Participants expressed their impression of the practitioners at the RLHIM (Sections 5.14.1&5.14.2), as well as their experiences in communicating with the practitioners (Section 5.14.3) and techniques practitioners used to improve their treatment experiences (Section 5.14.4). This theme is associated with self-directed integrative approach as knowledge availability at the RLHIM influenced the degree participants could care for themselves. It is also associated with the theme living with MSDs as communication with practitioners may influence participants' emotional status as supported by the following discussion in this section. Figure 5.15 shows the sub-themes under the theme ***patient-practitioner relationship***.

Figure 5 15 Sub-themes under the theme patient-practitioner relationship



5.14.1 Informative

Many participants (n=18) stated that the practitioners at the RLHIM explained and provided information to them during the consultation.

> *She [RLHIM nurse] was lovely. She explained everything. She was doing -- walk through what she's going to be doing, talk though the rationale (FG27, Acu).*

In a few cases (n=3), participants expressed feeling grateful that the practitioner shared medical knowledge with them, but felt worried as there was not enough further follow-up input. This is linked to self-care under self-directed integrative approach theme (Section 5.11.5).

> *What I quite like about him [RLHIM doctor] is that he shares – to be honest there're a lot going in my head, but he will share quite technical medical information. And if that's okay, I'll say, 'what does that mean'. He'll explain that. I think the shame for him is that sometimes he knows – he's really very knowledgeable and he recommends stuff that isn't available here. And sometimes I'll go and try find that myself. But I'm not sure what I found is exactly right, or in what kind of dosage to take, if it's not something that the hospital can prescribe. So I find that a slight issue. It might be good if they could have a follow up, because you are not seen for another 4 months. When you really need something, you really don't want to wait 4 months. Say if I found it, but I don't know whether to take it once a day, twice a day, or should I just take a higher dose, or lower dose (FG10, Homeopathy+Acu).*

5.14.2 Expertise

Participants (n=14) trusted the practitioners at the RLHIM as they felt they had professional knowledge which could reassure them and make participants feel understood.

> *I've just seen my practitioner earlier. I'm not travelling to different hospitals to find out exactly what is wrong, and I've got more information in the hour that I've been today, than I have in two years of seeing all different doctors (FG15, Physio).*

> *There's pain here. I can say it's here so they [RLHIM practitioners] know the pain and how to [treat] fibromyalgia spreads pain. So they [RLHIM practitioners] put it [needles] everywhere. It's not like other private treatments; they don't know about this [fibromyalgia]. They might only put the needle to where I say the exact place. That's the thing that's different (13, Acu).*

The others did not comment particularly on practitioners' expertise. In one rare case, a participant with primary progressive multiple sclerosis was given the suggestion to have a warm shower, which the participant felt was an 'absolutely wrong suggestion'.

5.14.3 Empathy and shared decision-making

This sub-theme refers to participants' understanding or experiences of practitioners being empathetic. Empathy represents the ability to understand and share the feelings of another (Oxford Dictionaries, 2015). Many participants (n=14) expressed positive experiences in interacting with practitioners at the RLHIM. These included the idea of being listened to, shared decision-making, and practitioners making equal effort to patients. The words participants used to describe this experience in this research study were 'two-way consultation', 'bedside manner', 'shared decision'. These reflect participants' experiences or their hope of an active interaction with the practitioner, with shared feelings.

> *Most of the practitioners here [RLHIM] appear to be empathetic and compassionate, and so receiving personal attention from them also probably helps one feel better (FG28, Acu+Homeopath).*

> *The thing I found in this hospital is that I was listened to and it's a two-way consultation (FG47, Acu+Homeopathy+Physio).*

> *I saw Dr [RLHIM] last week and he was disappointed that there was no improvement but still he's hopeful. As am I (FG12, Acu+Homeopathy+Physio).*

In some cases (n=7) where participants did not notice changes in their MSDs, they did not blame the practitioner, as they believed that their idea or suggestions were listened to and they made had a shared decision with the practitioners, or they felt they were understood by their practitioners.

> *And as I said, I wasn't keen on doing it [autogenic training] anyway, you know, mentally. He [RLHIM practitioner] sort of, virtually agreed with me, although*

> *he thought it might do some good… But I don't blame him. It's just that my condition is difficult. You know, he tried various things but nothing has done any good (05, Homeopathy+Physio+AT).*

> *To be honest, I couldn't blame Dr [RLHIM 1]. He's the only doctor who was willing to try, to try the neurotherapy. Hmm, and it's something that's not done by people any more. But I've actually spoken to the original doctor who's now quite elderly, who did the trial in neurotherapy up in Scotland thirty, forty years ago. So you know, I did come to the hospital [RLHIM] for the information. At least Dr [RLHIM 1] offered to do it [neurotherapy] (44, Acu+Homeopathy).*

> *Well, they [RLHIM practitioners] understood me and they understand my problem. You know, they feel sorry in the end that, you know, you are only allowed [certain numbers of sessions] (09, Physio+Acu).*

On the other hand, some participants (n=7) had negative experiences as they felt the interaction between the practitioner and themselves was inadequate, or they felt not listened to.

> *He's [RLHIM Dr.] done a lot of blood tests, he's done this, he's done that. But everything he does, I have to ask him to do. I asked him for specific blood test; I asked him to weigh me; I asked him to do my blood pressure. He didn't do that automatically, which – like I say, for me to come all this way, and a consultant of his standing, I kind of expecting him to do a little bit more [laugh] (40, Homeopathy).*

> *I feel not listened to. I feel you don't want to know how I feel. I feel misdiagnosed. Or you come to them, and they have a presumption of your condition from what they are seeing you, what they are treating you for already. So you present them with your symptoms, or you present them with new things. But they don't hear it because it's obviously directed by whatever they are seeing you for already. I don't know how well to explain it… I think sometimes when doctors are seeing patients, they get desensitise themselves and they forgot that we are not commodity. We are actual people, with feelings (41, Mindfulness training).*

In a few cases (n=2), participants felt they were not listened to and this lead to psychological changes, which links this sub-theme to the theme living with MSDs.

I know it sounds depressing but sometimes I just want to run away, you know, sort of – it IS very depressing. But I try not to depress other people with it, you know what I mean. I don't want to depress you guys. And I don't want to depress Dr [RLHIM]. But I do feel the times that I wasn't listened; do you know what I mean? I'm not trying to get sympathy because sometimes people think you are just trying to get sympathy. It's just – there's nowhere for it to come out, you know (FG35, Homeopathy).

5.14.4 Expectation management

During the interviews, some participants (n=6) stated that practitioners they saw at the RLHIM tried to manage their expectations.

They [RLHIM practitioners] are always very good about actually managing your expectations and kind of breaking bad news quite gently. And getting you to realise it is a long term chronic condition, not a cureable issue, and things like that… But it's always done in a very sensitive, quite constructive way here, which is kind of making things better than it can be… But it's that, yeah, at least the fact even people showing interest, you feel, 'right, I know I won't get cured. But you know what? I might manage myself better. I might be able to do more things'. And that's really encouraging (FG10, Homeopathy+Acu).

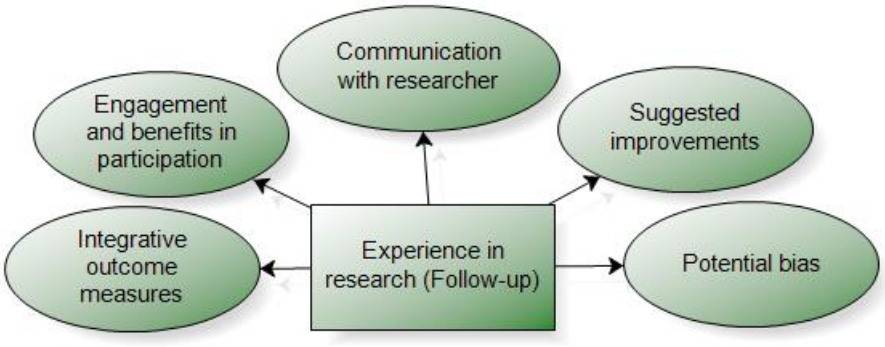
Summary of patient-practitioner relationship

- Practitioners at the RLHIM have professional expertise and some shared information freely;
- Practitioners' empathy and shared decision-making were positively related to participants' having positive experiences, while lack of interaction lead to negative experiences. This sometimes in turn affected participants' mental status;
- In several cases, participants reported that their expectations were managed by practitioners at the RLHIM.

5.15 Feasibility of research study (follow-up)

The theme experience in research contains information generated when asking participants the following question: "What is your experience of taking part in this study?" Relevant data when answering other questions were also coded within sub-themes under this theme. Participants' experiences in completing the outcome measures (Section 5.15.1), engaging in the research study and communicating with the research student (Sections 5.15.2 & 5.15.3), and suggestions in improving the study design and service at the RLHIM (Section 5.15.4) are discussed. At the end of this section, potential bias while interviewing the participants is presented (Section 5.15.5). This theme is associated with the theme living with MSDs. Figure 5.16 shows the sub-themes under the theme ***feasibility of research study.***

Figure 5 16 Sub-themes under the theme experience with the research



5.15.1 Integrative outcome measures

Ease of completing pain scales

The majority of participants (n=25) commented on their experiences completing VAS and sfBPI and the comments of the two tended to be very similar as described as 'pain scales'. Most participants (n=18) felt they were easy to follow and quick to complete; while others (28%, n=7) felt it was difficult to decide a score for their fluctuating pain or felt they were 'too literal', or 'ambiguous'.

M: is there a questionnaire which you think best explained your conditions?

21: well, the first one and the last one. They are quite straightforward and easy and quick to complete (21, Homeopathy+Diet).

I filled in the scale of – because one day it will be very good and one day it's very bad, so what I did is that I just averaged it on how I usually feel. On most days. Hmm, so I just put the average on. I thought it was quite straightforward. (FG7, Acu).

Narrative Approach to explore all aspects of Life

Some participants (n=8) felt that the questionnaires were not sensitive enough to capture all changes they observed, and would prefer a narrative approach by talking with the research student.

I'm able to be more precise [by talking with the research student]. And I think that might be the problem that this [questionnaire] is not precise. And I would say it all depends. Cos every Wednesday at 10 o'clock I feel worse. I'm joking. But you see what I mean [laugh]. It's different day to day, you know. Maybe when I have a bad sleep it will change… But I mean, I think it's a standard problem with trying to fit human being into a square hole. But I can also see that you have to fit these into a computer that has a section specifically you can't have 50 different answers cos you can't analyse them. But that's not my problem [laugh] (20, Homeopathy+Acu).

I haven't had any acupuncture for 10 weeks now. So it is a major change... There's no room for all of that on the form that you sent me (FG6, Acu).

In a few cases (n=4), participants felt that it was necessary to include lots of questions to fully understand their conditions, or felt that changes were slow and subtle and difficult to detect.

No it was perfect, it was fine. Let me put it like this, [the research student's name], I felt it is important because everything that you asked for, you need it. You know what I mean? You can't just ask one question. It's important because with chronic pain, there are so many questions that you have to ask (09, Physio+Acu).

> *I've changed. It's a major difference to the ordinary medicine approach... There's no room for all of that on the form that you sent me. But the changes are slow and subtle from going one direction because the sun's out and spring is in the air (FG6, Acu).*

Various views about mCSRI

Many participants (n=13) commented on the completion of the health economic questionnaire (mCSRI) and all expressed concerns, which included difficulties in remembering several types of treatments they were taking in the previous three months (n=9) and unclear boundaries between conventional treatment and CAM (n=2).

> *And then, how many days did you take it in the last 3 months. Well, 9 out of 10 people with fibromyalgia, they are taking every single day probably for the rest of their life. So, yeah, I don't quite understand that (40, Homeopath).*

> *also, questions 8 and 10 of the mCSRI were quite tricky and very time-consuming, particularly question 8. Some nutritional supplements and homoeopathic preparations can have a lot of different constituents, say a multivitamin. So completing this in full wasn't realistic. I'd prefer simply listing the brand and specific product for the researcher to follow up on the detailed ingredients listings (FG28, Acu+Homeopath).*

On the other hand, some participants (n=7) were interested in the CAM options listed in the questionnaire and saw them as suggestions to try in the future.

5.15.2 Engagement and benefits in participation

Most participants (n=22) had positive experiences of the research study during the year. But answers tended to be very short, stating they were 'fine' with participating. Some participants (n=11) stated that they benefited from participating in the research study.

In terms of it helped with self-reflection, advice/information from patients with similar conditions or from the questionnaires, and feeling better 'mentally' with the research or hospital environment.

> *Actually I found the questionnaires quite good. It made me think what I've had in the past few months and how I felt. I didn't think about it until I really looked into what precise treatment I had (FG7, Acu).*

> *Uhhm, I'd probably say I don't get a lot of support at home; mentally, physically, really, anyway. I'm quite often made to feel I'm a burden. If I say anything, I'm only talking about myself. I could go on forever [Laughter]. I think I'd finish that up actually. So, yeah, when I'm here, I would feel mentally better. Yes. Maybe because I'm away from my environment. It could be that (FG31, Acu+Homeopathy).*

The interaction among participants in the four focus groups, led to shared experiences (4/4 FGs), seeking confirmation (3/4 FGs), providing information (3/4 FGs), as well as emotional changes such as feeling assured when discussing with their peers (2/4 FGs).

> *In normal circle, people think you are bloody mad! 'why the hell you got problem with that!?' But if you are around other people, say with fibromyalgia, or got all these musculoskeletal issues or chronic pain, and you find you actually have a lot of similar issues. And that's a BIG BLOODY RELIEF!... And when I come here, it's like, I almost just physically relax as I enter the building. (FG10, Homeopathy+Acu).*

In a few cases (n=3), the participants expressed wishing to provide positive feedback to support the research study. This might lead to possible research bias which is discussed later.

> *I think basically to try help the situation in the hospital and the funding situation; and to gather information, to show the service offered, the treatment offered – actually do have a beneficial effect. So I think I was quite strategic really, in, in my participation. I just thought, 'well, anything I could do to support it or help'. And the government is looking to cut funding for complementary therapies. … I just wish I had more money and didn't just have Prince Charles propping them up and uhmm, because I do wonder, a bit like you*

were saying, if you haven't had this treatment, you're not sure if you were still able to walk. If I haven't had this hospital, I'm sure I'd still be around in one way or another of course, but I wonder how much more incapacity it might be (F10, Homeopathy+Acu).

I mean, I did this study because I thought that was important. You know, this hospital has been threatened with closure several times. And if this could help in any way, to show that musculoskeletal in homeopathic treatment helps, then I'm very happy to do it (F47, Acu+Homeopathy+Physio).

In one case, a participant expressed her wish to secure treatment by participating in research, although this was not the goal of this particular treatment.

I think more of an emphasis [in the study] upon actually securing treatment would have been helpful and what happens when a patient is not able to carry on receiving treatment or accessing it in the first place. Having said this, I realise that this was not central to your research study, although I think it is a big feature of the patient's experience of treatment at the hospital (FG28, Acu+Homeopathy).

5.15.3 Communication with researcher

Most participants (n=23) expressed that they had a good experience with the research study and the research student. They found the study process, including being recruited, being sent the information sheet and consent forms, and the communication with the research student was good.

I think your approach has been perfect. You've been very friendly (FG31, Acu+Homeopathy).

And I thought, you know, you asked questions as well about all the paper work. I thought you are very clear about our participation and making clear that it's voluntary. You know, made it known that we will come back and ask questions and so – and I was quite sure about the confidentiality and anonymization and so. So no, I was very happy to take part (FG10, Homeopathy+Acu).

Text and email were the two most commonly recommended contact methods by the participants (n=8).

It's all great. You are a good communicator by email, post and text. I can understand you and I can better plan my time that way (34, Homeopathy).

5.15.4 Suggested improvements

Some participants gave suggestions to improve research design (n=6), which included giving feedback to the practitioners who they were seeing (n=5).

It would be great if you can give feedback to Dr [RLHIM] on my progress as only in that way this could be beneficial for us, isn't it? Also, I'd like to know if I'm expected [to come to his clinic] or not (44, Acu).I think if Dr [RLHIM 2] asked about this. You can just tell him, the patient came across very angry. But I was angry because clearly he hadn't read my notes and he didn't know anything about MS (44, Acu).

And providing assessment within the study (n=1).

And I am happy to have an assessment included and possibly questions on fibromyalgia and family history might help, cos I think my mum is a sufferer [of fibromyalgia] but has never been diagnosed. My sister and cousin also have fibro (48, Homeopathy+Hypnosis/CBT).

In one focus group, suggestion was also given to improve the hospital service by having a support network available to patients who have similar experiences at the hospital (n=1).

One thing this hospital doesn't do, and I know there are support group out there, but if they do more sign posting to sources of support, or even have like patient user group... But you'll be interested if the hospital could perhaps kind of provide some support network. Cos often I know it is really interesting in the pharmacies. 'Oh I had a really good discussion. Shall we swap numbers', and then you go away and you don't – perhaps if something is organised, once a month or once every 2 months people could come along. And you don't have to make the way yourself. All you have to do is show up (F10, Homeopathy+Acu).

5.15.5 Potential bias

As discussed in Chapter 1 (Section 1.3), the research student was born and educated in China, had a background in traditional Chinese medicine. She noticed that

participants sometimes gave further explanations to her, to explain a certain term, or certain events that the research student may not be familiar with. During the interviews, some participants (n=7) asked certain questions regarding the research student's background, or sought therapeutic information and advice.

> *So, you come from a different culture, and obviously, you come from a wonderful country China. Have you got any pain relief that's better than the pain relief [05's name] gets because I don't know how she lives with this level of pain. Not occasionally, but every single day, wakes her husband up during the night, being very pleased for her life to come to an end… Can you think of anything we don't have, but you have in China? (05's friend, Homeopath+Physio+AT).*

Summary of experience in research

- Participants suggested integrative outcome measures, including simple pain scales and a narrative approach including questions targeting all aspect of life, in order to understand participants' chronic complex MSDs;
- A range of concerns were expressed on the utility and appropriateness of mCSRI (difficulties with recall, unclear boundaries between conventional treatment and CAM); however, some participants found the CAM options in mCSRI inspiring;
- Participants had positive experiences participating in the research study; they benefited from self-reflection, acquiring information from patients with similar experiences, and some felt it helped them mentally;
- Benefits from focus groups included sharing experiences, seeking confirmation, providing information, and feeling assured;
- A few participants reported wishing to provide positive feedback to support the research and the hospital, or help the research student which may have biased the results;

- Participants had positive experiences in communicating with the research student and taking part in the research process. Most participants liked to be contacted by text or email;

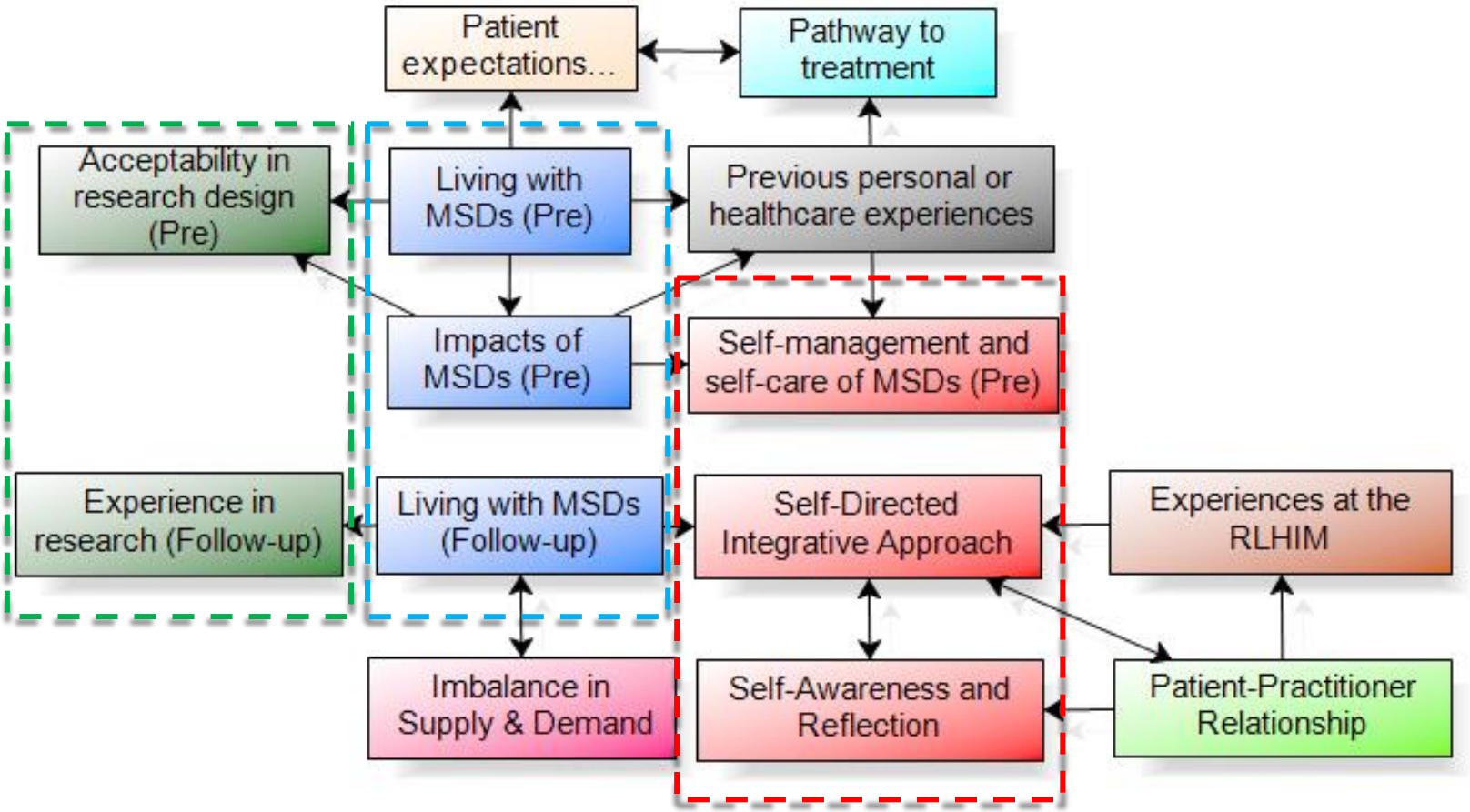
- Participants gave various suggestions on how to improve the research design and also the hospital services, including: sending feedback to practitioners, providing medical assessment/examination in the research study, and to improve the support network at the RLHIM;

- The research student's background was asked about during the interviews, which may have introduced some bias.

5.16 Summary of pre-treatment and follow-up interview results

As stated previously in this chapter (aim and structure), some sub-themes generated from the follow-up interviews (Sections 5.9-5.15) are similar to the sub-themes generated in the pre-treatment interviews (Sections 5.2-5.8). These similarities existed particularly in themes stating participants' experiences living with MSDs (Sections 5.2, 5.2 &5.9), their perceptions in self-management (Sections 5.5, & 5.10, 5.11), and their acceptability and experience in participating in this research study (Sections 5.8 & 5.15). Therefore, before triangulating and merging the quantitative and qualitative results, qualitative results from the pre-treatment and follow-up interviews in these three categories are compared and summarised with final qualitative results generated. This comparison and merging process involved the research student's interpretation and should be interpreted with caution as the two sets of qualitative interviews were conducted with not the exactly same group of participants and at different time points. Figure 5.17 shows where most of the overlaps in the pre-treatment and follow-up interviews were.

Figure 5 17 All themes developed from the pre-treatment and follow-up interviews



5.16.1 Comparison in participants' MSDs experiences and impact

Comparing the results of pre-treatment and follow-up interviews reveals that participants tended to report more about their life experiences with MSDs and how their life was affected by MSDs in the interviews before they received treatment. This may because of direct questions regarding their MSDs and their impact in the pre-treatment interviews. However, a new sub-theme emerged in the follow-up interviews about how participants adapted their life to MSDs, and shared more understanding of MSDs and how their understanding could influence the progress of MSDs. A summary of sub-themes identified on living with MSDs with overlapping sub-themes in pre-and-follow-up interviews presented in bold; different/additional sub-themes identified are presented not in bold (This rule is applicable throughout Sections 5.16.1-5.16.3).

- **Various MSDs** (Pre: with unclear diagnosis)
- **Chronic** (Pre: polypharmacy associated)
- **Co-morbidities**
- **A hidden disability** (Pre: with inadequate publicity awareness)
- **Fluctuating physical and emotional symptoms**
- **MSDs affected participants' life physically and emotionally**
  (Pre: relationship with family and friends, ability to work and financial impact)
  (Follow-up: adapt life to MSDs; understanding of MSDs)

5.16.2 Comparison in self-management

Self-care and self-management were seen as important in both pre-treatment and follow-up interviews, but participants tended to report more techniques in the follow-up interviews, especially on various CAM self-care techniques, and more control in their integrative and prolonged care which could have resulted from practitioners or directed by the practitioner they saw. In the follow-up interviews, participants shared their self-awareness and self-reflection, which was not common in the pre-treatment interviews.

- (Follow-up: accepting the consequences; importance of self-help; self-validation; experiencing discrimination)
- **Self-care includes various exercises and healthy eating** (Follow-up: TENS, acupressure, homeopathic tablets and massage; inadequate guide)
- **Self-management strategies include plan daily activities, get distracted, and self-learning**
- (Follow-up: Self-directed integrative and prolonged treatment)

5.16.3 Comparison of the acceptability and experience of the research

Participants' acceptability of outcome measurements in pre-treatment and follow-up interviews were similar, participants preferred the same two pain scales, and consistently felt that mCSRI was their least preferred outcome questionnaire. In the follow-up interviews, participants reported having CAM options listed in the mCSRI as helpful. They also suggested a narrative approach, in order to get the whole picture of their MSDs. Participants' decision making process in participating in the research study was consistent before and after.

- **VAS and sfBPI were preferred** (Follow-up: narrative was preferred)
- **mCSRI was the least popular** (Follow-up: although it provided some CAM options which were useful)
- **Participated to support research and help other patients** (Pre: no expectation)

5.17 Chapter Summary

This chapter presented the qualitative results of the feasibility study. Both qualitative data collected at pre-treatment and follow-up provided original and detailed results targeting different aspects of patients' perspectives on receiving integrative treatments for MSDs at the RLHIM: one focused on participants' expectations and the other focused on participants' experiences. Patients experiences in participating the research study are also summarised in this chapter.

Participants' had a variety of MSDs with most of them experiencing widespread pain all over their body priory to their treatment at the RLHIM. Patients had physical and

emotional symptoms and their MSDs tended to be associated with polypharmacy and poor general health. MSDs often affected all aspects of participants' quality of life.

Most participants had tried various types of conventional treatments and found more disadvantages than advantages in taking them. 57% of participants (n=16) had previous experiences in CAM treatments in either the NHS or privately, mainly acupuncture and massage being the most beneficial treatments. These participants perceived physical benefits from using CAM treatments but found private clinics unaffordable. Participants' self-help techniques included various types of conventional exercises; distraction from their MSDs, self-learning and understanding their MSDs, and carefully planning daily activities to suit their MSD. Participants' decision making processes to try CAM and how they came to receive treatment at RLHIM varied. Most were pleased with the time they waited to get referred but felt that ease and timeliness of referral depended on a number of factors.

In the pre-treatment interviews, participants' expectations prior to their initial treatment at the hospital were extensively explored. The terms expectation and hope were used inconsistently in interviews, with most believing that they had pragmatic and realistic expectations of the treatment. Most participants had no concerns about their impending treatments at the RLHIM and were aware of the treatment they were expecting and hoped for. Participants hoped to have better health in terms of symptom relief, improving functional ability, and to be able to reduce medication; they hoped to receive individualised, non-invasive treatment through having optimum treatment, and treating their conditions' root cause. Participants also expressed their hopes for better communication with RLHIM practitioners and engagement in the treatments; they expected RLHIM practitioners to be skilful professionals, working in conjunction with other healthcare professionals. Long term effects with more follow-up CAM treatments on a regular basis were also hoped for.

The follow-up interviews explored participants' experiences of receiving integrative treatments for their MSDs at the RLHIM. Similarly, these participants had various types of chronic MSDs and other co-morbidities, associated with various symptoms that affected a wide range of aspects of their life. During the interview, they shared their understandings of MSDs and how they were affected by them, with small number of participants feeling their MSD was a hidden disability. Participants who had a long term relationship with MSDs had generally accepted and adapted their life style to MSDs and were aware of the importance of self-help. Healthy eating, planning schedules ahead of time, distraction techniques, and attending social events were some of the strategies participants used to manage their lifestyle.

There was high demand for integrative treatments at the RLHIM and participants felt practitioners were under stress for the amount of work required. Participants received various types of treatments and a range of assessments at the RLHIM with more positive than negative experiences. Frequently perceived improvements were pain relief, better functional movements, feeling relaxed, better sleep, or reducing the medication taken. Participants believed that practitioners at the RLHIM are professional experts who share information with their patients.

In terms of the feasibility of performing the research study, participants took part in the study because they felt research is important and they wanted to help other patients with similar conditions. They generally had positive experiences in taking part in the study. Although participants claimed that they had no concerns about participating in the research study, physical barriers were observed during the interviews. VAS and sfBPI were the most acceptable outcome measures due to their simplicity and being less time consuming to complete, while the mCSRI was the least acceptable outcome measure, with difficulties reported in recall details and some sensitive questions. A narrative approach including questions targeting all

aspects of life was also suggested. Various suggestions were given to improve the study design and the hospital service.

Findings on patients' expectations and experiences of receiving integrative treatments at the RLHIM, and their expectations and experiences in participating in the research study have been presented in this chapter. Further interpretation and triangulation with the quantitative findings (Chapter 4) are presented in the Chapter 6.

Chapter 6 Integration, Comparison and Triangulation of Quantitative and Qualitative Results

Aims and structure

In line with the convergent mixed methods design described in Section 3.1.1, this chapter integrates, compares and triangulates the results of the quantitative and qualitative data reported in Chapters 4 and 5. These data provide details concerning the feasibility as required and outlined in the MRC framework for complex interventions. It provides some answers regarding whether it is feasible to carry out a mixed methods study on integrative treatment for MSDs in the UK.

Previously in Section 3.1.2, the approach taken to determine the feasibility of the research study was explored in relation to four main issues adapted from the Bowen's feasibility framework: perceived outcome of integrative treatment (Section 6.1); their acceptability of, and demand for integrative treatment for MSDs at the RLHIM (Sections 6.2 & 6.3); and practical issues regarding study design (Section 6.4). In addition, the quantitative and qualitative dimensions used to guide the reporting of this mixed methods feasibility study are presented alongside the four issues (O'Cathain *et al.*, 2015; Shanyinde *et al.*, 2011).

This is achieved by providing the QUAN and QUAL results using side-by-side comparison tables with evidence provided for each issue of feasibility (tables 6.1-6.4). In the side-by-side tables, column one and two represent the four feasibility issues and sub-dimensions based on the findings of the research study; column three and four represent the dimensions of quantitative and qualitative data; column five represents the final triangulated findings. The extent of congruency and divergence between the two sets of results are discussed for each dimension. Justification of how the final results are generated from the two strands is provided in each section for each of the Bowens's four issues of feasibility.

In order to generate explicit findings of the mixed methods feasibility study, this chapter only presents triangulated findings from these two strands. Its implications and further interpretation and implementation for future research are discussed in detail in Chapter 7. Findings that are based on the research student's interpretation or reflections on conducting the research study are mentioned, if related, but discussed in Chapter 7.

6.1 Limited-outcome testing

This section compares and summarises the findings on interventions provided for MSDs at the RLHIM and the outcomes of the interventions provided. Potential factors that may be associated with the treatment effects are also explored (table 6.1).

This mixed methods feasibility study explored the existing integrative NHS services routinely provided for people with MSDs at the RLHIM (row 1). QUAN and QUAL findings appeared to concur that MSD patients received a variety of integrative treatments; and that acupuncture was the most frequently received treatment, followed by homeopathy and physiotherapy. QUAN results provided additional information regarding the complexity of the treatment provided, especially in terms of the length and the numbers of modalities involved. QUAL results provided additional information on receiving diagnostic assessments and patients' understanding of treatment (row 2). Diagnostic assessment is an essential part of the IM practice and it is recommended that it should be explored and reported in future research. The unit costs of treatments provided by the hospital during this research study could not be provided and were not made available to the researcher (row 3).

Both QUAN and QUAL results demonstrated improvements in pain severity, physical function, and emotional status (row 4). QUAN findings provided preliminary evidence for the sample size calculation for pain severity, physical and emotional function at four, eight, and 12 months. This would depend on the future study design especially any control group(s). Additional QUAL findings reported by participants included changes in medication usage (reductions), minor but acceptable AEs experienced, changes in the way of thinking and adapting to living with their MSDs.

There were several components that appeared to potentially influence the effects of the integrative treatments provided for MSDs (row 5). QUAL results suggested a relationship between length of treatment and treatment effects, while QUAN results showed that positive changes may peak at four months but were maintained at up to 12 months. The QUAL participants were a sub set of QUAN participants that represented 60% (28/47) of the whole participants and only seven of these felt the treatment effects were associated with the length of treatments they received. As a sample size of seven was too small to run any robust statistical analysis, subgroup

analysis of the QUAN data for this group was not conducted. QUAN findings tended to suggest being non-smoker was a positive indicator of better pain severity improvement; while QUAL findings suggested individualised treatment, multidisciplinary collaborative teamwork, a holistic approach treating all aspects of life, and the patient-practitioner relationship were key components of the integrative treatment package. Since this research study was an exploratory uncontrolled feasibility study, none of these suggested components can be definite predictors of treatment effects. A larger sample size to explore the relationship between treatment effects and patients' lifestyle as a potential predictor, and a qualitative study to further explore these suggested components is warranted.

Table 6 1 Triangulation of QUAN and QUAL findings: limited outcome testing

F*		QUAN Dimensions	QUAL Dimensions	Triangulated Findings
LIMITED OUTCOME TESTING*	Intervention content and delivery	**1. Intervention development***** To what extent does the planned intervention need to be refined or adapted to make it more acceptable to users or more relevant or useful to the specific context in which it is delivered? This issue was irrelevant to this research study as the mixed methods feasibility study assessed the routine clinical practice in providing integrative treatment for MSDs at the RLHIM, rather than developing a new integrative treatment package.		Explored existing integrative treatment for MSDs at the RLHIM.
		2. Intervention received Acupuncture, homeopathy, and physiotherapy were the most commonly received. Length, frequency and type of treatment varied between participants (Section 4.4).	**Interventions received** Participants received various types of treatments at the RLHIM, among which acupuncture, homeopathy, and physiotherapy were the most commonly received. A range of assessments were received at the RLHIM. Services provided at the RLHIM were integrative with the services at UCH and NHNN. Many participants reported their expectations were managed by practitioners at the RLHIM (Section 5.13.1).	Patients received varied complex diagnostic and therapeutic integrative treatments, which involved expectation management and horizontal integration with other hospitals outside the RLHIM
		3. Cost and duration of intervention** Was it possible to calculate intervention costs and duration? Cost data were collected using the mCSRI but not analysed because unit costs from the RLHIM were unavailable to the research student. In addition the completion rate of the mCSRI was low and patients disliked completing it. Mean number of sessions of treatments received was 11.5, from one-off treatment to treatments lasting more than 12 months.		It was unclear how much the integrative treatments for MSDs cost at the RLHIM during the period of the research study follow-up.
	Outcome	**4. Sample size calculation**** Effect sizes in pain, physical, emotional function, as measured by: VAS: 4m=0.615, 8m=0.490, 12m=0.574; sfBPI pain severity: 4m=0.628, 8m=0.499, 12m=0.523; sfBPI pain interference: 4m=0.400, 8m=0.440, 12m=0.546; SF36 physical: 4m=0.326; SF36 emotional: 4m=0.388, 12m=0.350 (Section 4.7).	**Breadth of outcomes***** Do some trial participants feel that they have experienced or noticed improvements in some outcomes that need to be included in the full trial? Participants experienced improvements in pain, physical and emotional function, and reduction in medication taken. Treatment produced minor but acceptable AEs. Participants who had a long term MSD accepted and adapted life to their MSD (Section 5.13.2).	Potential improvements in pain severity and HRQoL at 4 months, sustained at 12 months; reduction in medication use. Effect sizes provided preliminary evidence for sample size calculation. Treatment produced minor but acceptable AEs. Patients accepted and adapted their life to MSD.

F*		QUAN Dimensions	QUAL Dimensions	Triangulated Findings
	Potential factors associated with outcome	**5. Potential predictors of outcome** No relationship between length, complexity of treatment, or location of pain for primary outcome. Those participants who were non-smokers and those who had greater pain at baseline showed significantly better improvement in pain severity at four months: F(2, 44)=7.914, p=0.001, R^2=0.265; A higher expectation at baseline had greater decrease in expectation at four months: F(1, 45)=9.218, p=0.004, R^2=0.170 (Section 4.9.2).	**Intervention components***** How do the intervention components and delivery processes work in the real world? Consider the different aspects of the intervention and which are fixed and flexible. The intervention may be different in practice from the planned intervention and may need to be documented so it can be delivered consistently in the full trial. Several components were suggested important by participants including: • Length of treatment (Section 5.13.2) • Individualised treatment (Section 5.13.3) • Multidisciplinary collaborative teamwork (Section 5.13.3) • Treating all aspects of life (holistic) (Section 5.13.3) • Patients' expectation (Section 5.13.4) • Patient-practitioner relationship (Section 5.14) Participants shared their understanding of MSDs mechanism and possible psychological associations related to their MSDs (Section 5.9.4). They were aware of the importance of self-help and a self-directed integrative approach; they received options for self-care techniques from the RLHIM (Section 5.16.2 summarised from 5.5&5.10). It was anticipated that all patients would be triaged from a MSK physician. Potential patients referred through BMAS and 'choose and book' service were missed. **Mechanisms of action***** How might the intervention be working? How might it produce the outcomes important to the trial? Data collected to address these questions may be interpreted in relation to the theory upon which the intervention is based or may help to develop new theory. Participants perceived that their positive experiences of integrative treatment were associated with the components stated above.	Larger samples are needed to explore lifestyle and life styles changes as predictor s of integrative treatment effects. Qualitative studies to explore associations between treatment effects and individualised treatment, holistic approach, patient-practitioner relationship, multidisciplinary collaborative teamwork, and self-help are warranted.

*indicates the four issues in feasibility (Bowen *et al.*, 2009); ** indicates methodological items suggested for reporting quantitative feasibility study (Shanyinde *et al.*, 2011); *** indicated dimensions suggested for reporting qualitative feasibility study (O'Cathain *et al.*, 2015); N/A: Not available

The explanations of dimensions (texts in table in blue) were designed for reporting trials or qualitative research along trials. However, these feasibility frameworks are not restricted to trial therefore were used as a guide in this mixed methods study in reporting feasibility.

6.2 Acceptability of integrative treatment

This section presents participants' decision making process, their acceptability of the referral pathway, their adherence to intervention, and their acceptability of receiving integrative treatment at the RLHIM (Table 6.2). There were various reasons which prompted patients to decide to seek CAM treatments but the main reason participants sought treatment at the RLHIM was that they believed the practitioners were qualified, knowledgeable professionals (row 1). This finding on patients' decision making processes was only based on QUAL results and there were no QUAN results to support or refute this.

There was approximately 1.5 months between participants getting referred to the RLHIM to them receiving their initial appointment (QUAN) and this was perceived to be acceptable by participants (QUAL) (row 2). Additional QUAL results indicated that participants encountered initial difficulties in getting referred to RLHIM; and shared their understanding about possible factors/barriers and the ease of referral to the RLHIM. The research student subsequently explored the quotes of participants who were referred from different boroughs (presented in Section 4.3). QUAN results show that 37% of participants' GPs belonged to North East London CCG, which tended to agree the QUAL findings that the postcode where they lived /or their GP was registered may have affected their chances of obtaining a referral to the RLHIM. Further interpretation was carried out to explore whether there was a high demand for treatment at the RLHIM, which proved to be true as presented in the next section (6.3).

Patients' adherence to treatment appointments was good over the 12 months follow-up (QUAN) (row 3), and the acceptability of the integrative treatment provided at the RLHIM was considered good as evidenced by congruent QUAN and QUAL findings (row 4). Good adherence and retention indicated the treatments provided were acceptable (QUAN), while QUAL findings suggested good acceptability in terms of benefits perceived in symptoms relieved and positive experiences with practitioners. QUAL findings indicated that both practitioners and patients themselves played important roles in the treatments provided at the RLHIM, therefore practitioners or healthcare professionals' perceptions about how they provide integrative treatments at the RLHIM are warranted (in Section 7.7.2). Due to the uniqueness of the

integrative treatments provided for MSDs at the RLHIM, these findings may represent the specific situation within NHS secondary care, and should be interpreted with caution.

Table 6 2 Triangulation of QUAN and QUAL findings: acceptability of integrative treatment

F*		QUAN Dimensions**	QUAL Dimensions***	Triangulated Findings
ACCEPTABILITY	Decision	**1. N/A**	**Decision to seek RLHIM treatment** Participants decided to try CAM treatment because of their families and friends and their relationship at the suggestion of healthcare professionals, previous conventional treatments not helping, personal knowledge or interests. Having qualified, knowledgeable professionals were the main reason participants came to the RLHIM (Section 5.6.1-5.6.3).	Various reasons enabled participants to decide to seek CAM treatments; having qualified, knowledgeable professionals was the main reason participants came to the RLHIM.
	Referral	**2. Acceptability of referral pathway** Though not directly assessed, mean time interval between referral & 1st appointment: 44.0 (24.9) days. GPs location: NEL (37%), non-NEL CCG (27%), outside greater London (37%).	**Acceptability of referral pathway** Most participants accepted the amount of time they had to wait for a referral. Many experienced initial difficulties in persuading their GPs to refer them to the RLHIM. They believed it was due to a lack of access to CAM services, caused by a lack of funding. Participants felt which borough they were in and who referred them were two main aspects affected whether they could get referred (Sections 5.6.4&5.6.5).	44 days referral time was felt to be acceptable. Participants experienced difficulties in getting referred; potential factors influencing referral were where and from whom they were referred.
	Intervention	**3. Adherence to intervention**** Did participants adhere to the intervention? Initial appointment cancelled/changed (by hospital or patients): 9/60 (15%). Overall cancelled/changed: 26/60 (43%). Apart from three participants, all attended all treatments.	**N/A**	Although there were some cancel/changes in schedule, there was good adherence to treatment appointments.
		4. Acceptability of intervention** Was the intervention acceptable to the participants? Despite not directly assessed, high rate in cancelled/changed appointments but good adherence to interventions (above, row 3) and good retention at 12 months (Table 6.4, row 9) indicated good acceptability.	**Perceived value, benefits, harms or unintended consequences of the intervention***** What value do service providers and intervention users place on the intervention and the outcomes it plans to deliver? What benefits and harms do they feel they have experienced from the intervention so that these can be measured in the full trial? Participants perceived benefits in symptoms relieved (Table 6.1, row 4) with minor acceptable AEs (Section 5.13.2). A few participants had positive experiences in sharing experiences with the Friends volunteers (Section 5.13.7). Practitioners perceived by patients were professional expertise who shared information, interacted with patients, and tried to manage their expectations (Sections 5.14.1-5.14.4). Patients took an important role in their intervention as they actively involved in lifestyle management; were the main driver/direct of seeking consistent follow-up treatment; played an important role in an optimum package of treatment; and treated themselves using a range of CAM self-care options (Sections 5.11.1-5.11.5).	Positive experiences with practitioners, perceived benefits, and good adherence to treatment indicated good acceptability of integrative treatment at the RLHIM. High cancelled/changed but good adherence. The MSD service at the RLHIM was unique and should be interpreted carefully when used in other settings.
			Acceptability of intervention in principle*** Are service users or health care providers unhappy with any aspect of the content or delivery of the intervention? #Healthcare providers' experiences of the integrative treatment provided were not explored in this research study and are recommended for future study (Section 7.7.2).	

F*	QUAN Dimensions**	QUAL Dimensions***	Triangulated Findings
		Feasibility and acceptability of intervention in practice*** What are service users or health care providers' views of the implementation of the intervention? Has implementation varied by setting? Are there any important intervention-context interactions? Should implementation be tailored by setting? Intervention implementation was irrelevant to this research study as the mixed methods feasibility study assessed the integrative treatment for MSDs already provided at the RLHIM, rather than developing an integrative treatment package. The integrative treatment service for MSDs was perceived as unique in terms of the professional treatments provided, their general impression of it, and that it was covered by NHS (Section 5.13.6); #Healthcare providers' experiences of the integrative treatment provided were not explored in this research study and are recommended for future study (Section 7.7.2).	

*indicates the four issues in feasibility (Bowen *et al.*, 2009); ** indicates methodological items suggested for reporting quantitative feasibility study (Shanyinde *et al.*, 2011); *** indicated dimensions suggested for reporting qualitative feasibility study (O'Cathain *et al.*, 2015); N/A: Not available

6.3 Demand for integrative treatment

This section presents the findings on participants' demand for integrative treatments at the RLHIM (Table 6.3). Findings on the four dimensions: living with MSDs, previous personal or healthcare experiences, participants' expectations and hopes, and imbalance in supply and demand are presented. The first two dimensions (rows 1&2) are stated in this section as they are related to participants' demand for integrative treatment, and will help understand the reasons behind the demand.

Most patients had complex musculoskeletal pain (QUAN), and their MSDs tended to be chronic, associated with polypharmacy and co-morbidities, and affected all aspects of life and they felt this needed more public awareness (QUAL) (row 1). Patients' diagnoses were unclear as ICD codes were unavailable for most participants, therefore the identification of the conditions were only based on the patient-reported location of pain (QUAN). QUAL results complement the QUAN results and provided information on participants' life experiences with their MSDs.

Findings on patients' previous healthcare experiences were purely based on QUAL results, suggesting that their previous conventional healthcare experiences were not satisfactory; some had previously benefited from CAM treatments but found them unaffordable (row 2). It is worth noting that patients' previous consultation histories were partially available on the hospital system but not explored quantitatively as it was not part of the initial study design protocol and subsequent ethical approval.

Patients' MSD experiences and their previous healthcare experiences potentially influenced their expectations. QUAN and QUAL findings complemented each other showing that patients felt their expectations were pragmatic and realistic (7/10 on the hospital at the same time, although these expectation VAS), and tended to be consistent over 12 months (row 3). Higher expectations tended to be associated with poorer treatment experiences (QUAL). While QUAN findings showed no change in expectation score over the 12 months' period, QUAL findings provided useful additional information on what exactly participants expected or hoped for; and their needs in more IM services

There tended to be an imbalance in supply and demand of integrative treatment provided for MSDs at the RLHIM (row 4), which was supported largely from the QUAL results. QUAN findings available were limited, however 37% patients travelled from outside of greater

London. Patients were given 11.5 sessions (median) of integrative treatment during the 12 months' period. This approximately once per month treatment was regarded by patients as insufficient as evidenced by QUAL findings, suggesting that the treatments were in demand in terms of variety and quantity. They felt thankful to have treatment at the RLHIM and felt the practitioners were working under stress due to an imbalance in supply and demand. Potential reasons for the imbalance were substantiated by patients (QUAL).

Table 6 3 Triangulation of QUAN and QUAL findings: demand for Integrative treatment

F*		QUAN Dimensions**	QUAL Dimensions***	Triangulated Findings
DEMAND FOR INTERVENTION*	Living with MSDs	1. All participants had pain: 35% had widespread pain, 25% low back pain, 12% knee pain; 18/60 primary ICD codes not available (N/A); 60/60 secondary ICD codes N/A.	Most participants had various and multiple chronic MSDs; they believed that MSDs were associated with polypharmacy and co-morbidities; fluctuating symptoms affected all aspects of their life. Some participants had an unclear diagnosis; Some felt MSDs were 'hidden disabilities' with inadequate public awareness (Section 5.16.1 summarised from 5.2, 5.3 & 5.9).	Chronic MSDs tended to be associated with polypharmacy and co-morbidities, affect all aspects of life and need more public awareness.
	Previous personal or healthcare experiences	2. Partially available from the hospital but was not collected as this was not included in the protocol or included in the ethical approval	Participants had extensive experiences with various types of conventional treatments for their MSDs and some other health issues, and were concerned about AEs caused by conventional therapies, especially in the long term and with their co-morbidities (Section 5.4.1&5.4.2). Nearly half of the participants had no experience of CAM previously. Most participants who had CAM/IM treatments previously experienced physical and emotional benefits and improved quality of life. They were becoming reliant on CAM but felt private clinics ere unaffordable and the effects worn off (Section 5.4.3-5.4.5). Participants felt there was a lack of communication with previous practitioners (Section 5.4.6).	Participants had extensive experiences in various conventional treatments but were concerned about AEs in long term; they had previously benefited from CAM treatment but felt they were unaffordable; they felt there was a lack of communication (not restricted to CAM or conventional).
	Expectations and hopes	3. Participants' expectation score pre-treatment: mean (SD): 7.17 (1.579). No significant change during the 12 months follow-up: $F(3, 138) = 1.647$, $p=0.181$.	Most participants believed they had pragmatic and realistic expectations (Section 5.7.2); they had no concern in their upcoming treatments apart from travelling far and difficulties in getting re-referrals (Section 5.7.3); while they did have some difficulties in getting referrals (Section 6.2, row 2). Most participants were aware of what treatment they were going/hoped to receive; they hoped to have better quality of life with meaningful activities in long term; they hoped to receive more integrative treatments with individualised, non-invasive treatment that adopted optimum treatment, treat their conditions from the root, and to better communicate with skilful practitioners and engage in the treatment (Sections 5.7.4-5.7.8). Participants' pre-treatment expectations and their follow-up experiences at the RLHIM were inversely related (Section 5.13.4).	Participants felt they had pragmatic, realistic expectations which seemed to be consistent over 12 months, but tended to be inversely related to their follow-up treatment experiences. Participants hoped IM would alleviate symptoms and improve quality of life; they hoped to have more IM services.
	Imbalance in supply and demand	4. Though not directly assessed, 37% participants travelled from outside greater London (Section 6.3.3) may suggest RLHIM treatment was in demand; A median of 11.5 sessions/patient were provided over 12 months (Section 6.2.1)	**Dose of intervention***** Is the right amount of the intervention getting to the right recipients in the right way? Integrative treatments at the RLHIM were in demand in terms of availability of different types, amount of sessions, and length (both consultation and follow-up sessions) of CAM treatments provided for their chronic complex MSDs; and input on self-help information (Section 5.12.1). Participants felt practitioners were under stress with the amount of work required (Section 5.12.2). They perceived having integrative treatment at the RLHIM as a 'precious opportunity' and felt there was a lack of funding resources and that was the reason for inadequate amount of treatment (Sections 5.12.3&5.12.4). Participants' with extensive experience at the RLHIM observed changes in the referral pathway and funding restraints at the RLHIM over time (Section 5.13.5); Participants felt RLHIM was unique in terms of the professional treatments provided, their general impression of it, and that it is covered by NHS (Section 5.13.6).	Patients perceived the integrative treatments provided at the RLHIM were in demand.

*indicates the four issues in feasibility (Bowen *et al.*, 2009); ** indicates methodological items suggested for reporting quantitative feasibility study (Shanyinde *et al.*, 2011); *** indicated dimensions suggested for reporting qualitative feasibility study (O'Cathain *et al.*, 2015); N/A: Not available

6.4 Feasibility of research design

This section details twelve dimensions addressing the practical issues in the feasibility of conducting this mixed methods research. It mainly focuses on two categories: aspects of study design, conduct and processes (row 1-10), and aspects of outcome measures (row 11&12) (Table 6.4). Final findings presented in the Table 6.4 are mostly generated from both QUAN and QUAL findings as they complemented each other, with QUAN findings giving precise data and QUAL findings explaining how and why. A few dimensions are generated solely from one strand: a). Solely QUAL findings on study participation (row 5) and impact of study on staff, the researcher, participants, and the health system (row 9), and b). The research student's reflections and experiences in conducting this research, included: issues in identifying eligible patient (row 1), the feasibility in carrying out multicentre study (row 7), and reflections on patient involvement (row 10).

Being ineligible for recruitment into the study was mainly due to unexpected staff turnover and issues in reliance on administration staff and clinicians potentially missing identifying MSD patients within their busy clinics (row 1). Recruitment was very difficult (37%) and the reasons patients participated in this research study varied, mainly due to the desire in supporting IM research (QUAL) (row 2). However, it was unclear whether the participants would have been willing to be randomised or not. Retention (78%) over 12 months was acceptable and encouraging (row 3). In this research study, patients were not purposively sampled and were recruited sequentially. The majority were middle aged, female, Caucasian, with a higher educational background (QUAN). They were also a group of patients who were with chronic complex MSDs and were aware of the importance of self-management, healthy lifestyle and self-care (QUAL) (row 4).

Findings on patients' perceptions and experience of taking part in research were solely based on the QUAL results. Their positive experiences with the research student, and their experiences of the process of participation including; being contacted, providing informed consent, and arranging appointment was acceptable. QUAL findings also suggested that patients felt that they had benefited from participating and provided their opinions on how the research could be improved (row 5&6).

The logistics of running a multicentre research study (row 7) and the fidelity and reach of intervention was not assessed (row 8) in this feasibility study as this research study evaluated an NHS routinely delivered integrative treatment service at the RLHIM rather than developing an intervention. Findings from this research study can be used in future IM research at the RLHIM or in similar settings but needs to be interpreted with caution (details in discussion Section 7.7.2). Potential impact on patients and practitioners, and advantages of having a patient involved suggested by this research study are worth considering in future research (row 9&10). Future study exploring patients' acceptability in randomisation, and qualitative research exploring healthcare providers' experiences in study recruitment are warranted (discussed in Section 7.7.2).

Convergent QUAN and QUAL findings tended to indicate that the outcome measures selected in this research study assessed and captured main concerns of patients (row 11). The completion of outcome measures were considered successful (row 12) as evidenced by good completion rates. Additional QUAL findings provided details in what they believed were key in capturing their MSDs; and patients' acceptability in completing the cost questionnaire was less positive.

Table 6 4 Triangulation of QUAN and QUAL findings: feasibility of study design

F*		QUAN Dimensions**	QUAL Dimensions***	Triangulated Findings
FEASIBILITY OF RESEARCH DESIGN*	STUDY DESIGN, CONDUCT AND PROCESSES	**1. Eligibility**** What factors influenced eligibility and what proportion of those approached were eligible? 161 patients were eligible. Several issues in identifying eligible participants occurred due to unexpected staff turnover and issues in reliance on administration staff and missed identification of some potential patients (discussed in Section 7.5).		Ineligibility was mainly due to nothaving MSDs and potential failures in identifying patients.
		2. Recruitment** Was recruitment successful? 121/161 eligible patients not willing to take part; Changes in administration staff at the RLHIM may influence recruitment. Two major ethical revisions were applied to improve the recruitment rate (detailed in Section 7.6.4)	**Recruitment***** How do the planned recruitment practices work in the field? Do recruitment practices need to be improved to increase recruitment rates and levels of informed consent? If so, how? Are the trial participants willing to be randomised? Are clinicians willing to recruit patients, or are they uncomfortable? Reasons for participating included to support research, help other patients, and to help the research student (Section 5.16.3 summarised from 5.8.2). Though participants claimed that they had no concerns participating in the research study, some physical restrictions were noticed during the interviews; Participants had no clear expectation for the research study and their expectation seemed to be associated with their decision to participate (Sections 5.8.3&5.8.4). Randomisation was not assessed due to the design of this mixed methods feasibility study; #Healthcare providers' experiences in study recruitment were not explored in this research study and are recommended in future study (Section 7.7.2).	Recruitment was very difficult, mainly due to administration changes; and participants having physical restrictions.
		3. Retention** Was retention to the study good? 10%, 17%, and 22% dropped out at 4, 8, and 12 months (Section 4.1).	**Retention***** Are there ways in which trial procedures could be improved to increase retention rates? Five participants dropped out from the quantitative study but were interviewed at the 12 months, but no obvious sub-theme identified these from other participants (Section 4.1).	Retention over 12 months was acceptable and encouraging. There was no clear feature for loss follow patients.
		4. Participants' characteristics Most of the participants were middle age, married, female, married, white British, native English speakers Christian; with a most common education level as college/diploma level or above. 68% participants were not working full time or retired and 78% were professional/technical/skilled. Most participants were in chronic widespread pain, LBP or knee pain (Section 4.2).	**Diversity of participants***** Are the planned recruitment practices likely to result in recruitment of the desired range of participants for the trial? If not, how might recruitment practices be improved? Participants with chronic complex MSDs (Table 6.3, row 1); had a basic understanding of self-management and self-care (Sections 5.5.1-5.5.5).	Most patients were middle age English, with a higher educational background, who were with chronic complex MSDs and were aware of the importance of self-management, healthy lifestyle and self-care.
		5. Acceptability in research procedures **N/A**	**Trial participation***** How is the planned trial communication implemented by recruiters and received by participants? How can trial communication be improved to ensure recruiters understand patients' views about participating in the trial? Participants had positive experiences in communicating with the research student regarding the research process (Section 5.15.3). The MSK physician (who helped identifying eligible pstients)'s perspectives were not explored and worth researching in future study (recommended in section 7.7.2).	Participants' experiences in the research process were acceptable; they perceived some benefits in participating and suggested several improvements to the study.

F*	QUAN Dimensions**	QUAL Dimensions***	Triangulated Findings
		Acceptability of the research study in practice*** Is the trial design acceptable to patients, recruiters and service providers in practice, or are there ways in which participants try to alter the procedures? The research study helped participants self-reflection; they reported benefits particular from focus groups in sharing experiences, seeking confirmation, providing information, and feeling assured (Section 5.15.3). Participants were happy to be contacted by text or email by the research student (Section 5.15.4). Participants suggested improvements to the research study included: sending feedback to their practitioners, providing medical assessment/examination in the research study, and to improve the support network at the RLHIM (Section 5.15.4).	
		Acceptability of the research study in principle*** Is the trial design acceptable to patients, recruiters and service providers in principle? According to acceptable retention rate, it was anticipated that participants' acceptability was generally good.	
	6. Consent** Did eligible participants consent? 60/161 (37%) consented	**Ethical conduct***** Are the informed consent procedures appropriate and acceptable to likely trial participants? No theme particular identified on participants' acceptability on informed consent procedures but their general experiences of participating were good (Section 5.15.3).	Low conversion to consent
	7. Logistics of multicenter** Were the logistics of running a multicenter trial assessed? This has not been assessed		
	8. All components of the protocol work together** Did all components of the protocol work together? Another primary outcome measure: VAS was added; participants were selected sequentially due to difficulties in recruitment; cost data were not analysed as part of this research study.	**Fidelity and reach of intervention***** Do those delivering the intervention and/or receiving it adhere to the **planned** intervention? If not, what are the reasons for this? What are the limits of acceptable tailoring of the intervention? Since this research study evaluated a developed integrative treatment service at the RLHIM rather than developing an intervention, fidelity and reach of intervention was not assessed.	Minor revisions to the pre-set protocol; Fidelity and reach of intervention was not assessed.
		Adaptation of research study conduct to local context*** Will the planned trial procedures allow the trial to operate effectively in the proposed context? Do any changes need to be made to these procedures? Findings of this research study can be used in future IM research at the RLHIM or in a similar setting. A few participants wished to provide positive feedback to support the research. Details of changes recommended are in Section 7.7.2.	
	9. Impact of research **N/A**	**Impact of trial on staff, researchers, participants and the health system***** Does this trial have any unanticipated negative impacts on recruiters, participants, other stakeholders and the health system? How can these impacts be minimised (e.g. workload involved in recruitment, numbers of measures undertaken)? Participants felt practitioners were under stress with the amount of work required (Section 5.12.2). One participant asked to be withdrawn from the research study (discussed in Section 7.6.4). # Further qualitative study with recruiter and stakeholders to explore their acceptability in recruitment, numbers of measures undertaken are recommended (Section 7.7.2).	There were potential impacts on patients and practitioners caused by the research study

F*		QUAN Dimensions**	QUAL Dimensions***	Triangulated Findings
		10. Patient and public involvement*** How is patient and public involvement best achieved in the trial? One patient representative (RP) was involved in the study design (Section 3.1).		Patient representative involved
	MEASURES	**11. Selection of most appropriate outcomes**** Were outcomes measured those that were the most appropriate outcomes? VAS, sfBPI, and SF36 captured changes in pain severity, pain interference, and HRQoL over 12 months (Section 4.7).	**Selection of outcomes***** Are outcomes important to service users selected for measurement in the full trial—both primary and secondary? Pain severity and interference and quality of life were important for participants as most of them had chronic various MSDs and co-morbidities, with pain and physical and emotional symptoms, affecting all aspects of their life. This required them to adapt life to their MSDs (Section 5.16.1 summarised 5.2&5.9).	Outcome measures tended to assess main issues patients concerned; VAS and sfBPI, and a narrative approach were preferred.
		12. Outcome assessment** Were outcome assessments completed? Questionnaire completion was good at 12 months: VAS, sfBPI and SF36: no missing data for completers. 77% completed the mCSRI at 12 months. Cost data were collected (mCSRI) but not analysed mainly due to unit costs from the RLHIM being unavailable to the research student. Thirty participants were interviewed pre-treatment; 28 at follow-up.	**Accuracy of measures***** Are the process and outcome measures valid for this participant group? See below row**.**	PROMs completion and interview attendance were good over 12 months Cost was not assessed but quantitative data were collected, participants' acceptability in the mCSRI were discussed; Participants had individualised length of intervention PROMs in integrative treatment targeting patients' holistic HRQoL are warranted.
			Completion of measures*** Can completion rates of measures be improved? How outcome measure completion rate can be improved was not directly asked in interviews, participants reported that they felt measures that were easy and quick to understand, and the opportunity to talk (a narrative approach) were preferred as questions can target all aspects of life are needed to understand participants' chronic MSDs. The contents in mCSRI were inspiring but wording can be improved; Participants also expressed difficulties in remembering what they spent in past three months, and found unclear boundaries between conventional treatment and CAM (Section 5.16.3 summarised from 5.8&5.15).	
			Development of measures*** If validated measures do not exist for all the outcomes to be measured in the full trial, can they be developed in preparation for the trial? VAS, sfBPI, and SF36 tended to be appropriate outcome measures (Section 4.7), however, PROMs on integrative treatment that capture holistic aspects of patients' conditions are warranted.	

*indicates the four issues in feasibility (Bowen *et al.*, 2009); ** indicates methodological items suggested for reporting quantitative feasibility study (Shanyinde *et al.*, 2011); *** indicated dimensions suggested for reporting qualitative feasibility study (O'Cathain *et al.*, 2015); N/A: Not available

#Refers to future research that can be done, which are discussed in Section 7.7.2.

6.5 Summary of findings

This chapter presented the final triangulated results on the feasibility of carrying out a mixed methods study within an existing integrative treatment programme for MSDs at the RLHIM. Results showed that complex integrative treatments, including diagnostic assessment, expectation management, and horizontal integration provided at the RLHIM had the potential to produce moderate pain relief and improved HRQoL at four months, which was sustained (with smaller effect size) at 12 months. Effect sizes of PROMs at different time points provided preliminary data for future sample size calculation. Integrative treatments produced a few minor but acceptable AEs. Through this treatment process, participants accepted and adapted their lifestyle to MSD; and had an increased awareness on a self-directed integrative approach. Possible key components that may be associated with treatment effects were; lifestyle, complexity of treatment, level to individualisation, holistic approach, patient-practitioner relationship, multidisciplinary collaborative teamwork, and self-management.

Patients had experienced some difficulties in getting referred, while their acceptability of the integrative treatment was generally good. This was evidenced by acceptable referral time, good adherence to treatment appointments, positive experiences and perceived benefits in what they hoped from receiving the integrative treatments. Patients' acceptability on treatments received may be associated with their decision making process. In this research study, the reasons patients seek CAM treatments varied, but having qualified, knowledgeable professionals was the main reason participants came to the RLHIM. Therefore, qualifications and theoretical background of practitioners may be worth exploring in future research as this may affect patient expectations and outcome.

Patients' demand for integrative treatment for MSDs was explored. Their personal or healthcare experiences in MSDs were potential influential factors of patients' expectation and hopes. Most patients had chronic MSDs associated with polypharmacy and co-morbidities. All aspects of life were affected by their MSDs and patients suggested more public awareness needs to be available. Patients' previous unsuccessful conventional healthcare experiences enabled them to seek CAM treatment, which they benefited from and some became reliant on, but they felt were unaffordable with their health conditions. Patients felt their expectations were pragmatic and realistic and they seemed to be consistent over 12 months, and their expectations tended to be inversely related to their follow-up treatment experiences. Patients hoped for symptom alleviation and improvement in quality of life with IM care, and hoped to access self-help information. These expectations and hopes may potentially have an impact on their demand for treatments at the RLHIM. Patients hoped to receive more availability in types of integrative treatments, with more sessions, and longer length in consultation; and felt practitioners were under stress from the amount of work required. These all indicated a short supply of integrative treatment for MSDs, patients perceiving it being due to a lack of funding resources.

In terms of the practical issues in the feasibility study design, ineligibility was mainly due to not having MSDs and potential failures in identifying patients. Recruitment was very difficult as it heavily relied on administrators at the RLHIM, while the retention over 12 months was acceptable and encouraging. With a low conversion to consent, the sixty patients recruited in this research study may not be representative to population with different socioeconomic background as most of the patients were middle age, female, Caucasian, with a higher educational background. They tended to be aware of the importance of self-management, healthy lifestyle and self-care. This may be a self-selected group of patients, so findings should be interpreted with caution if this research was to be conducted in other settings.

Patients' experiences of the research process and communication with the research student were reported as acceptable and often complimentary. They felt that the research study helped them with self-reflection and feeling assured. They also benefited from sharing experiences and information in focus groups. Findings also suggested VAS, sfBPI, and SF36 tended to assess main issues patients concerned, which were the alleviation in symptoms and improvements in quality of life. The completion rate of these PROMs and interview attendance were good over 12 months. Patients preferred VAS and sfBPI, and a narrative approach to capture their conditions holistically. The mCSRI was perceived too long but patients found the CAM treatments listed in the form inspiring. Minor revisions made to the pre-set protocol should be noted.

Some recommendations are given based on the feasibility aspects. Firstly, future research should use larger samples to explore lifestyle as a predictor of integrative treatment effects for MSDs. Quick-to-complete PROMs targeting integrative treatment for patients' holistic HRQoL are warranted. Some of the wording of the mCSRI needs to be revised to be more comprehensive for participants. Patients' recommendations on being contacted through text or email, sending feedback to their practitioners, providing medical assessment/examination in the research study, and improving the support network at the RLHIM are worth consideration. In future research, the logistics of running a multi-centre research, the fidelity and reach of integrative treatment, and the randomisation procedure should be assessed. Costs of the integrative treatment for MSDs should be compared over time. In addition, qualitative research exploring the association between suggested components and treatment outcomes, and the potential impacts on patients and practitioners caused by the research study is suggested.

Chapter 7 Discussion and Conclusion

Aims and Structure

This chapter answers explicitly the two research questions specified in Section 1.5; and discusses how these aims were achieved by comparing and contrasting with current available literature. Sections 7.1-7.5 discuss the results of the mixed methods feasibility study presented in Chapter 6 and related them to the findings from the reviews presented in Chapter 2. Specifically, an IM model is proposed in Section 7.1. Sections 7.2-7.5 discuss the feasibility of the research study focussing on four pre-specified aspects of feasibility: limited outcome testing, acceptability, demand for integrative treatment, and feasibility of the study design (Section 6.1-6.4).

Reflections on strengths and limitations encountered in conducting this research study are discussed (Section 7.6). The significant contributions to knowledge are highlighted in Section 7.7, and implications for research and IM practice and future directions are presented (Section 7.8), and the thesis ends with a conclusion about the whole study (Section 7.9).

By adopting the complex intervention framework suggested by the MRC, this research study was able to add new knowledge by exploring the theoretical understanding of IM and assessing the feasibility of carrying out MMR on integrative treatment for MSDs in a secondary care NHS setting. The results of these steps lead to the future evaluation stage of the MRC framework by informing a definitive pragmatic trial.

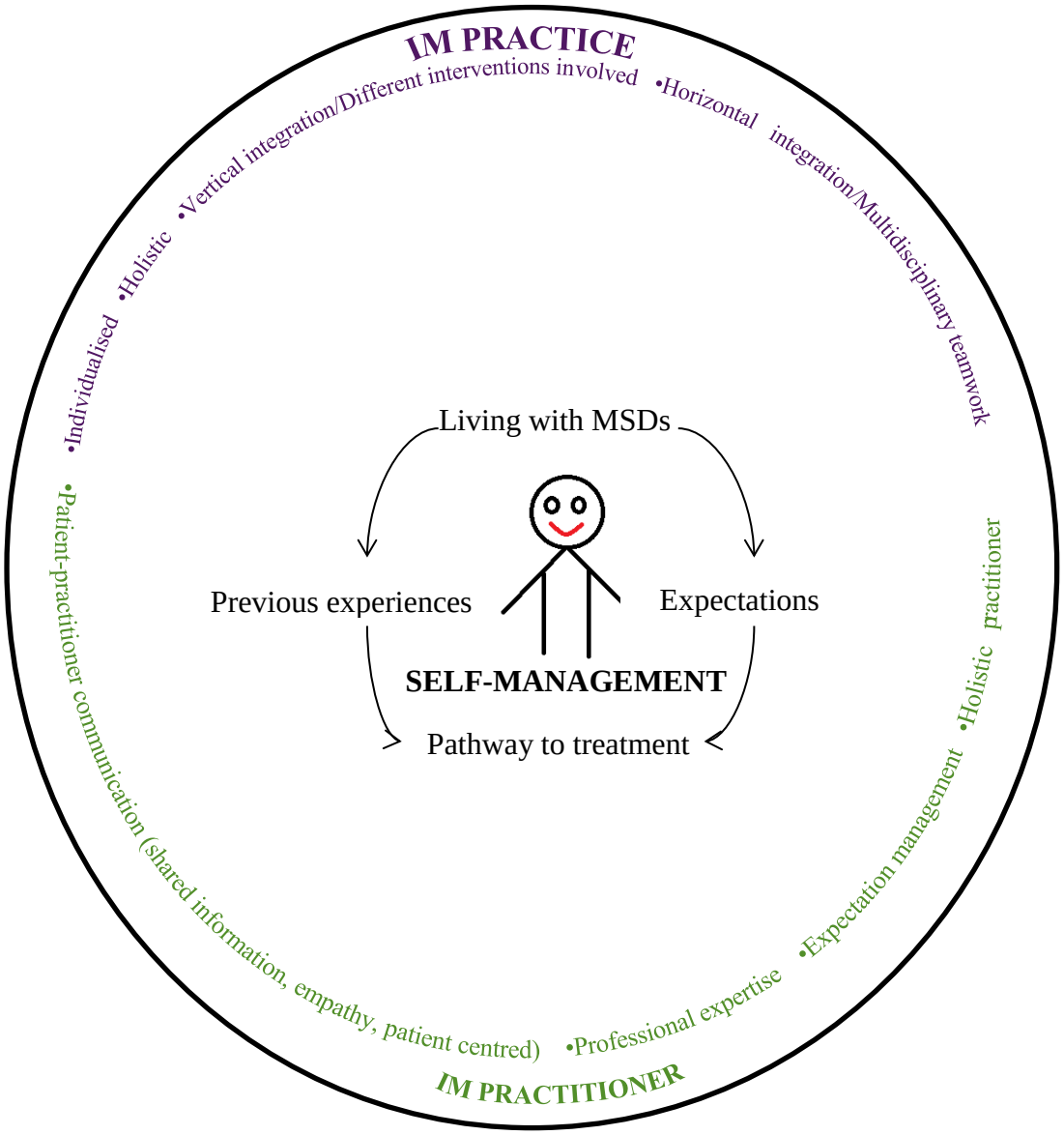
7.1 An integrative medicine model for musculoskeletal disorders

This section summarises the potential key components of IM generated from findings identified from the patients' perspectives (Chapter 6), a comparison and discussion in relation to the key components of IM as identified from IM definitions in the mapping review, and hypothesising a specific IM model for MSDs. Using this

approach, findings from the feasibility stage helped in interpreting and elaborating the discussion on the available IM components that is already available in the literature. This approach allowed information on modelling the components of IM, which has been suggested to be essential in complex intervention development stage in the MRC framework.

The IM model hypothesised in this study may provide a template to: guide further evaluation of IM practice, provide indicators and suggestions for monitoring the service at the RLHIM, or provision in other similar settings for MSDs (Figure 7.1). The suggested IM model consists of two parts: the inner circle represents the importance of a patient centred self-management approach for IM (Section 7.1.1); while the key IM components around the central figure are categorised into two groups: IM practice, and IM practitioners (Sections 7.1.2&7.1.3). These reflect the components previously identified from the mapping review (Section 2.2), and the many components identified as important in IM definitions in the literature and reported as being essential by patients in this research study. Explorations of the different sections of the model are discussed in detail.

Figure 7 1 The proposed integrative medicine model for MSDs



Key: The central figure represents the influences experienced by an individual

7.1.1 Self-directed integrative care

Patient's self-direction is essential in their IM journey. The way they direct or manage themselves was associated with their personal and healthcare experiences, expectations, and their pathway to treatment (Figure 7.1, central part).

This research study suggested that by receiving integrative treatment at the RLHIM, patients improved their basic understanding of MSDs and how their treatment and/or self-help techniques could help their MSDs. This in turn appeared to empower them to become their own "health keeper". The realisation of the importance of self-help, along with the received information on self-care techniques from the RLHM may enable patients to actively engage in their MSDs journey. A self-directed integrative approach is considered essential for the management of widespread pain, especially when patients are likely to have various co-morbidities. This tended to influence their healthcare experiences, their expectations, and their pathway to treatment. The findings from this research also showed that non-smokers had significantly better improvements in pain scores at four months (Section 4.8). The majority of patients were non-smokers and non-drinkers, and this might indicate that patients with healthier lifestyles are potentially more actively engaged in health-seeking behaviours and self-management. This in turn may be associated with positive treatment outcomes. This seems to suggest that IM and self-help go hand in hand. A previous systematic review investigated the effectiveness of CAM self-care approaches to treat chronic pain conditions; and similarly showed preliminary positive evidence for treatments such as yoga, qigong, tai chi, acupressure, TENS, and relaxation (Delgado *et al.*, 2014), which were beneficial and acceptable to patients (Cramer *et al.*, 2013; Eyles *et al.*, 2015). Attention to self-care using IM for a complex condition together with the investigation of the effectiveness of individualised self-management has been suggested (Delgado *et al.*, 2014).

The importance of self-management was insufficiently emphasised in the IM definitions identified in the mapping review (Section 2.2.3). Given that self-help approaches were not initiated as part of treatment received in this research study, future research should explore this aspect in detail using a mixed methods approach.

7.1.2 Integrative medicine practice

Complex conditions therefore require an individualised diagnosis and treatment that holistically targets all aspects of life. Investigating complex integrative care packages in a holistic manner or as a whole systems approach is becoming more recognised by researchers (Verhoef *et al.*, 2004). As identified from the mapping review (Section 2.2.3), 71% of IM definitions emphasised individualised and holistic approaches as key components of IM. Findings from the feasibility study showed patients valued being treated as individuals and having a consultation with their hospital practitioners which focussed on their expressed needs. Similar research in an NHS setting (Glasgow Homoeopathic hospital, now the Centre for Integrative Care), has also demonstrated the benefits of an individualised and a whole person approach (Mercer and Reilly, 2004). However, integration at diagnostic level, which has been suggested as being an important element in IM in the mapping review (Section 2.2), has rarely been reported in research (Hu *et al.*, 2015b). Receiving diagnostic support and excluding pathology were suggested as the main reasons patients seek conventional care (Andersson *et al.*, 2012). Patients tend to seek CAM treatments after they have received a diagnosis, mainly to ensure CAM treatments would not interfere with their conventional treatments; or to ensure there was no sinister pathology before receiving CAM treatment (Raphael *et al.*, 2003; Nayak *et al.*, 2003).

The RLHIM has developed clinical services emphasising integration vertically, including various diagnostic assessments and various types of treatments with

different combinations, doses, lengths and frequencies, self-care and working closely with primary care (Sections 6.1&6.2). Although in the mapping review a high proportion (76%) of IM definitions emphasised the combination of CAM and conventional interventions in IM practice (Section 2.2.3), in the feasibility study, more than half of the patients received only one type of treatment at the hospital (Section 4.4). This indicated that although patients received different treatments, there was a lack of variability in the different combinations and these were only provided to a small number of patients at present in the RLHIM. It was unclear what patients may receive outside the hospital at the same time, although these were captured during interviews and in the mCSRI. An IM research study in the USA, where CAM is more integrated to main stream healthcare, observed treatment for pain at nine integrative clinic sites with non-standardised individualised treatments, and provided a larger variety of combination of treatments, with some patients receiving eight types of IM interventions and most receiving four IM interventions (Abrams *et al.*, 2013). However, whether patients felt individualised treatments were successfully delivered was not explored (Abrams *et al.*, 2013).

Individualised and holistic treatments have been suggested to be key features of personalised care (Tarrant *et al.*, 2003). Previous research has particularly emphasised the importance of individualised care in complex chronic conditions that required health services from multiple providers (Lion et al., 2014). Assessing and documenting individualised care is problematic and challenging (Kärkkäinen *et al.*, 2005). Mixed methods designs have been used to assess individual patients' experiences and outcomes in receiving various individualised integrative care (Seers *et al.*, 2009; Bronfort *et al.*, 2012; Nichol *et al.*, 2013; Lagesen, 2014). Findings on the association between individualised management and outcome remain sparse (Lion *et al.*, 2014) but are worth emphasising and testing in future research.

Considering the needs for individualised and holistic care, providing a complex IM model of treatment is seldom achieved by a single practitioner and usually requires multidisciplinary teamwork with practitioners either from different departments in the same hospital, or practitioners working in different settings (Beswick *et al.*, 2008). The RLHIM horizontal integration strategy aims to promote collaboration in secondary and tertiary care, with clinical partners from other parts of UCH, such as the integrated pain service developed in collaboration with the Eastman Dental Hospital or that with the NHNN, where acupuncture, hypnotherapy, homeopathy, and autogenic training are provided to complement conventional treatments; an integrated antenatal service in collaboration with the Elizabeth Garrett Anderson Hospital (Fisher, 2015; Royal London Hospital for Integrated Medicine, 2015). Although these collaborations were reflected in the findings of this research study, and some patients were referred from partner hospitals, patients believed that they could get a better chance of referral if they were referred through a doctor from partner hospitals of the RLHIM (Section 6.2). As identified from the mapping review (Section 2.2.3), less than a quarter of the IM definitions emphasised the importance of a collaborative approach in IM. This indicates that integration in partner hospitals with a systematic collaborative teamwork is occurring in the UK, but this has not been sufficiently reflected in IM definitions and may not be well recognised as an essential component of IM. Bridge-building activities including the connection between research and clinical facilities, positive promotion of partnership and co-location of practices should be established for creating bonding between members of teams internal as well as externally in different health professions (Gaboury *et al.*, 2012; Dobos and Tao, 2011; Gamst *et al.*, 2006; Haahr and Launso, 2006; McCarty *et al.*, 2012).

Collaboration between multidisciplinary teams is also an essential aspect of IM practice. Healthcare managers are essential in IM interprofessional collaborations. In

normal practices, it is common that patients find difficulty in choosing who to consult among various professional groups, which may involve exposure to competitive and conflicting claims on legitimacy and risk (Tovey and Adams, 2001). Therefore, it is important that healthcare managers are aware of the usage of potential multiple practitioners, and are prepared to discuss and communicate with their patients before and at commencement of their treatment (Broom *et al.*, 2012). The system in both establishing leadership roles and responsibilities when CAM and CM practitioners collaborate within an IM system is still ambiguous (Gaboury *et al.*, 2012). Some CAM practitioners are against and distrust IM because they believe that CAM might be 'co-opted' or 'adopted' by CM (e.g. physiotherapists adopting acupuncture) (Tovey *et al.*, 2003). However, one of the key challenges for interprofessional collaboration in IM is preserving the epistemological stance of CAM when it is used with other disciplines (Chung *et al.*, 2012). The perceived power differential between the two paradigms needs to be reduced to promote interprofessional collaboration in IM (Chung *et al.*, 2012).

7.1.3 Integrative medicine practitioner

IM practitioners play a vitally important role in ensuring the degree of integration achieved (Maizes *et al.*, 2009). In this research study, some patients benefited from active communication with their practitioners, with shared information and patient centred empathetic care; while patients who had negative experiences at the RLHIM tended to have less interaction with their practitioners (Section 6.2). 71% IM definitions identified in the mapping review emphasised the importance of patient-practitioner communication (Section 2.2.3). IM providers have the responsibility to ensure the creation and maintenance of best treatment plans for patients (Shelley *et al.*, 2009) and the patient-practitioner relationship has been acknowledged as having an important therapeutic role and should be integral to clinical practice (Rao *et al.*, 2007). Since IM is not simply the process of simultaneous use of CAM and

conventional medicine, the value of open communication is essential between individual practitioners and among patients (Brien *et al.*, 2011). A systematic review showed practitioners who adopt a warm, friendly, and reassuring manner provided more effective treatments than those who keep consultations formal and do not offer reassurance (Di Blasi Z *et al.*, 2001). Meaningful communication that makes patients feel heard and respected was suggested essential to fostering lifestyle change (Maizes *et al.*, 2009), which may offer a better method to encourage a self-directed integrative approach to patients. Research has also demonstrated a clinically significant effect for acupuncture provided with empathic consultations compared to non-empathic consultation (White *et al.*, 2012) and benefits in compassion and caring, explanations and information, and shared decision making with patients (Mercer and Reilly, 2004). However, there is often misunderstanding and insufficient communication between practitioners and patients about the use of IM, particularly when 'who is the health keeper' is unclear. This may lead to inefficient care and could harm patients (Hsiao *et al.*, 2006). Therefore, early input in delivering complex interventions from healthcare providers must avoid poor communication between clinician-initiated and patient-initiated treatments.

Another important aspect in IM practitioner identified in this research study was practitioners being professional experts who were qualified and had the knowledge of IM (Section 6.2). Nearly half of the patients felt the practitioners they were seeing had the appropriate professional knowledge, which could make them feel reassured emotionally. Being seen by medically qualified professionals at the RLHIM was one of the main reasons patients reported coming to the RLHIM (Section 6.2). It has been suggested that IM should be led by 'dual-trained' practitioners who are familiar with the two divergent clinical paradigms as it allows them the ability of sharing a similar coherent conceptual framework (Hsiao *et al.*, 2006). Therefore, education units that run courses on IM for qualified practitioners and healthcare managers may

improve the development of IM. Currently, the education department of the RLHIM runs various courses for all statutory registered healthcare professionals (UCLH, 2015a). A course on integrating complementary medicine in everyday practice, focusing on six types of therapies including acupuncture, herbal medicine, homeopathy, nutrition, manual medicine and autogenic training is already provided (UCLH, 2015a).

Patients' expectations have increasingly been taken into consideration as a major determinant of patients' satisfaction (McKinley, 2002). Findings from this research study suggested that patients noticed improvements associated with practitioners managing their expectations (Section 6.1), and a high expectation tended to be positively associated with a lowered treatment satisfaction (Section 6.3). It has been suggested that lowering patients' expectations might be one of the ways of avoiding disappointment, if this is appropriately managed. Managing expectations is perceived essential in patient centred care and may improve outcome by ensuring highest quality healthcare delivery (Lateef, 2011); and could minimise the risk of confusing patients by offering different answers or suggestions by different healthcare professionals (Baker, 2011). Interviewing practitioners may help better understand whether expectation management is part of their integrative treatment strategies and their understanding of its contribution to treatment effects (further discussed in Section 7.8.1).

A holistic patient centred approach is an essential component not only to the intervention process, but also in providing an appropriate referral pathway and a patient friendly setting. In some IM organisations, it is recommended that practitioners design their own "self-wellness plan" based on their experience (Greater Lawrence Family Health Centre, 2013). Sufficient consultation time in a welcoming setting that values human beings over technology and encourages patients' involvement was highly valued by patients receiving integrative treatments,

and was considered essential in providing patient centred care (Mercer and Reilly, 2004). However, patients in this research study reported otherwise as practitioners were perceived as being under pressure. The 2014/2015 RLHIM audit reported a maximum of 40 minutes as the standard pharmacy waiting time for completion of prescriptions which is needed to ensure the accuracy, compliance with all legal requirements, and double checking of patients' names and labels on issued prescriptions (Berkovitz, 2014). Broader acknowledgement and the importance of a patient centred care between practitioner and the hospital setting are important and should be an open dialogue as receptionists, and facilities are part of the service for patients (Maizes *et al.*, 2009).

Section 7.1 discussed the IM components perceived important by patients in the mixed methods feasibility study. Active engagement in a self-management and a self-directed integrative approach was considered as a central key component in their IM journey. The importance of considering individualised holistic care with different treatment options, multidisciplinary teamwork and cooperation between different departments or partner hospitals were discussed. Patients valued communication with knowledgeable, empathetic practitioners who were happy to share information in a patient centred way, and were holistic individuals. They also benefited from expectation management by the RLHIM practitioners. These key IM components represented the opinion of patients who received IM service for MSDs in this UK secondary care NHS setting which shared many similarities with the theoretical basis of IM as evidenced in the mapping review. These components are worth exploring in future research, so that the connections between them and their potential contribution to treatment outcomes can be better understood. This has been further discussed in 7.7.1.

7.2 Improvements in patient outcomes

The IM model at the RLHIM and the complex integrative treatments delivered appeared to produce moderate pain relief and improved HRQoL at four months, which was sustained (with a smaller effect size) at 12 months. Although these are preliminary feasibility findings from this uncontrolled observational study, results showed a trend towards benefits in pain, physical and emotional function as indicated by the improvement in HRQoL (Section 6.1). Similarly, findings generated from the systematic review (Section 2.3) indicated integrative treatments appeared to be useful for relieving pain and improving function in LBP at equal or less than three months' follow-up. Heterogeneity did not allow a meta-synthesis for trials with a more than three months' follow-up, but 60% reported a statistically significant improvement in pain condition and back function. However, though included trials apparently evaluated packages of integrative treatments, information was inadequate to decide whether included trials evaluated authentic integrated practice. Therefore, this review should be interpreted with caution. Evidence available on various CAM modalities for MSDs tended to show a small to moderate effect size for treatments such as acupuncture (Vickers *et al.*, 2012; Thomas *et al.*, 2005), manipulation (UK BEAM Trial Team, 2004; Bronfort *et al.*, 2008b), chiropractic (Cassidy *et al.*, 2008), herbal medicine (Christensen *et al.*, 2008; Gagnier *et al.*, 2004), homeopathy (Rossignol *et al.*, 2012; Lert *et al.*, 2014), nutraceuticals (Goldberg and Katz, 2007), and non-pharmacological or non-invasive interventions (Chou and Huffman, 2007; Hurwitz *et al.*, 2008).

Despite the fact that patients' all aspects of life were severely affected by their MSDs at the follow-up (Section 5.16.1), they perceived improvements in MSD symptoms. Noticeably, the greatest improvements in pain and physical function observed in this research study occurred at four months, however, 78% of patients were still receiving treatment at the hospital after this period, and 48% received treatment for

longer than 12 months. This indicates that the increased costs of treatment for more than four months may fail to produce any additional value, in terms of a further significant reduction in patients' pain severity or their functional ability, but there was evidence to suggest that these improvements may have been maintained. Providing a short course of integrative treatments could provide cost savings for the NHS but limited evidence supporting this was available from this research study. Previous research showed that a short course up to 10 sessions of individualised acupuncture significantly reduced LBP compared with usual care at 24-month follow-up (Thomas *et al.*, 2005). An evaluation of a previous UK IM service reported changing 12 sessions of CAM treatment to six sessions could allow opportunity for re-referrals if the health issue was severe (Robinson, 2005). However, findings of the mixed methods feasibility study showed patients hoped to receive prolonged treatment for their MSDs given their chronicity and complex nature and this may have been related to their expectation as discussed above.

CAM is mainly provided privately in the UK which patients in this research study reported was unaffordable, particularly given their limited ability to work due to long-term MSDs. The provision of 6-8 sessions of CAM treatments by the RLHIM, described by patients as a 'taster' was thought to be 'not enough' due to the long term chronic nature of MSDs. Therefore, the suggestion of limiting treatment length should be interpreted with caution as some patients may need more treatment in line with an individualised intervention. It was not clear whether improvements occurred even before four months; whether dispersed treatment with less frequent treatments spread over a longer period of time would be beneficial. In addition, there are many factors that may influence treatment outcome such as changes in patients' expectations, whether patients started to engage in more self-help activities. This needs further exploration with a larger sample size.

Apart from experiencing benefits in pain reduction and physical function, patients reported experiencing relaxation and having better sleep which they attributed to treatment at the RLHIM. This confirms previous clinical research conducted after standard 8-week autogenic training (AT) at the RLHIM reported improvements in additional quality of life (QoL) indicators; sleep patterns, well-being, anxiety and depression scores (Bowden *et al.*, 2012); and other research which showed positive changes in patients' beliefs about their MSDs (Bishop *et al.*, 2015). Previous trials on integrative treatment for LBP have focused on pain and physical function and have rarely considered emotional factors or patients' general quality of life (Section 2.4.1). This may suggest a need to use more holistic integrative outcome measures in research. A similar observational study on IM emphasised the importance of whole person care and showed significant improvements in mood, stress, quality of life, fatigue, sleep, well-being, and increase in 25-hydroxyvitamin D levels at 12 weeks (Abrams *et al.*, 2013). Being able to reduce medications is a benefit perceived by patients with complex conditions. Frequently this was a driver for them seeking other treatment. In the qualitative interviews conducted prior to taking part in the research, many patients reported wishing to reduce or stop their medications. This data suggests that these personal aims were partially met by receiving integrative treatment at the RLHIM.

7.3 Acceptable integrative treatment model

Patients' acceptance of treatments provided may be affected by their previous healthcare experiences, expectations, and their decision making process. Having qualified, knowledgeable professionals appeared to be the main reason participants came to the RLHIM (Section 6.2). This tends to confirm the previous arguments on important role of practitioners (Section 7.1) in patients seeking IM practice.

Patients' acceptance of integrative treatment for MSDs was considered generally good as adherence to treatment appointments was good. A larger observational study has shown that patients' adherence to IM practice over six months period was acceptable, and this may be associated with acceptance of individualised integrative treatment and benefits perceived by patients (Abrams *et al.*, 2013). Patient perceived symptom improvements and positive experiences with practitioners tended to suggest good acceptability of integrative treatment at the RLHIM (Section 6.2). 94% of patients recommended the services at the RLHIM on the NHS choice (NHS Choices, 2015b). Issues regarding difficulties in getting referred may indicate the demand for treatment and may be related to policy and regulation. These are discussed in Section 7.4.

The qualitative findings identified that patients receiving acupuncture reported minor AEs, including pain, feeling sleepy, thirsty, and nausea. The AEs tended to be acceptable by patients as they felt 'it's just the way it goes' (Section 6.2). This is similar to previous research, in which acupuncture related AEs reported were minor pain, circulatory problems, minor aching, minor discomfort, soreness, or no severe AE (Hu *et al.*, 2015a). A large scale survey suggested that acupuncture is a relatively safe intervention when practised by regulated practitioners; most commonly reported AEs were severe tiredness and exhaustion, pain at the site of needling, and headache (MacPherson, 2004a). A prospective observational study showed a small number of minor AEs from acupuncture provided by physicians, most common AEs were bleeding or haematoma, pain and vegetative symptoms, suggesting the treatment was relatively safe (Witt *et al.*, 2009). Other studies showed fewer AEs in conventional treatments using acupuncture compared to conventional treatments alone (Leibing *et al.*, 2002; Meng *et al.*, 2003). In this research study, one patient had non-epileptic seizure whilst enrolled in the study. It was unclear whether this was a reaction to homeopathic tablets, or to other treatments the patient may have been receiving at

the time, an interaction between them or an unrelated event. Research suggests that classical homeopathy has few AEs or toxic effects when properly used (Bornhoft *et al.*, 2006). Patients receiving homeopathy reported less AEs (7.8%) compared to those who had conventional treatment (22.3%) in a primary care setting (Riley *et al.*, 2001). Similar results have been observed for patients taking St John's Wort who experienced fewer AEs than those taking antidepressants (Linde *et al.*, 2008). There are however other considerations when using herbal medicines as there may be interactions. For example, St John's Wort may alter the metabolism of various cancer treatments including Irinotecan, Imatinib and Docetaxel (Meijerman *et al.*, 2006). Although various CAM treatments may help in reducing medication used (Rossi *et al.*, 2009), which may in turn help reduce the chances of having ADRs, there is still a lack of research on exploring interactions between different modalities within an integrative treatment package. It was also unclear whether an AE can be attributed to any specific component of the treatment package. Potential interactions should however be documented and should be explored.

7.4 Integrative treatments in demand

This research study has highlighted the demand for integrative treatments for MSDs but patients perceived limited resources within the NHS to support IM (Section 6.3). As previously discussed in Section 7.1, the demand for integrative treatments may be associated with the complexity surrounding patients with MSDs. Although in this research many patients reported benefit from various conventional treatments, they were not satisfied with their long term progress. Patients were reliant on and hoped to receive CAM treatment within the NHS setting as private CAM was unaffordable given their health problems and possibly lack of employment. This confirms findings from other qualitative research on patients' (Bishop *et al.*, 2011; Bishop *et al.*, 2013; Son *et al.*, 2013) and practitioners' (Zhang and Verhoef, 2002; Bishop *et al.*, 2012) perspectives, which reported that patients were financially restricted in seeking CAM

privately but NHS care was constrained by Trust policy. For those with chronic MSDs, they wished to have long term integrative treatments at the hospital to maintain their health.

Qualitative research suggests that market demand for CAM is the primary motivation for most insurers and hospitals (Hsiao *et al.*, 2006). Apart from consumer demand, health service managers, and influential stakeholders responsible for organising and directing health care policy and practice are essential to facilitate effective IM practice (Singer and Adams, 2013). In the UK, IM services could be funded by CCGs, previously primary care trusts (PCT). In England, 50% GP practices and 43% of PCTs provided access to CAM healthcare (Thomas et al., 2003; Wilkinson et al., 2004). In 2010, the UK government has committed to extending patient choice through their policies of Any Qualified Provider (AQP) for appropriate services to empower patients and carers and to improve practice (DH, 2010) and the use of personalised budgets has subsequently been piloted. In the transitional year 2012/2013 for the AQP program, musculoskeletal services for back and neck pain were identified as a priority for implementation by the DH, which could enable MSD patients more power to select the treatment they preferred.

However, current resources available for IM may not meet patient demand. This research study identified that patients found getting referrals problematic within current referral schemes allowed by their local CCGs. Particularly, those patients who had previous extensive experience attending the RLHIM who now perceived it was more difficult to get referred, and if they were successfully referred, fewer sessions and types of treatments were received. They believed this was due to recent funding restraints and budget cuts due to service reprovision. In England, CCGs have specific and different policies on the extent to which patients can access CAM treatment. GPs are the gate keepers in giving patients access to specialist treatments by considering patients' individual conditions and their wishes (NHS Career, 2015).

Findings from this research suggest that patients who were referred from the North East London CCGs experienced an easier referral pathway as there were specific contracts with the RLHIM (NHS Career, 2015) and this appeared to be the main route for referral.

Apart from issues of referral schemes, patients felt IM practitioners were working under stress, with limited time available for each patient. This is a common situation in the NHS, where practitioners experience anxiety and depression, not exclusively in IM practice (Jalmbrant, 2015). In the UK as well as some other western countries, IM practices are emerging, with current literature focusing on IM models and strategies for integration within health care settings and systems (Coulter *et al.*, 2010; Adams *et al.*, 2009; Singer and Adams, 2014). Findings from this research study tended to suggest there is a lack of IM resources in terms of available practitioners and treatments offered to patients.

7.5 Feasibility of integrative medicine research

This section discusses the feasibility and issues experienced in carrying out this mixed methods feasibility study and its potential generalisability to IM research in other settings (Section 6.4). The research student's interpretation and reflection on the feasibility issues in conducting the research study and some practical issues are also presented in this section.

7.5.1 Identification of eligible patients and recruitment

Although many eligible MSD patients were identified in this research study, issues arose as not all patients were identified. Several clinical codes were considered as rheumatoid arthritis and were not recorded as MSDs. These were included immediately after this issue was realised. Another factor affecting recruitment was that some GPs used a 'choose and book' system or booked through the British

Medical Acupuncture Society (BMAS), without going through patient service department. A 'choose and book' service was available for patients to choose which hospital, clinic or service to go to. This service was available for patients seeking CAM interventions from 2008 (The National Archives, 2015) but replaced by an NHS e-Referral Service in June 2015 (NHS Choices, 2015a; National Archives, 2015). This eligibility identification and recruitment issue should be considered in any clinical research conducted within the NHS. Considering the RLHIM is the largest sector providing IM service in the UK, identifying eligible patients for research is an issue for other UK IM research, especially considering the imbalance in supply and demand for IM practices and increased stress on practitioners.

In this study, 63% of eligible patients (101/161) refused to participate. This may be because the patients were a special group of patients with chronic, complex MSDs, for whom all aspects of life were affected by MSDs. Other problems were due to changes in hospital administration, and lack of commitment and awareness of clinicians to the research study and potential failure in identifying patients. Working with and relying on busy NHS practitioners and healthcare professionals was one of the key challenges in this research study. There was unexpected staff turnover and issues meaning reliance on administration staff, for example, a key person who initially made first contact with patients resigned from the hospital during the research study. Half way through data collection, the fact that some potential patients attending clinics had not been approached was realised. After discussion with the clinical director, this was resolved with the clinical team and recruitment improved. As previously mentioned (Section 3.8), two substantial ethics amendments were submitted, aiming to improve recruitment. The first amendment application was submitted in January 2013, requested changes to the invitation letter and patient information sheet making them user-friendly and easier to understand by a lay person (Appendix 7.1), the second amendment application requested changing the

initial contact to patients by two members of the research team (the research student and JH) rather than patient service staff, who were under time pressure and lacked the knowledge to answer patients' questions regarding the research study (Appendix 7.2). In this research study, one of the members in the research team was the key link between the research student and all the clinicians and patients. As a practitioner seeing participants at the RLHIM, he was also involved in the development of this research study. This potentially helped in gathering the musculoskeletal physicians at the hospital to help with screening patients, and locating staff in patient service department, data department to help with contacting patients and obtaining participants' ICD codes. This highlighted the vigilance required in monitoring recruitment which is reportedly the same for any clinical research study (Rai, 2011). The trial recruitment processes should be carefully planned and piloted regardless of size or complexity. In this feasibility MMR, the research student was the only investigator managing the study, and recruited, interviewed, informed patients about the study and questionnaire, and analysed, interpreted, and disseminated the results. This may potentially have introduced performance, detecting, and reporting bias (Higgin and Green, 2011).

The NIHR HTA programme recommends the involvement of a dedicated trial manager, who has a lead role in the whole process of planning, coordinating, and completing a project, which is key to the success of all primary research (Farrell et al., 2010). Active management for every aspect of a trial requires the trial manager to be good at communication and presentation, with the ability to organise and motivate others, and with motivation, enthusiasm, innovation and leadership when faced with challenges. It has been suggested that factors affecting recruitment levels of both collaborators and participant may include general aspects such as changes in the season, and other more specific aspects such as ethnic makeup of the population, or may be due to problems within the collaborating centres (Ward et al., 2010).

Offering educational programmes to stakeholders and practitioners may improve recruitment when there are difficulties in recruitment due to collaborator factors (Ward et al., 2010).

7.5.2 Participant retention

Retaining participants is always important and challenging, especially with a long term follow-up. However, the retention over 12-month period was good for this research study. Several strategies for retaining participants were used (Robinson *et al.*, 2007) : 1). Community involvement: as pre-specified in Section 3.1, one patient was involved in the research and was involved in the design stage of the study, gave ideas on when/how to contact patients, and provided suggestions on designing several questionnaires (Fischer *et al.*, 2014; Burston *et al.*, 2014); 2). Study identity: All documents including the patient information sheet, consent form, questionnaire package, and reminders to participants were formatted using similar colours and fonts, with a project logo, LSBU and RLHIM logos as headers. (Appendices 3.1-3.3); 3): Study description: Patients felt the description of research process was clear; 4) Reminders: Phone calls or text reminders were sent to participants one week before sending out the questionnaire package; before both pre-treatment and follow-up interviews took place, consented participants were sent a text reminder the day before interviews and patients preferred to be contacted by text or email; at the end of initial appointment with the participants, the research student reminded the participants about the research timeline; 5). Visit characteristics: In order to minimize participants' burden, the research student tried to contact participants at a convenient time, e.g. working participants were contacted after work hours, retired patients were contacted during morning workdays; the research student also offered flexible appointments to the participants.

Apart from these five strategies supporting retention, some techniques suggested in securing patient retention were not fully achieved in this research study. For example, the research student was the only research personnel who contacted participants. Contacting and scheduling was only carried out by the research student, rather in a systematic monitoring approach such as using electronic patient tracking systems (Nhavoto *et al.*, 2015). No special tracking method was utilised to follow-up patients. Updating participants' contact information every two months has been suggested (Pappas *et al.*, 1998) and multiple attempts to contact subjects for complete data by phone and mail (Goldberg and Kiernan, 2005). Inadequate funding meant there was no financial incentives/reimbursement for participating in this research study. Patients were generally seen on routine appointments to minimise cost of travelling. A small amount of travel expenses were reimbursed to participants as part of the research study, when requested. Findings from this research study also revealed patients wanted to have a more supportive patient group at the RLHIM and have a free physical examination (Section 6.4). Patients asked about access to possible publications during the interview. Non-financial incentives in this research study reported by patients included benefits in self-reflection, acquiring and sharing information, empowerment for health and social changes and their mental status. Previous research suggests financial incentives tend to influence judgment (Halpern *et al.*, 2004), therefore it remains challenging to establish a balance between encouraging research participants and avoiding coercion that might affect the integrity of a study or compromise respect for individuals and justice (Groth, 2013).

7.5.3 Participants' characteristics

This research study was conducted in London. Patients participating were predominantly middle aged, female, Caucasian, and generally with a higher educational background. They tended to be a group of patients with healthy lifestyle

and were aware of the importance of self-management. They may have been a self-selected group of patients so findings may not be generalisable to other settings. Patients who were interviewed were not purposively sampled. Some patients did not participate in the follow-up interviews as they were not receiving any treatment by the time they were contacted by the research student. This may have led to potential bias as patients who participated in the follow-up interviews may have had more treatment thus perceived more benefits, therefore findings should be interpreted with caution.

7.5.4 Patients' experiences in participating

In this research study, patients generally reported they had a positive experience communicating with the research student and felt that the research procedure was clear. This was encouraging as most participants were chronic MSDs sufferers; some patients had health restrictions which hampered participating in the research study, such as completing questionnaires, or committing additional time to meet the research student for interview. During the research, some participants sent regular greeting emails and Christmas cards to the research student, which exhibited a good communication between them. The research student showed her empathy towards participants in scheduling appointments and cancellations. However, there was a potential issue with the research facilities. From December 2014 to April 2015, there was a shortage of rooms available for patients' interviews at the hospital. This potentially affected the quality of the interviews as sometimes there was no quiet environment and participants may have felt anxious as they were not close to the consultation room for their appointment. Interviewing patients in a quiet and private environment can also emphasise patient autonomy and active involvement in the interview (Lichstein, 1990). One patient asked to be withdrawn from the study after consenting. No reason was given and they were withdrawn with their data not used. Anecdotal communication data between the research student and patients in

arranging appointments and explaining the research study were generated through emails, texts and letters. Although these data were not analysed or reported in this research study, these data could provide additional information on the study feasibility, particularly on communication between researcher and patients.

Timing of interviews was also crucial: conducting interviews immediately before a participants' appointment may have saved time and was convenient for the participants, but may have produced anxiety as some patients checked the time during the interviews. Benefits from participating in the research study included helping patients reflect on their conditions, gain information, feeling reassured and better mentally. Patients sought confirmation about what they were having and how they were being treated by communicating with patients who shared similar experiences. In the focus groups, seeking confirmation, providing information, and sharing experiences was valued by patients. Choosing to participate in this research study was mainly because participants wanted to help other patients like themselves, and they felt research was needed (Section 6.4). The researcher's friendliness and helpfulness and the status of the administering practitioner largely affected participant recruitment and retention, and may have also influenced the reporting of study outcomes. This highlights that outcomes of trials should be interpreted as products of complex environmental, social, interpretive and biological processes (Scott *et al.*, 2011).

Patients gave various suggestions for improving the research design as well as hospital services. They expressed their willingness in being contacted by the researcher through text or email. A systematic review showed digital interventions such as supporting patients remotely by giving them self-care information showed small but significant effects in health management (Webb *et al.*, 2010). This may also potentially enhance patients' experiences in participating in research. In terms of research benefits, they hoped additional diagnostic assessments could be offered as a

result of the research; and hoped that the researcher would be able to feedback to the practitioners. They also expressed their wish to have a support group where they could communicate and share their experiences with peers. These aspects are highlighted to be considered for service change (Section 6.4).

7.5.5 IM outcome measures

In terms of data collection, accessing patients' ICD codes to classify musculoskeletal disorders by diagnosis was problematic and depended on the hospital administrative staff providing this information. Slow recruitment at the beginning of the study added to the already lengthy study. Patients' MSDs were therefore categorised based only on the location of pain collected from the sfBPI body graph. Disagreement between clinically observed changes and patients' perceived changes may be attributable to inaccurate recollection (recall bias), especially with a longitudinal cohort design (McPhail and Haines, 2010). In this research study, the completion rate of mCSRI over the study period was not high (77% at 12 month). For example, participants had difficulties in remembering things such as money spent on petrol. This potential recall bias will tend to result in an under or overestimation of the association between exposure to a risk factor and outcome (Bayona and Olsen, 2004).

Currently there is no consensus on the use of a well-recognised outcome measure for IM or holistic whole system research. As IM practices emphasise patient tailored care with a holistic approach, patient-identified health outcomes such as MYMOP and the patient generated index were considered. However, the patient generated index is complicated and tends to have a high rate of invalid scoring, and MYMOP can only measure one or two symptoms, whereas patients using IM usually have comorbidities (Hunter and Leeder, 2013). IM stakeholders suggest that, apart from evaluations of physical and mental health, lifestyle, health-related aspects of life

satisfaction, quality of life, and healthcare evaluation are important topics worth assessing for IM (Hunter *et al.*, 2013).

This research study suggested that both quantitative PROMs and qualitative interviews were critical. The PROMs used in this research study tended to assess the main patient concerns. The VAS and sfBPI were generally considered acceptable, comprehensive, easy and quick to complete. Potential cognitive bias effects have been suggested to be greater when using PROMs due to their subjective nature outcomes (Wood *et al.*, 2008). Narrative approaches, e.g. interviews or open ended questionnaires may be useful in understanding complex MSDs. These were evidenced by good completion and interview attendance over a 12 months' period. In addition, quantitative findings showed that VAS and sfBPI captured the changes in pain severity and functional status of MSD patients at four, eight, and 12 months. Other outcome measures successfully captured changes in individualised integrative treatments for MSDs included a combination of pain measures using NRS with 0.5 to 12 months follow up (Sundberg *et al.*, 2009; Eisenberg *et al.*, 2012; Eisenberg *et al.*, 2007), physical function and HRQoL measures using SF12 with 0.5 to 12 months (Eisenberg *et al.*, 2012; Eisenberg *et al.*, 2007), SF36 with 3-12 months (Little *et al.*, 2008; Hollinghurst *et al.*, 2008; Sundberg *et al.*, 2009), mRMDQ with 0.5 to 18 months (Little *et al.*, 2008; Hollinghurst *et al.*, 2008; Hurwitz *et al.*, 2002; Hurwitz *et al.*, 2006; Eisenberg *et al.*, 2012; Eisenberg *et al.*, 2007), and wellbeing score at 10 weeks follow up (Grunnesjo *et al.*, 2011). Apart from these quantitative changes, a holistic integrative understanding of patients' MSDs requires qualitative research input, to understand the change process (Hsu *et al.*, 2010; Cramer *et al.*, 2013) and to help understand the potential contribution of important components in IM practice such as communication between patients and practitioners, being knowledgeable, empathetic, and kind, from patients' perspectives (Rowell and Polipnick, 2008).

Although cost data are not presented in this research study, data were collected for a 12 months' period. Data were often incomplete and patients reported that the mCSRI questionnaire used was too long and complicated. A range of concerns were expressed on the utility and appropriateness of the mCSRI including; having sensitive questions, difficulties in patients separating the treatments participants had for MSDs and those they had for other health conditions, unclear boundaries between CAM and conventional treatments, and difficulties in recalling information in the previous three months. However, CAM treatments listed in the mCSRI inspired patients to some extent. Since interactions within IM may be triggered by having CAM treatments or conventional treatments, it needs to be holistically evaluated by someone who has knowledge of both systems. This requires sharing clinical notes, assessments results, which challenges the model unless there is a shared medical system. Two earlier research studies evaluated costs of NHS services using CSRI (over three to 15 months) (Wye and McClean, 2012; Thompson *et al.*, 2014), showing how the measure could be used to evaluate CAM. Though a mixed methods design was utilised (McClean *et al.*, 2015), the acceptance of patients using CSRI was not explored in these two studies.

Overall, the feasibility of carrying out a mixed methods research study on integrative treatment for MSDs in a secondary care NHS setting was considered acceptable. This has been evidenced by patients' perceived benefits in symptoms and an improvement in HRQoL, acceptance and demand in integrative treatments, and a comparably smooth experience of participating in the research study. Issues with recruitment, patients sampling, and shortage in research facilities are part of the limitations of this research study (Section 7.6) and should be considered carefully. Minor revisions that were made to the pre-set protocol should be noted. Patients' suggestions about outcome measures and the way patients are contacted

7.6 Strengths and limitations

This section discusses the research student's reflection on the methodological strengths, weaknesses and limitations of performing this research study. Strengths and limitations in conducting the mixed methods review in order to develop a theoretical understanding of IM (Section 7.6.1), and in carrying out the mixed methods feasibility study on integrative treatment for MSDs are discussed (Sections 7.6.2&7.6.3).

7.6.1 Strengths and limitations of the literature review

The mixed methods review contained three reviews: a mapping review on the available definitions of IM, a systematic review which evaluated clinical effectiveness and safety of integrative treatment for LBP, and a narrative review on qualitative research exploring patients' experiences of receiving CAM treatments (Chapter 2).

There were many strengths of this mixed methods review, among which the most important was that it provided a broad summary of both empirical and theoretical literature utilised, based specifically on IM (Whittemore, 2005). Secondly, both the systematic review (as the main part of the mixed methods review) and the mapping review (potentially determined the theoretical background of IM) were performed in both English and Chinese language data bases, in order to provide and facilitate a broader understanding of IM. As a common language is being built among CAM practitioners internationally (Linde *et al.*, 2001; Napoles-Springer *et al.*, 2005), increasingly non-Chinese researchers and clinicians are starting to notice the importance of not discarding Chinese articles and Chinese researchers and practitioners are starting to publish papers in English as well. International conferences and research collaborations contribute to this dissemination which may influence government and policy decisions. Relevant organisations have invested

more effort and funding in multi-national conferences and developing research cooperation all over the world (Lee *et al.*, 2007; Joos *et al.*, 2008; Boon *et al.*, 2004), which indicates the policy makers' interests in developing IM. However, Chinese literature fails to be widely cited due to language and potential publication bias (Efficace *et al.*, 2006; Chan, 2008). Chinese research has been criticised for various reasons such as imprecise inclusion and exclusion criteria, inadequate follow-up, high dropout rates, lack of blinding and allocation concealment details and poor choice of endpoints and inappropriate statistical procedures (Pittler *et al.*, 2000).

The biggest limitation of the mixed methods review was that apart from the mapping review, which focused on IM definitions, the systematic review and the narrative review were not specifically focused on IM due to the difficulties identified with a lack of standard terminology. The term IM and CAM are used interchangeably with much less research focused on IM. This resulted in problems when trying to identify and synthesise studies on IM. A wide range of search terms are necessary to identify all potential IM studies due to the absence of standardised terminology or definition of IM and a lack of a shared conceptual framework and taxonomy for IM models, therefore many studies are not labelled as IM so may not be captured in searches using IM keywords/MeSH terms; and many studies purport to be 'IM' but they may not be (Khorsan *et al.*, 2011; Hu *et al.*, 2015a). In addition, reporting details of studies are imprecise, making it difficult to distinguish whether IM was intrinsic to the intervention. Further challenges are also faced with regards to inadequate information to decide whether authentic IM practices were provided or not, and differences between countries and manuscripts published in different languages, with extensive work required in order to identify search terms and synthesise findings (Hu *et al.*, 2015a).

It has been suggested that systematic reviews are inappropriate for complex interventions and a realistic review, explaining rather than judging and using

qualitatively narrative synthesis, may be more appropriate (Khorsan *et al.*, 2011). Rather than attempting to review all examples of IM worldwide, the mapping review reported results from such a qualitative narrative review of IM definitions in literature from the US, UK, Australia, and China, provided a starting point to begin to explore the issues faced when synthesising IM research and practice for research purposes. However, the mapping review compared and discussed the situation in only four countries which was limited especially as resource and regulation of IM vary in other countries. In addition, key components were identified solely by the research student using thematic analysis.

Though there are many difficulties in evaluating IM evidence, it was important to conduct the systematic review as guided by the MRC framework to evaluate existent evidence on the target intervention. Due to a lack of standard definition of IM, IM treatment was narrowed down to integrative treatment that provided combined conventional and CAM treatment in the same clinical settings or clinical partners settings. This was controversial as researchers have argued that IM is not simply a synonym of conventional medicine with CAM (Bell *et al.*, 2002; The Bravewell Collaborative, 2015; Osher Center for Integrative Medicine, 2015; Rees and Weil, 2001; National Institute of Integrative Medicine, 2015; Boon *et al.*, 2004); and more details on the model/framework of integration should be provided (Caspi, 2001; Morrell, 2001; Woolfson, 2001). As there are few trials evaluating the effectiveness of a package of IM in western countries, this exploratory systematic review was restricted. The trials conducted were poor in terms of reporting and methodological quality. Inadequate information on randomisation and the lack of allocation concealment may result in study bias. Many trials did not have a sham control design thus specific effects of treatment cannot be identified. The inclusion criteria were tightened compared to the pre-set protocol as there were abundant eligible trials with the pre-set criteria. Therefore, trials using global assessment/effect rate without any

recognised/standard/validated outcome measurements were excluded, which largely reduced the amount of eligible trials. Apart from one systematic review on IM there were no trials evaluating IM and LBP (Lee *et al.*, 2011), there were no previous reviews that investigated integrative treatment and compared it to single CAM or conventional treatment. Issues around IM definitions should be addressed. Before carrying out another update on IM evidence, clear reporting guidance for IM is urgently required (as summarised with potential recommendations in Section 7.7.2). However, this review provided previously unexplored aspects of integrative treatment which should be considered in future IM reviews. Though only LBP was evaluated in the exploratory systematic review, most MSDs, as complex conditions, may benefit from an integrative approach and deserve further exploration (Park *et al.*, 2010).

There were various limitations in the narrative review on patients' experiences of receiving CAM for MSDs and these included: only English databases were searched, although Chinese qualitative research is rare; and the research student was the only reviewer of the qualitative research. The search topic was focused on CAM for MSDs rather than IM specifically due to the limit in reporting IM which has been discussed above. However, this provides information on patients' perspectives on receiving CAM treatment and enables comparison with this study, added theoretical basis of understanding IM.

7.6.2 Strengths and limitations on overall research design

The absence of a control group is the major limitation of this MMR study design. It could be argued that the improvements shown in the limited outcome testing (Section 6.1) may not be related to the integrative treatments provided at the hospital. A few design issues were not assessed in this research study: Firstly, the theory and the feasibility of designing a suitable control group for IM was not

assessed. Standard care is one control option, but there are potential issues with this approach. Variability in terms of what may be involved in usual care is often unclear, for example, the NHS care provided may vary between different CCGs; patients may have CAM privately and there may be inadequate information sharing between private and NHS sectors regarding multidisciplinary input into patient care. For example, many patients choose to use private CAM alongside their conventional NHS care (Sawni-Sikand *et al.*, 2002; Thomas *et al.*, 2001). In addition, as IM practice is not simply combination of CAM and conventional treatment, there may be cases when only single CAM or single conventional treatment is provided in IM group. Open dialogue between practitioners is recommended to improve the integration (Brien *et al.*, 2011). Secondly, randomisation was not assessed in this study therefore it is unclear whether randomisation would be feasible or acceptable to patients, and how many patients may dropout after randomisation. The suitability of the selection of control and patients' psychosocial context of randomisation procedure still needs to be assessed (Barlow *et al.*, 2011). Thirdly, this research study was restricted as the sample recruited were mainly middle aged, female, Caucasian, with a higher educational background. However, this reflects those individuals who tended to visit the hospital at the RLHIM. This may restrict the generalisability of the findings to other IM settings with more diverse populations.

Situated under a pragmatic epistemology, this research study explored personalised and individualised treatments routinely provided for MSDs at the RLHIM, with no change to or standardisation of treatments. The whole-system approach considering complex, multicomponent IM interactions as a whole has increasingly been recommended due to its high external validity and the individualised nature of IM interventions (Langevin *et al.*, 2011; Ritenbaugh *et al.*, 2003; Verhoef *et al.*, 2005). Researchers have recommended whole system research (WSR) using pragmatic, observational, and mixed methods approaches to overcome the challenges of

evaluating complex interventions such as IM (Verhoef *et al.*, 2005). However, pragmatic trials have been suggested to be conducted once evidence of the intervention has been proved (Power and Hopayian, 2011). Power and Hopyian argued that the evaluation of a 'package of care' is misleading and unscientific as pragmatic trials and exploratory trials share valuable but distinct responsibilities (Thorpe *et al.*, 2009; Power and Hopayian, 2011). Some authors argue that the exploration of components in the 'black box', such as patients' expectations and relationship with practitioners, should not be an excuse for focusing on the package of care rather than the components; and doing so does not close the integrative medicine evidence gap (Power and Hopayian, 2011)(Macfarlane *et al.*, 2012). On the other hand, policy makers use evidence based on non-specific effects from unblinded pragmatic trials. NICE guideline (NICE, 2009) and German federal joint committee of physician and health insurance plans have suggested the use of acupuncture based on the overall effect of evidence (O'Connell *et al.*, 2009). The King's Fund also called for more unblinded pragmatic trials on CAM (Black, 2009).

In order to address the accepted challenges to enhance internal validity of observational design, it has been suggested that medical documentation, baseline measurement, and a non-randomised comparison group can be used (Verhoef *et al.*, 2005). In this research study, patients' medical documents including their clinical notes, referral information were checked on the UCH system; there was no major significant difference in baseline characteristics between patients who were on a waiting list or not. It was planned that patients who were on the waiting list could be used as their self-control, to avoid issues in these and randomisation when patients prefer target treatment (Haake *et al.*, 2007). However, the number of patients who were on waiting list control was too small to provide information on effectiveness and the average time on the waiting list was approximately 10 days. Having access to patients' clinical notes and the hospital digital system assisted in providing data on

patients' conditions, detailed treatment provided during the period of research, and their GPs' locations, which helped in understanding their referral pathway and expectations. This sharing system may allow incorporation of EBM to the real world by combining three sources: research evidence, clinical practice, and the patients' story in a new medical model as suggested by Jones et al. (Jones *et al.*, 2009).

In this research study, the number of participants in any one theme of MSDs and who had one theme of interventions was small and therefore statistical subgroup analysis was not carried out on integrative care provided for any specific single MSD. Therefore, this research study shows the overall effects of real world practice individualised to each patient at the RLHIM. Observational design has also been recommended for use in assessing side effects of an intervention and deciding which conditions respond well to interventions (Flower *et al.*, 2012), and for framing future research questions more effectively (MacPherson *et al.*, 2009). In this research, patients reported their experiences of minor AEs (Section 6.2) though it was not a target question in the qualitative study.

The length of follow up in this research study with good retention is considered appropriate and allowed adequate observational information to be collected. In addition, for some cases, there were long gaps between patients' treatment and some treatments were limited in their provision. Therefore, though the most significant benefits were observed at four months, a 12 months follow up was considered appropriate to detect difference over the long term, and a long term follow up is considered appropriate for an observational design with chronic conditions (Verhoef *et al.*, 2005).

Apart from the limitations identified in conducting the mixed methods feasibility study, several issues emerged from its design. One major limitation was that frameworks to guide and explore feasibility were not involved in design stage but

were utilised only at the interpretation stage of the research study. This potentially restricted the findings identified as specific questions on feasibility were not asked directly in interviews, e.g. how did patients feel about the consent process. The feasibility frameworks would have guided developing research questions, identifying questions asked in interviews, which may also guide the data analysis process (Bowen *et al.*, 2009; Shanyinde *et al.*, 2011; O'Cathain *et al.*, 2015). The main reason for not doing this was that this research study was initially designed as a full mixed methods study but the ethics committe requested it was changed to a mixed methods feasibility study but the design kept the same. This was because no study exploring IM for MSDs had been carried out at the RLHIM prior to this research study. Therefore, further feasibility research should use the feasibility frameworks to guide design, data collection, data analysis, interpretation, and reporting. Another minor issue limiting the research study was that information on precise treatments received by patients relied on the research student reading through participants' clinical notes as completion of treatment log was very poor, which is time consuming and likely to be inaccurate. These all require close collaboration with clinicians and careful project management planning.

7.6.3 Strengths and limitations of the mixed methods design

The mixed methods design is the main strength of the research study. Using both quantitative and qualitative methods of data collection and data analysis allowed the exploration of different aspects posed by the same overall research question on feasibility and provided a more comprehensive account of the situation. Themes generated from qualitative study could help in framing future research questions and maybe help researchers understand the potential active components that may contribute to the overall effects of integrative treatment. For example, associations between patients' expectation management and treatment effects may be worth further exploration; how this enables self-care, the patient-practitioner relationship,

and a holistic individualised approach and these seem to be essential as part of IM treatment.

Appropriate, well recognised research methods are essential to secure qualitative credibility (Shenton, 2003).The adoption of interviews and focus groups were both recognised as appropriate methods to explore patients' expectations and experiences of integrative treatment at the RLHIM and in participating in this research study. Similar findings of patients' experiences with MSDs and treatments they received at the hospital were presented by patients in one-to-one interviews and in focus groups (Sections 5.9-5.16), while participants in focus groups felt they engaged and benefited in participating in the research study by exchanging their health information, self-help techniques, and experiences of receiving integrative care at the RLHIM (Section 5.15).

There is a lack of research focusing on the difference between one-to-one interviews and focus groups on the topic of IM/CAM but qualitative research literature suggested focus groups require more careful time and budget planning (Morgan, 1997). The research student felt that the interactions with participants as a group was different to the way she interacted with patient in one-to-one interviews as in the latter, she was more sensitive to the topics that patients were reluctant to discuss or expand in focus groups as discussing a topic that participants felt uncomfortable with is not productive in qualitative research (Morgan, 1997).

Though the follow-up interviews aimed to have 6 to 10 participants in each focus group with a total of two to five groups for the qualitative part of this research study, fewer patients participated in each focus group therefore altogether four focus groups were arranged (Section 5.1). Recruitment to the focus groups tended to be more challenging compared to one-to-one interviews, especially later in the study (late

2014 and early 2015) when interview room space could be booked for limited time and focus groups required an appropriate room in the hospital.

Random sampling of individuals serving as informants has been recommended as essential to improve credibility in qualitative research (Shenton, 2003). Minimising sample bias with purposively selected samples rather than achieving generalisability may improve data quality and has been recommended in focus groups (Morgan, 1997). However, qualitative participants were not randomly sampled or purposively sampled as there were challenges in recruiting participants for the research study from the outset; therefore a sequential approach was adopted. Participants were self-selected volunteers, which may lead to bias e.g. patients who are more positive about the treatments provided at the RLHIM.

Becoming familiar with the culture of participating organisations may aid in improving credibility in qualitative research (Shenton, 2003). Before starting the research study at the RLHIM, the research student had several research group meetings in the hospital; and one meeting with all MSD practitioners at the RLHIM. The research student was familiar with the interview room as they were the places she was based in the hospital, when extracting patients' data from the hospital system etc. During the recruitment period, the research student was based in the hospital approximately 2/5 days per week.

Other methods of securing credibility achieved in the qualitative study include using triangulation of different methods (Shenton, 2003). In this research study, four sources of data, quantitative outcome measures, interviews and focus groups, participants' clinical notes, and treatment logs completed by the practitioners at the RLHIM were triangulated. In order to ensure honesty in informants and data collection dialogues, debrief sessions between researchers and superiors, ensure peer scrutiny of project with reflective commentary (Shenton, 2003), two supervisors

checked every single transcript by reading the transcripts. Regular meetings were carried out during the process of qualitative data collection and analysis, with inter-rater coding conducted with two supervisors who are experienced in the topic and qualitative research for 10% of the transcripts in both pre-treatment interviews and follow-up interviews. These utilised extensive extracts of text and gave more contexts to the second coders to aim for greater concordance. Negative case analysis (Shenton, 2003) was presented with rare or extreme cases stated in the results. Background, qualifications and experience of the researcher are important in improving credibility (Shenton, 2003) and have been provided in Section 1.2.

Transferability of qualitative research provides background data to establish context of study and detailed description of phenomenon in question, allowing comparisons to be made (Shenton, 2003). Details on the process of qualitative data recruitment, data collection, and framework analysis were provided in the methods chapter (Chapter 3). Transferability was also improved by taking field notes, self-reflexivity and inter-rater coding, which allowed the readers to decide whether the prevailing environment is similar to the situation in the RLHIM and whether the findings from this research study could be applied to other settings (Shenton, 2003).

Dependability of this qualitative study was improved by employing overlapping methods (Shenton, 2003) including one-to-one interviews and four focus groups in the follow-up interviews. In-depth methodological descriptions (Shenton, 2003) were presented throughout methods chapter (Chapter 3) to allow the study to be replicable, with quantitative, qualitative, and mixed methods reporting guidelines considered.

Methods in improving confirmability in qualitative research included reporting admissions of the research student's beliefs, and the epistemology and ontology perspectives (Shenton, 2003) (Section 1.2); recognising shortcomings by discussing

limitations (Section 7.3) in study design and their potential effects (Shenton, 2003); presenting detailed justification of methodological design (Section 3.1) to allow integrity of research results to be scrutinised (Shenton, 2003); and presenting diagrams to explain audit trails (Shenton, 2003). This allows readers to trace the course of the research step-by-step via the decisions made and procedures described (Section 3.3).

7.7 Contribution to knowledge

This research study builds on the available definitions and evidence of IM in the literature. It goes some way towards filling the evidence gap between the high prevalence of MSDs and increasing popularity and benefits in the use of CAM, and the limited evidence on IM for MSDs. As far as we know, this is the first mixed method study assessing the feasibility of evaluating IM for MSDs in a secondary NHS setting in the UK.

This study has provided essential information needed to move the evidence base for IM in the UK forward. The effect size presented for various PROMs at different time points allows sample size calculation for future research. Although this research study was limited by the absence of a control group and lack of power to test effectiveness, findings provide valuable insights on patients' experiences of the treatments and participating in the research study. This mixed methods feasibility study has also provided original data on the practical issues of performing study in this setting, with this special group of patients who had all aspects of their life affected by their MSDs. These findings may provide information useful to the participating hospital but most importantly it can inform decisions on the future definitive research directions for IM, not only in the field of MSDs.

The IM model proposed in this research study is new, reflecting what patients perceived good IM practice would be. Key components in the model were verified

both from patients' perceptions and the IM literature. These components may provide previous unexplored aspects of integrative treatment for consideration in future IM reviews and IM research, and could influence reporting requirements of clinical trials. In particular exploring possible interactions between components and the contribution of these components to the overall IM effects may be important. These components can also be considered in IM practice as a reflection of patients' hopes.

7.8 Implications and future directions

7.8.1 Implications for IM research

The key IM components for MSDs proposed in the IM model in this research study need further exploration. IM is the optimum (package of) treatment(s) which considers the aspects of both CAM and conventional treatments. It emphasises an individualised holistic approach, active self-management, with cooperative multidisciplinary teamwork from practitioners who are patient centred, empathetic, happy to share information, and actively manage patients' expectations. From this research study, it is unclear whether the interactions between these IM components or the change process of these components contributed to the overall effects of IM treatment. Future research confirming or adding to the proposed IM model, developing methods to measure these components and investigating the impact of the proposed IM model are warranted (Coulter *et al.*, 2014).

Having established the feasibility of this study, the next step following the MRC framework is to develop a definitive trial evaluating the effectiveness of IM. Considering the IM components in the IM model, testing comparative effectiveness using a mixed methods design will yield the most useful information in researching the complexity of IM in a real world situation and is recommended. Researchers in the field have also recommended that the first phase of evaluating IM should not

unpack the 'black box' of IM, but rather assess IM as a whole system medicine by evaluating the overall effects of IM (Fischer *et al.*, 2012; Fischer *et al.*, 2014; Institute of Medicine, 2009; Jones *et al.*, 2009).

This research study provided valuable insights into the detailed procedures of evaluating IM services for MSDs provided at the RLHIM which may have implications for future research. Potential issues with recruitment and possibilities in failing to identify patients due to relying on busy NHS healthcare professionals; and inability to purposively sample, suggested that recruitment strategies need to be clearly articulated and thoughtfully considered. Researchers are recommended to realistically anticipate challenges and develop contingency plans. Effect sizes should be applied with caution in research in other IM settings due to the uniqueness of the RLHIM and the population recruited. A larger sample would be needed to explore predictors of integrative treatment effects before any definitive conclusion can be made. The use of the VAS and sfBPI with a long term follow up, and a mixed methods approach with interview performed at follow up point can be recommended. Patients' suggestions for improving IM research should be considered to improve their engagement in research. Future research should also explore the logistics of running a multi-centre research, the fidelity and reach of integrative treatment as these were not addressed in this research study.

Looking to the future, evaluating IM using a pragmatic mixed methods design comparing IM with usual care could be one option. Potential usual care could be standard conventional treatment provided in collaborating GP practice. Another potential option for future research would be exploring large scale epidemiological and clinical observational data using data mining. Data mining has been recommended in healthcare, with promising outcomes (Raghupathi and Raghupathi, 2014), and has been particularly suggested for individualised care such as IM (Li and Liu, 2015). Various features of IM such as syndrome differentiation, genetic

disposition, omics, biomedical assessments, various symptoms, data on patients' expectations, practitioners' education and qualifications etc. can be explored, with components identified as key features of IM. This would suit research on complex interventions such as IM where regular statistical tests are not perfect in calculating too many predictors. Among different data analytic approaches, Bayesian analysis, the natural method of assessing inductive/abductive scientific reasoning (starting from data and assessing the probability of effect, p(H0|data), may significantly impact on the interpretive nature of the qualitative research, and reduce the complexity of the data during the data transformation process (Martin and Felix-Bortolotti, 2014). However, this approach is controversial and still under discussion (Chen *et al.*, 2007).

Funding is needed for IM research as commissioners and service providers want to see data on cost effectiveness, especially in the NHS. The most common obstacles in IM are lack of research on efficacy and health economic data and the next step should consider evaluating cost effectiveness alongside the pragmatic trial. In this research study, economic data as measured by the mCSRI was documented, and patients' experiences in completing mCSRI explored. A user friendly mCSRI requires simplification and consideration of the potential for recall bias is needed. Challenges in gathering unit costs from NHS hospitals should be addressed if economic analysis is to be feasible.

Locating IM research funds is problematic as research funding agencies are prone to support research evaluating individual components of IM in line with a traditional scientific reductionist approach (Abrams *et al.*, 2013). New interpretation on methodological issues in assessing a whole system approach requires cooperation of both healthcare professionals and policy makers, and attention and support from policy makers and commissioning.

7.8.2 Implications for reporting IM research

In order to spread the use of standard terminology to help research, stakeholders in this field are recommended to limit the inappropriate use of the umbrella term of IM in research, policy making and education. From the definitions identified (presented in Section 2.1.1), it became clear that there are a number of similarities as well as differences in ways of interpreting the key elements of IM, which need to be taken into account if IM is to be reported in a standardised way, not only considering the integration at therapeutic level, but also at the theoretical and diagnostic level. Future research using a Delphi design could be considered to facilitate the standardisation of the IM terminology and developing guidelines for reporting IM research, which may ultimately add to improving the evidence for IM.

7.8.3 Implications for IM practice

This research study provided insights into the feasibility of evaluating IM treatment for MSDs at the RLHIM, identifying potential areas for service improvement and possible cost saving.

Although CAM treatments were generally considered safe, reliable research investigating AEs is scarce (Fischer *et al.*, 2014). Mechanisms of possible interaction within a package of care such as IM have not been extensively investigated. Risk and cost-benefit ratio has been recommended to be one of the core areas to focus on in the next five years (Fischer *et al.*, 2014). Therefore, monitoring AEs of IM as a whole package is recommended, as well as single components of IM. Understanding of potential AEs in IM treatments by IM practitioners is encouraged in order to ensure good IM practice.

This research study identified an imbalance in supply and demand for IM. Challenges in getting referred and a shortage of availability in types of integrative

treatments, with more sessions, and longer consultation time was perceived as important by patients along with the high demand for IM for MSDs. Findings of this research study showed six to eight sessions were considered insufficient for their chronic MSDs which had associated polypharmacy and co-morbidities. In addition, more qualified healthcare professionals who are dual trained in IM are needed to alleviate the stressful clinical environment. Educational programmes for IM practitioners with consultation techniques such as patient centeredness, information sharing, being empathetic; and working collaboratively with other practitioners should be emphasised. Potential biotechnological development such as sharing clinical history among different hospitals may help improve IM services.

After the IM evaluation has been completed, the final stage of the MRC framework is implementation into practice. Dissemination, surveillance and monitoring of integrative treatments for MSDs with long term follow-up are essential during the implementation stage. This will contribute to the cyclical complex intervention framework, which ultimately aims to promote health (Craig *et al.*, 2008). High demand for IM services suggests secure funding is required in this area to strengthen IM research capacity. The most appropriate way to influence commissioning decisions may be the use of evidence-based guidelines (Ubbink *et al.*, 2013). Although the use of CAM is increasing, a large number of CAM professional bodies are unaware of clinical guidelines which include their therapy (Lorenc *et al.*, 2014). Between 2006 and 2013, 60 (45 from NICE and 15 SIGN guidelines) available guidelines mentioned CAM (mostly on acupuncture), with recommending and advising against CAM equally common (Lorenc *et al.*, 2014). Improving the western medical health professionals' awareness of CAM guidelines and the evidence base might help integrate CAM into healthcare provision, and may ultimately influence commissioning. The recent WHO Traditional Medicine strategy 2014-2023 has clear aims for harnessing the use of traditional medicine to improve population health

(World Health Organization, 2015b). The WHO is currently developing the 11th version of ICD codes and traditional medicine will be included in this version (Morris *et al.*, 2012). These indicate the potential to open up significant doors for integration into the mainstream medical systems, and may assist IM practitioners to diagnose in a common language that can be understood by the majority.

7.9 Final conclusion

This research study is the first step in evaluating IM for MSDs. Following the MRC framework, the theoretical understanding of IM and the feasibility of carrying out a MMR on IM for MSDs in the NHS were explored. Although IM services are increasingly being developed and used in practice, the current evidence on IM for MSDs is still lacking, especially in the UK. Identification of previous studies of truly integrated treatments was not possible due to lack of reporting of the intervention details and components. The lack of a standard definition of IM and an absence of guidelines for reporting IM has hindered the process of developing its evidence base.

This research study is the first mixed methods study to demonstrate the feasibility of assessing the effectiveness of integrative treatment for MSDs in a secondary care in NHS outpatient setting. The overall study was feasible as evidenced by patients' perceived moderate pain relief and improved HRQoL at four months, which were sustained (with smaller effect size) at 12 months. The effect sizes identified from various PROMs at different time points could allow estimation of sample sizes for future definitive studies, depending on their design. Apart from problems with referrals, integrative treatment for MSDs provided at the RLHIM was generally acceptable in terms of the treatment process. Integrative treatments for MSDs provided at the RLHIM were in demand. Most patients had chronic complex MSDs, with associated co-morbidities and polypharmacy, having tried various conventional treatments with little persistent improvement. Though patients stated they had

realistic expectations, they hoped to receive prolonged, non-invasive, patient centred treatment, from practitioners who were qualified and interacted with patients. The feasibility findings showed that identifying eligible patients and recruitment were challenging, but there was a high attendance and good completion at 12 months. This was reflected in the qualitative findings where participants reported positive experiences in the research process. VAS and sfBPI targeting patients' specific symptoms, pain and physical function, and a narrative approach to explain their complex MSDs holistically were preferred.

An IM model has been developed based on components of IM perceived as important by patients for MSDs. Patients' self-management was an essential part of their IM experiences. Other key components of IM include: providing individualised treatment in a holistic approach; considering different treatment options including both CAM and conventional treatment; and working collaboratively in a multidisciplinary team. It also emphasises the communication between patients and practitioners, who are professional experts, patient centred, empathetic, share information, and actively manage patients' expectations. These components are recommended to be explored in future research.

The mixed methods design is the strength of this research study. Utilising both quantitative and qualitative methods of data collection and data analysis has allowed to answer different questions regarding feasibility of the research study. Triangulating the data during the interpretation phase has enabled a more comprehensive account of the data. However, the absence of a control group raises the question as whether the effects are really attributable to the treatment. Lack of ethnic and socioeconomic diversity of participants does not permit generalisation of these findings to other populations of MSDs patients. Considering the increasing population with MSDs, the increasingly elderly population and the demand for IM service, evidence on IM effectiveness, cost-effectiveness and safety are required to

develop guidelines for IM provision. Future mixed methods research developed using a pragmatic approach to investigate IM with the proposed identified key components is warranted.

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Appendices

Appendix 1 1 Original published protocol of the mixed methods feasibility study

ORIGINAL ARTICLE

A Pragmatic Observational Feasibility Study on Integrated Treatment for Musculoskeletal Disorders: Design and Protocol

Xiaoyang Hu[1], John Hughes[2], Peter Fisher[2], Ava Lorenc[1], Rachel Purtell[3], A-La Park[4], and Nicola Robinson[1]

ABSTRACT **Background**: Musculoskeletal disorders (MSD) comprise a wide range of conditions, associated with an enormous pain and impaired mobility, and are affecting people's lives and work. Management of musculoskeletal disorders typically involves a multidisciplinary team approach. Positive findings have been found in previous studies evaluating the effectiveness of complementary therapies, though little attention has been paid to evaluating of the effectiveness of integrated packages of care combining conventional and complementary approaches for musculoskeletal conditions in a National Health Service (NHS) setting. **Objective**: To determine the feasibility of all aspects of a pragmatic observational study designed: (1) to evaluate the effectiveness and cost effectiveness of integrated treatments for MSDs in an integrated NHS hospital in the UK; (2) to determine the acceptability of the study design and research process to patients; (3) to explore patients' expectation and experience of receiving integrated treatments. **Methods**: This is an observational feasibility study, with 1-year recruitment and 1-year follow-up, conducted in Royal London Hospital for Integrated Medicine, University College London Hospital Trust, UK. All eligible patients with MSDs newly referred to the hospital were included in the study. Interventions are integrated packages of care (conventional and complementary) as currently provided in the hospital. SF-36™ Health Survey, short form Brief Pain Inventory, Visual Analogue Scale, and modified Client Service Receipt Inventory will be assessed at 4/5 time points. Semi-structured interview/focus group will be carried out before treatment, and 1 year after commence of treatment. **Discussion**: We intend to conduct a pragmatic observational study of integrated medical treatment of MSDs at a public sector hospital. It will inform the design of a future trial including recruitment, retention, suitability of the outcome measures and patients experiences.

KEYWORDS integrated medicine, musculoskeletal disorders, feasibility study, mixed method

Musculoskeletal disorders (MSDs) comprise a wide range of conditions, associated with an enormous pain and impaired mobility, and are affecting people's lives and work. It is reported that 70%–84% of adults in the UK experience nonspecific low back pain[(1)] and 70% experience neck pain[(2)] during their lifetime. The incidence of MSDs appears to be increasing, with a corresponding impact on primary health care provision.[(3)] MSDs treatments cost $389 million to the retail industry in the US in 2007.[(4)] Annually in the UK they cost approximately £7.4 billion and cause £9.5 million lost working days.[(5)]

Management of MSDs typically involves a multidisciplinary team approach, including reduction in workload, increased rest, stress management, behavioural intervention and physiotherapy. Drug therapies include simple analgseics such as paracetamol, non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, topically or systemically, opioids and tricyclic antidepressants; as well as surgery. Complementary and alternative medicine (CAM) is commonly used to treat musculoskeletal conditions, especially pain such as back pain, neck pain and shoulder pain.[(6-8)] The National Institute for Health and Clinical Excellences's (NICE) guideline on low back pain recommends consideration of manual therapy and acupuncture, traditionally considered CAM therapies.[(9)]

A recent systematic review reported the 12-month prevalence of any use and visits to CAM practitioners in

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15 countries, with prevalence ranging from 9.8%–76.0% for the use of any CAM and 1.8%–48.7% for visits to CAM practitioners, respectively.[10] An increasing number of English primary care practitioners offer CAM to their patients rising from 39% in 1995 to 50% in 2001.[6]

The Royal London Hospital for Integrated Medicine (RLHIM) is the largest public sector provider of integrated medicine in Europe and is part of University College London Hospitals (UCLH) National Health Service (NHS) Foundation Trust. MSDs are the most frequent reason for referral. In 2010, the hospital received over 15,000 patient referrals, of which 3,633 cases (24.2%) were MSDs referrals.

The effectiveness of many complementary therapies for MSDs has been explored in previous studies, with some positive findings.[11-14] However, little attention has been paid to evaluating of the effectiveness of integrated packages of care combining conventional and complementary approaches for MSDs in an NHS setting. Therefore, a feasibility study is required to pilot the study design in order to inform a future definitive trial.

This study aims to determine the feasibility of all aspects of a pragmatic observational study designed: (1) to evaluate the effectiveness and cost effectiveness of integrated treatments for MSDs in an integrated NHS hospital in the UK; (2) to determine the acceptability of the study design and research process to patients; (3) to explore patients' expectation and experience of receiving integrated treatments.

METHODS

Setting and Design

This study will be conducted in the outpatient department at the RLHIM. It will use a pragmatic observational, mixed methods approach (quantitative and qualitative methods), with 1-year follow-up.

Ethical Approval

Ethical approval for the study was obtained from City and East London Research Ethics Committee (REC reference number: 12/LO/1341). Anonymous data will be held securely and transferred only between the research team members.

Inclusion and Exclusion Criteria

This study will include all eligible patients with MSDs attending RLHIM in a 12-month period from January 2013 to January 2014. Table 1 shows the inclusion/exclusion criteria for the study. All eligible patients who give informed consent and indicate they are willing to participate in the study over the 12-month period will be recruited.

Table 1. Study Eligibility Criteria

Inclusion criteria	Exclusion criteria
1. *New referrals to RLHIM for MSDs; 2. Patients who are at least 16 years old of both gender; 3. Patients who have a primary diagnosis of ICD-10 codes-musculoskeletal system and connective tissue; 4. Patients who are able to take part in the study for 1 year.	1. Patients who are unwilling to take part in the study; 2. Patients who are unable to speak English and therefore unable to understand the patient consent form or patient information form; 3. Patients who have severe progressive disorders with life threatening condition or poor prognosis; 4. Patients who have cognitive impairment such as dementia or psychological disorders.

Notes: *Including all MSDs patients who have had treatment for MSDs previously but are now presenting for a new episode of care. Either a single MSDs diagnosis or with a combination MSDs diagnoses will be included; ICD, international classification of diseases

Qualitative data will be collected both before and after treatment in a manner which will ensure that the views of a range of participants are reflected. Patients will be purposively selected on the basis of their expectations of benefit from the treatment, age and gender (at 1st interview, before treatment). A second sample of participants will be purposively selected following treatment based on the results of their SF-36™ Health Survey (SF-36), short form Brief Pain Inventory (BPI-sf), Patient Expectation Questionnaire (PEQ) scores, medical condition, age and gender. This data will be collected at the 2nd interview or focus group at 1 year starting treatment.

Routine Practice for MSDs at RLHIM

Patients who present with MSDs typically receive integrated packages of care from RLHIM. The integrated packages of care combine conventional and complementary approaches, including dry needling and acupuncture, trigger point therapy, prolotherapy (injections to ligaments), homeopathy, phytothera, electrotherapies; medical manipulation, orthotics, cognitive behavioural therapy, occupational therapy, musculoskeletal physiotherapy, nutritional and dietary assessment and advice.

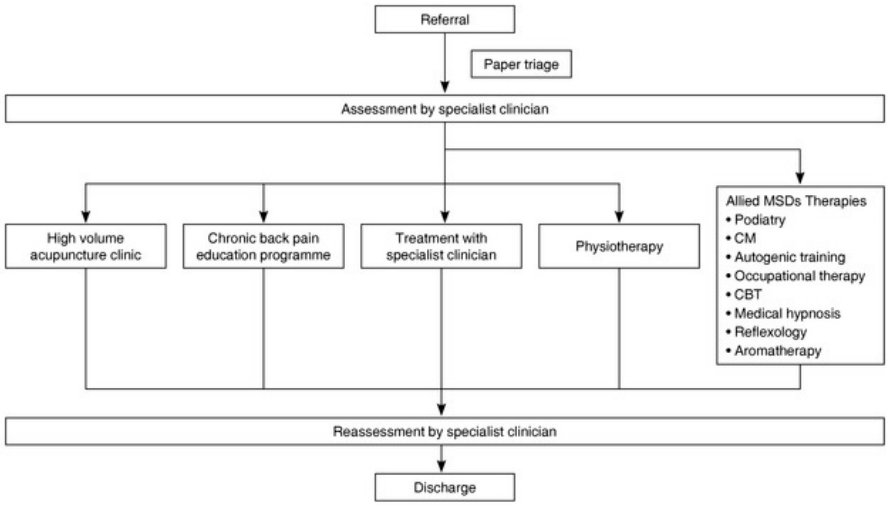

Figure 1. Musculoskeletal Care Pathway at RLHIM for Integrated Medicine
Notes: CM: Chinese medicine; CBT: cognitive behaviour therapy

As per routine standard practice, all musculoskeletal referrals to the RLHIM will be triaged by a specialist clinician and referred to various departments (Figure 1). All patients will be reassessed by a specialist clinician before being discharge.

Participant Recruitment and Flow

Figure 2 details the process of recruitment and data collection procedures for the feasibility study. Patients will be screened using the inclusion/exclusion criteria. Eligible patients will receive a Patient Information Sheet (PIS) and invitation letter, and a reminder about the study from the patient services department when arranging their hospital appointment. Patients will be further screened on the phone by the chief investigator (CI). Those providing verbal consent will be sent a questionnaire package including consent form, sociodemographic questionnaire, PEQ with a reply paid envelope to patients who are happy to be contacted. Those patients who provide written consent and return the questionnaires will be contacted by the CI to arrange a face-to-face meeting prior to their 1st hospital appointment.

Patients who present with MSDs typically receive packages of care from RLHIM. During the 1st appointment, some patients receive treatment immediately, others may receive an initial treatment but then have to wait before the beginning of a course of treatment.

OUTCOME MEASURES

A range of outcome measures will be employed in order to determine their appropriateness and acceptability for accessing integrated packages of care for patients with MSDs.

Sociodemographic Questionnaire

The sociodemographic questionnaire includes: level of education, occupational status, first language, religious affiliation and ethnic origin. It takes approximately 2 min to complete, and will be administered once in the period between the 1st appointment being booked and attending this appointment.

PEQ

As expectation of benefit has been shown to impact on clinical effectiveness,[15] we have developed a PEQ to assess patients' expectation of benefit from their integrated treatment, and how much faith they have in complementary therapies in general, both measured on 10-point ordinal scales. The PEQ takes approximately 2 min to complete, and will be administered once, at the same time as the

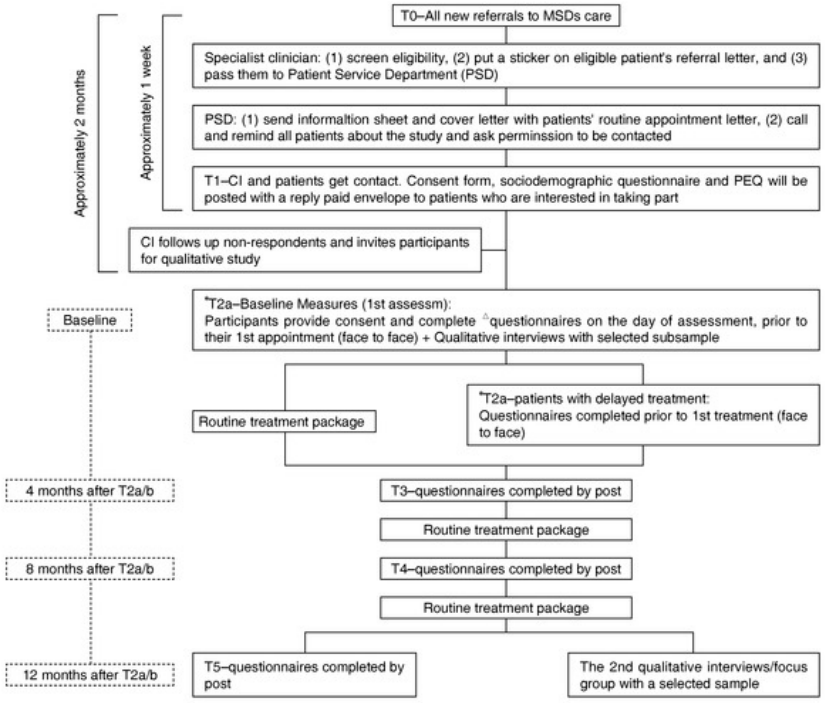

Figure 2. Participant Flow

Notes: *In routine practice, some patients may have one-off treatment or commence their treatment immediately at T2a, some patients may have to wait for their treatment. For those who are put on the waiting list (up to 5 months), an additional evaluation will be administered at T2b before their 1st treatment. △Questionnaires include SF-36, BPI-sf, Visual Analogue Scale and modified Client Service Receipt Inventory

sociodemographic questionnaire.

Primary Outcome Measures

The SF-36—Bodily Pain Subscale

The SF-36 is a multi-purpose, short-form health survey with 36 questions. It yields an 8-scale profile of functional health and well-being scores as well as psychometrically-based physical and mental health summary measures. It is a generic measure, as opposed to one that targets a specific age, disease, or treatment group. The internal consistency of the SF-36 had been extensively evaluated with most studies finding a reliability coefficient (Cronbach's alpha) over 0.80.[16]

Bodily pain is one dimension of SF-36 consisting of two questions. The bodily pain subscale is an accepted, validated and reliable sub-scale, useful for making comparisons across populations.[17]

Secondary Outcome Measures

The SF-36 —Other Dimensions

In addition to the SF-36 bodily pain dimension, there are 34 questions on physical function, physical role, general health, and mental health, emotional role, social function and vitality. SF-36 has been used and validated with numerous studies in a variety of patient populations, including patients with MSDs.[18-22] This questionnaire has also been suggested for routine use within the NHS.[23] The SF-36 (including SF-36 Bodily Pain Dimension) takes approximately 10 min to complete.

BPI-sf

The BPI-sf is a valid and reliable tool for evaluating pain status.[24,25] It has been used widely for various kind of pain, especially in musculoskeletal pain.[26-29] It includes 9 questions and provides information on the intensity of pain, along with the degree to which the pain interferes with everyday

functioning. The internal consistency of the BPI-sf has been extensively evaluated with studies finding a reliability coefficient (Cronbach's alpha) of 0.77 to 0.91.[30] Numerous studies have used the BPI-sf in a variety of patient populations, including patients with MSDs.[31] It is routinely used for MSDs at RLHIM. The BPI-sf takes approximately 5 min to complete.

Visual Analogue Scale

Visual Analogue Scale (VAS) is a commonly used outcome measurement to monitor variations in intensity of pain. It will provide additional confirmation together with BPI-sf and SF-36 Bodily Pain subscale to validate patients' reports of pain. The VAS takes less than 1 min to complete.

Modified Client Service Receipt Inventory

Health and social care service utilization will be explored by asking participants about quantity/frequency of service use. The Client Service Receipt Inventory (CSRI) is an internally validated instrument.[32] A modified version of the CSRI (mCSRI) has been designed to collect retrospective data on the impact of integrated medicine approaches on use of our health and social care services. The mCSRI takes approximately 10 min to complete.

Qualitative Study

In the 1st semi-structured interview, a interview schedule with a series of prepared, open-ended statements will cover the participants' condition, treatments previously used, referral process to RLHIM and their expectation of the integrated treatments. The 2nd semi-structured interview or focus group will cover patient's experiences of the integrated treatments they received at the RLHIM, their experiences of participating in the study, including recruitment, drop-out and compliance, acceptability of the study design and outcome measures. Both interviews and focus groups will last 60 min, and will be digitally recorded and transcribed verbatim.

Sample Size

Although a feasibility study does not require a sample size calculation, we hope to recruit 150 patients and anticipate that this will provide a sufficiently large enough sample to capture the range of patients and conditions presenting at the RLHIM.

Previously at RLHIM a pragmatic observational study was carried out on a group of 152 patients (presenting for a variety of conditions) receiving a course of autogenic training over 12 months.[33] This project demonstrated the feasibility of this approach and the ability to recruit and demonstrate change after completing the autogenic training programme at RLHIM. It is anticipated that there will be more eligible patients in the proposed study as MSDs are the group of conditions mostly frequently presenting at the hospital.

There were 311 new MSDs referrals in 2010 to the RLHIM and estimating that approximately 50% would be ineligible or do not consent to take part in the study, it is anticipated that there will about 150 eligible patients. Data on patients who drop out during the study will be collected for further comparisons.

For the qualitative study, a limit of 30 patients was set for each of the two nested qualitative studies, as it is anticipated that this will be a sufficient sample size to ensure theoretical saturation of emergent categories and themes.[34]

DATA COLLECTION

Data Collection on Feasibility

During recruitment, data will be recorded on number of past/new referrals, eligible patients for the study, number of patients consenting/declining to take part, and reasons for not participating.

At the end of the study, attendance for appointments, patient follow-up and drop-out/completion rates will be generated from treatment logs. Rates of completion of the outcome measures, data collection and analysis will be explored by the CI. The study timeline as measured by the time taken to recruit and complete the study will also be evaluated.

Quantitative Data Collection

Data will be collected at 4 time points (5 if patients have delayed treatment, Table 2): T1 (mail) after an appointment is arranged but before the patient has attended T2a before their 1st treatment; T2b (if treatment is delayed, face to face) immediately prior to starting their package of treatment; T3, T4, (mail) at 4, 8, 12 months respectively after T2a/b; T5 (mail or interview/focus group for subset) 12 months after T2a/b. The CI will post a copy of the SF36, BPI-

Table 2. Schedule of Outcome Measures

Measurements	Waiting time between referral letter and treatment initiation (T1)	Before initiation of RLHIM treatment (T2a)	Before initiation of RLHIM treatment (T2b)	4 months after T2a/b (T3)	8 months after T2a/b (T4)	12 months after T2a/b (T5)
Sociodemographics	X					
PEQ	X					
SF-36		X	X	X	X	X
BPI-sf		X	X	X	X	X
VAS		X	X	X	X	X
mCSRI		X	X	X	X	X

Note: X rpresents the time point at which this questionnaire data will be collected

sf, VAS and mCSRI to patients with a reply paid envelope. A list of the outcome measures schedule is given (Table 2).

Qualitative Data Collection

Qualitative data will be collected at T2a and T5. Interview/focus groups will be conducted at RLHIM, patients homes, or other location convenient for participating patients.

DATA ANALYSIS

The analysis of data (both qualitative and quantitative) will be undertaken by the CI under the supervision of the research team.

Frequency Data Analysis

Frequency data on the number of past/new referrals, eligible patients for the study, number of patients consenting to take part and with explanation of reasons in detail will be manually entered into Microsoft Excel. A record of all patients will be kept on: their attendance for treatments, the treatments provided, and the completion of questionnaires and interview/ focus groups with dates specified. A timeline of the whole pilot will inform the future study protocol.

Data Analysis for the Quantitative Pilot Trial

Data from the sociodemographic questionnaire, SF36, BPI-sf, VAS and mCSRI will be entered in Excel, and analysed using Statistical Packages for Social Sciences (SPSS) version 18 using appropriate between-group tests.

The primary time period is the change in scores over a 4-month period after starting definitive treatment and at 12 month follow-up assessment, in order to assess the feasibility of measuring the potential long-term treatment effect. Data on the feasibility of the study design including recruitment, compliance, follow-up, outcome measures, time scale and acceptability to patients and clinicians will be used to develop a protocol for a full trial. In order to calculate the sample size for the full trial, data will be used to calculate the effect size. Exploratory data analysis will be conducted on all the relevant parameters. If the data is normally distributed, an ANOVA will be conducted comparing scores in mean of different time points, followed by Pearson correlation and regression test for possible combinations. If appropriate and if there are sufficient numbers, sub analysis will be conducted to evaluate the differences in improvement between different categories of patients, for example: patients with various MSDs diagnosis; presence of one or multiple MSDs; sociodemographic characteristics; package of care received, including group treatment or one-to-one clinics and number of different therapies received. Differences between patients who do not complete their course of treatment and completers will be evaluated. Sensitivity analyses will be performed by varying a wide range of parameters in terms of costs.

Patients are routinely discharged from the hospital if they fail to attend for an appointment on two consecutive occasions. Intention to treat analysis using last value carried forward will be used, so if patients are discharged before completing treatment or are otherwise lost to follow-up, all the data collected up to the last point will be used. This helps in preventing skewed data and those data will be collected for a subgroup analysis, to evaluate the differences between those patients and those who consistently come to the clinics.

Data Analysis for the Interview/Focus Group

The semi-structured interviews and focus groups with patients will be digitally recorded and transcribed

verbatim. Qualitative data will be analysed thematically and major categories and themes identified using NVivo10.

DISCUSSION

This study is developed based on data from everyday practice at the RLHIM. Based on this we plan a feasibility study to evaluate the effectiveness and cost effectiveness of the integrated package of treatment for MSDs provided at the RLHIM. We plan to recruit 150 patients by January 2014.

There is a dearth of published research evaluating the impact of integrated treatments for MSDs in a NHS setting. This research will inform all aspects of the design of a future trial including recruitment, retention, suitability of the outcome measures, patients views and experience. A definitive trial is important because these conditions are highly prevalent and complementary therapies often used by patients, although usually outside NHS settings. Such a trial would improve policy, inform guidelines and decision-making for MSDs practitioners and MSDs patients; provide policymakers/commissioners with economic evidence, which may facilitate optimal resource allocation decisions; and to inform clinical practice for future patient care at the RLHIM and elsewhere by suggesting which treatment combinations are associated with the best outcomes for MSDs patients.

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The authors thank Mr. Jonathan Hearsey, Valerie Lawler and all patients services staff at the RLHIM for recruiting, screening the eligible patients, and the clinicians of RLHIM for their cooperation.

Conflict of Interest Statement

We acknowledge that there is a patient and staff from RLHIM involved in this study, however, there is no conflict of interest as there is no direct financial or other connections with other people or organizations or that can inappropriately influence our work, there is no professional or other personal interest of any nature or kind in any product, service and/ or company that could be constructed as influencing the position presented in, or the review of, the manuscript.

Disclosure Statement

No competing financial interests exist.

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Appendix 2 1 Published research paper on scoping and defining integrative medicine

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Review article

Defining integrative medicine in narrative and systematic reviews: A suggested checklist for reporting☆

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Abstract

Introduction: The use of the term integrative medicine (IM) is evolving over time but its exact definition remains imprecise. In this paper we use IM to mean complementary and alternative medicine (CAM) provided holistically and in conjunction with conventional medicine. Drawing from the experience of experts in different geographical areas (USA, UK, Australia, and China), this review aimed to identify key elements which could be used to define IM in order to develop a potential guide for reporting IM in clinical research.
Method: A total of 54 sources were searched (including websites of governments, key authorities, representative clinical sites, academic journals, relevant textbooks) to identify definitions of IM from the four countries from 1990 to 2014. Key elements characterizing IM were extracted and categorized using a thematic approach in order to identify the key items to consider when reporting IM in research studies.
Results: Seventeen definitions were identified and extracted from 17 sources. The remaining 37 sources did not provide a definition of IM. The most common key elements which defined IM were: using aspects of both CAM and conventional medicine; goals of health and healing; holistic approach; optimum treatment; and the body's innate healing response. Integration was also defined at three levels: theoretical, diagnostic and therapeutic. A potential checklist of items is proposed for reporting IM in clinical studies.
Conclusion: This paper identifies the key elements which define IM and provides a potential reporting guide for IM clinical trials and which could be used in narrative/systematic reviews. Further debate, discussion and input is now needed from the research and clinical IM communities to further advance this agenda.

This article belongs to the Special Issue: *Traditional and Integrative Approaches for Global Health*.

Keywords: Integrative medicine; Definition; Cross-cultural; Reporting guidelines; Checklist; Systematic review

Introduction

The term integrative medicine (IM, also called integrative/integrated healthcare) is frequently used in different healthcare sectors/systems, education, research, and clinical practice. There is no standard definition. The terminology has evolved over the last 20 years from "unconventional medicine" to "holistic", to "complementary and alternative medicine (CAM)", reflecting the dynamic state of this field. The term IM, is often used for example in palliative care. For this paper, IM was considered as a holistic approach that involves CAM.

In western countries, various IM practices are emerging, with current literature focusing on IM models and strategies for integration within health care settings and systems [3–5]. In the West, the clinical evidence for IM consists largely of studies of individual CAM practices. However, the research evidence on

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the effectiveness of IM provided as a package of care is limited due to its complex nature and definition, lack of standardization and challenges in methodological design [6–10]. IM in the west has generally been an ad hoc development, which has been gradually emerging and is available in different forms and in different settings.

In the UK, healthcare is provided by the National Health Service (NHS). Integration within the NHS is unusual although many patients choose to use CAM privately alongside their conventional NHS care [11,12]. For example, in the primary care setting there are three forms of IM: referral between the primary health care team and local CAM practitioners; CAM practitioners working directly within the same setting as the primary health care team; or a primary health care team member with training in CAM, such as acupuncture [13,14]. In the secondary care setting, there may be statutory registered health professionals who have undertaken additional training in a CAM modality, such as in the clinical delivery at the Royal London Hospital for Integrated Medicine [15], where autogenic training is provided [16].

In the US, the National Institutes of Health (NIH)'s started an Office of Research on Unconventional Medical Practices which subsequently became the Office of Alternative Medicine (OAM) in 1992. It changed to the National Center for Complementary and Alternative Medicine (NCCAM) in 1998; as of 2014, its new name is – the National Center for Research on Complementary and Integrative Health (NCRCI) [17]). Initially, the OAM focused on practices not typically taught or provided in conventional medical settings, and not covered by most insurance. Over time, as CAM therapies were integrated into curricula, care, and insurance plans, this definition has proved problematic. For example, by 2005, acupuncture was offered in over 1/3 of academic pediatric pain programs in North America [18]. Professional organizations have developed interest groups or committees focusing on CAM since 1990s [19–21]. In primary care and in various specialty settings, a combination of biomedical and mental health care is regarded as IM. There are many similar examples which focus on using treatments in parallel or in combination. Such approaches consider patients' needs and require careful coordination, such as: nutrition (e.g. prenatal vitamins are universally recommended; folate supplements being advised for use by pregnant women; older adults are advised to take vitamin D), and therapies routinely provided in a rehabilitation setting such as acupuncture and physiotherapy, etc. Insurance coverage and licensure for chiropractic is universal in all US states. Professional licensing has also grown; acupuncture is licensed in over 85% of US states, and naturopathic physicians are licensed in 19 states, districts and territories in the US. In 1999 NCCAM funded 14 training programs at medical schools and teaching hospitals [22]. By 2013, over 20 family medicine residency programs offered tracks in IM and, in 2014, five pediatric residencies began offering similar IM training programs. Meanwhile the formation of the Consortium of Academic Health Centers for Integrative Medicine was founded at the most recent turn of the century with 8 centers, and has grown to include over 54 North American programs and centers [23].

In Australia, the integration of some CAM within conventional medical and healthcare settings remains largely ad hoc and informal [24], despite interest in CAM amongst some GPs, midwives and other health professionals [25]. Recent research suggests referral networks and communications between doctors and CAM practitioners are still often poor [26]. However some health professionals, midwives and nurses in particular, do appear to be engaging in direct integrative practice whereby they are trained and practicing another therapy [27].

IM in China always refers to the integration of Traditional Chinese Medicine (TCM) and Western medicine. The Chinese integrative health care system was purposively created and promoted by Mao Zedong in 1956, "*to integrate the knowledge of Chinese medicine and materia medica with the knowledge of western medicine and pharmacology, to create our unique new medicine and new pharmacology*" [28]. Subsequently, integration developed within education, licensing, clinical practice, research and policy. It is embedded in Chinese culture as it is a part of a long-term policy in China and is extensively used throughout China. Both TCM and Western medicine are regulated and supported by the Chinese government and national funding executive agencies. They coexist and share methods of diagnosis and treatment based on both TCM and Western medicine theories [28]. Due to its political stance, IM in China has been a planned development, rather than growing organically as in the west. In China, IM is actively practiced in the Chinese medicine departments in western medicine hospitals, all departments of Chinese medicine hospitals, as well as all departments of integrative medicine hospitals for various conditions [29]. China is the only country with medical licensing in IM, allowing clinicians to practice both conventional and TCM [28]. In most cases, the same clinician can provide both an IM diagnosis and treatment using the knowledge from both disciplines. They also have opportunities to cross refer to multidisciplinary collaborative teams as a result of the unifying paradigm which is shared jointly with other clinicians.

Problems emerge when trying to identify and synthesize studies on IM [6,10]. A wide range of search terms are necessary to identify all potential IM studies due to the absence of standardized terminology or a recognized definition of IM. The lack of a shared conceptual framework and taxonomy for IM models is also problematic. There are further challenges due to differences between countries and manuscripts published in different languages, often extensive work is required in order to identify search terms and synthesize findings [10]. Difficulties include the fact that many studies are not labeled as IM so may not be captured in searches using IM keywords or MeSH terms; and many studies purport to be 'IM' but this may not be the case [6,10].

These problems have been previously identified for complex interventions, suggesting it is not useful or problematic to conduct systematic reviews for such interventions [6]. A realistic review, explaining rather than judging and using qualitatively narrative synthesis, may be more appropriate [6]. This paper reports results from such a qualitative narrative review of IM definitions in literature from the US, UK, Australia, and China and aims to identify the key elements of defining IM. Rather

than attempting to review all examples of IM worldwide it provides a starting point to begin to explore the issues faced when synthesizing IM research and practice for research purposes.

Various checklists for researchers and reviewers have been developed to enhance the quality of reporting in clinical studies, e.g. Consolidated Standards of Reporting Trials (CONSORT) [30] and the Consolidated criteria for reporting qualitative research (COREQ) [31]. However, many of these checklists may not be suited to complex interventions such as IM. Some extensions have already been developed to adapt these checklists for alternative interventions, such as Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) [32] and the complex interventions extension for CONSORT [33]. The second purpose of this paper was to begin to develop a guide for reporting IM (along the lines of CONSORT), which could be further developed for research purposes.

Method

A range of data sources, including government, key authorities, academic organizations, representative clinical sites, academic journals, relevant textbooks (those viewed as authorities on IM, with either integrated or integrative in their title, but not condition specific, were selected by the authors), and relevant research papers (Table 1) were selected from four countries (US, UK, Australia, and China) and were searched for definitions of IM (1990–2014). These four countries were chosen (as represented by the authors) to provide an international context covering different cultural backgrounds and models of IM practice. Key elements characterizing IM were identified and categorized in a thematic approach, in order to determine and define the elements of IM for future narrative and systematic reviews, provide guidance, and stimulate wider discussion in the research community.

The guide used the CONSORT reporting items as its basis, and added possible items/statements specific to IM, based on the data in this review, and the authors' experiences. The development of a guide is intended to be the first stage in developing a checklist for reporting IM.

Results

Key elements of defining integrative medicine

A total of 54 sources were searched (Table 1). Thirty seven sources did not have a specific definition of IM. Seventeen definitions from 17 sources were identified and extracted. These were identified from the US (13), China (2), UK (1), and Australia (1) [1,2,45,47,48,57,58,63,80–88]. Thirteen (out of 17) emphasized the integration of CAM and conventional approaches [45,47,48,57,58,63,80,82–88], followed by treatment focusing on goals of health and healing (using approaches and methods to optimize health and healing) (12/17), holistic approach (emphasizing all aspects of a person, also including individualized treatment) (12/17) [1,2,45,47,57,63,81–83,85–87], optimum treatment (the use of the most appropriate combination or single CAM/conventional treatment for a condition) (8/17) [2,47,48,58,82,86,88], and the body's innate healing response (4/17) [45,57,81,82]. Though multidisciplinary team work has for some time been emphasized as an integral component of complex interventions [89], only four definitions identified in our review emphasized a collaborative approach to patient centered care (see Fig. 1) [2,45,87,88]. Apart from the key elements mentioned above, integration at the theoretical, diagnostic, and therapeutic levels has also been suggested [63].

However, none of these elements are totally unique to IM, although they are not commonly part of conventional care. Many definitions also included other elements which commonly define conventional medicine and so are not included in our definition of IM. These were: patient–practitioner relationship (12/17) [1,2,45,47,48,57,58,80,82,83,86,88], evidence-based (9/17) [2,45,48,58,80,81,84,85,87], effectiveness (5/17) [1,58,63,80,88], safety (4/17) [57,58,80,88], and low cost (2/17) [57,87].

In summary, the IM definitions were identified from reference sources from the US, UK, Australia and China, and consisted of many of the same elements (Fig. 1). In addition the Chinese definition emphasizes that integration can occur at theoretical, diagnostic, and therapeutic levels. These elements can be seen as occurring at each of the three levels, which forms the basis of our discussions.

A potential reporting guide for integrative medicine

The authors used the elements identified in Fig. 1 and explored whether these could be recommended for reporting within a checklist. The frequency of the elements identified was used to develop the checklist for determining whether the health care intervention/provision reported was IM. The recommended items for reporting are linked to the key elements identified (where appropriate) and this is followed by detailed discussion.

In order to capture the details on integration in published papers and systematic reviews, we suggest that researchers working in this field should consider routinely providing the specific details as shown in Box 1 , in order to demonstrate whether their intervention could be defined as IM and to improve the quality of reporting in IM research.

This recommendation needs further debate, discussions and input from other researchers. One of the ways to look at IM may be through these three levels, which has been recommended and operates in China [63]. Integration at least one of the three levels (theoretical, diagnostic or therapeutic), with a consideration of all of the key elements could be regarded as IM.

Discussion

Determining the defining elements of IM

In this review, 17 definitions were identified, the majority from the US. IM may be interpreted differently depending on the country and its healthcare practices over time, with no standard definition it may be appropriate to have different

Table 1
Forty-nine sources used to identify definitions of integrative medicine in four representative countries.

Websites	China	UK	US	Australia
Governments	State Administration of Traditional Chinese Medicine (SATCM) [34]	National Health Service (NHS) [35]	National Center for Complementary and Alternative Medicine [36]	Department of Health [37]
Key authorities, academic organizations	China Association of Integrative Medicine (CAIM) [38] China Academy of Chinese Medical Sciences (CACMS) [39]	CAMbrella (European) [40] Research Council for Complementary Medicine (RCCM) [41]	Consortium of Academic Health Centers for Integrative Medicine [23]	Australasian Integrative Medicine Association [42]
Clinical sites	CACMS affiliated hospitals	Royal London Hospital for Integrated Medicine [43]	Arizona Center for Integrative Medicine [44]; Osher Center for Integrative Medicine [45]; Center for Integrative Medicine, University of Maryland [46] Ohio State University Integrative Medicine [47]	National Institute of Integrative Medicine [48]
Academic journals*	•European Journal of Integrative Medicine [49]; •Chinese Journal of Integrative Medicine [50]; •Integrative Medicine: A Clinician's Journal [51]; •Journal of Integrative Medicine [52]; •Advances in Integrative Medicine [53]; •Alternative and Integrative Medicine [54]; •International Journal of Integrative Medicine [55]; •Journal of Experimental and Integrative Medicine [56];			
IM textbooks *	•Integrative Medicine, by David Rakel [57]; •Introduction of Integrative Medicine, by Shikui Chen [58]; •Integrative Medicine: Principles for Practice, by Benjamin Kligler, Roberta Anne Lee [59] •Scientific Basis of Integrative Medicine, by Leonard A. Wisneski, Lucy Anderson [60] •Integrative Health Care, by Victor Sierpina [61]			
Others	•Wikipedia [62] •Baidu Baike [百度百科] [63] (Chinese version of Wikipedia) •Key project, review papers, and opinion papers on IM [8,24,64–77] •Divining integrative medicine [78] •Integrative Medicine and the Health of the Public: A Summary of the February 2009 Summit [79]			

* Journals and textbooks which specifically have either integrated or integrative in their title, but not condition specific were selected.

definitions which incorporate a cultural context. Moreover, the dynamic nature of the rapidly changing and growing field means that it is hard to create an enduring definition that works across all cultures and times. However, from the definitions identified in this analysis, it became clear that there are a number of similarities as well as ways of interpreting the key elements of IM, which need to be taken into account if IM is to be reported in a standardized way. Some may argue that the term IM has become outdated since conventional care has adopted or promoted so many of these concepts, e.g. patient-cantered care is not just an IM concept and is paramount in conventional care. It might be that in the future, IM is just

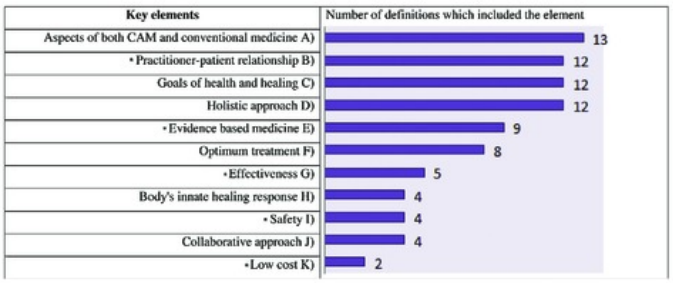

Fig. 1. Frequency of key elements identified from seventeen selected definitions of IM from four countries. *These elements are also important in conventional health care (not unique to IM).

Box 1. Suggested checklist items for reporting IM studies

- Identification of IM in the title

IM rationale

- Rationale of chosen interventions providing the potential optimum treatment for the target condition (element F).
- Details of each treatment and their theoretical background (for both CAM and conventional medicine) (element A).

IM evidence

- Evidence for the effectiveness of component treatments and for the combined treatment, if available (elements E/G).

IM safety

- Previous studies/reviews on safety of each single treatment, as well as the combination of treatment, if available (element I).

Study design

- Explanation and justification of the choice of study design and methods which are appropriate for IM, e.g. pragmatic trials, nested qualitative trials.
- Outcome measures addressing multiple dimensions, including physical, mental, safety and economic conditions.

Integration in diagnosis

- Integrative methods of diagnosis, i.e. does it involve a combination of both biomedical tests, i.e. the use of X-rays, blood tests; and traditional or CAM theory, i.e. Chinese medicine syndrome differentiation, Sasang constitution medicine etc.
- Use of any conventional medical or CAM diagnostic guidelines.

Personnel

- Details of all practitioners providing the IM (licensing, education background/length of training).
- Division of care, i.e. different interventions provided by the same/different practitioners. If provided by different clinicians, details of the nature of the work collaboration (interdisciplinary/multidisciplinary teamwork) and communication, how the information was shared if they are not provided by the same practitioner (element J).

Clinical setting

- Were the different interventions provided in the same clinical location? If not, what is the link between the practices? (element J).

Interventions

- Detailed description of each intervention (element A/H).
- Regimen for each treatment: number of treatment sessions, frequency and duration of treatment sessions, when and how each intervention was provided.
- Details of the integration, i.e. when and how treatments were integrated (elements A/J).
- Any take home or self-care/lifestyle/family care general advice? (elements B/D).

Results reporting

- If used both quantitative and qualitative approach, triangulation of the results.
- Any harm caused or interactions between/among interventions (element I).
- Cost, with least opportunity cost (element K).

Element A: Aspects of both CAM and conventional medicine.
Element B: Practitioner–patient relationship.
Element C: Goals of health and healing.
Element D: Holistic approach.
Element E: Evidence based medicine.
Element F: Optimum treatment.
Element G: Effectiveness.
Element H: Body's innate healing response.
Element I: Safety.
Element J: Collaborative approach.
Element K: Low cost.

good medicine [90,91]. However, in order to assess its relevance and effectiveness in research studies and in reporting systematic reviews, information should be accurately recorded.

It is important to emphasize that IM is different from CAM therapies [58]. Combination of CAM and conventional medicine therapies should not considered IM because it may lack the reporting of the key elements identified in this review, which enables researchers/reviewers to decide whether IM was provided or not.

The clinician plays a very important role in the degree of integration as they need to be actively involved in every aspect of IM diagnosis and treatment to provide optimum treatment based on patients' need; ensure a holistic approach, at the same time interact and communicate with the patients to maintain a good patient–clinician relationship [69].

Theoretical level

As agreed in many existing definitions, IM is not the same as CAM, nor is it simply a synonym of conventional medicine with CAM [1,45,48,68,81,82]. Studies simply combining CAM and conventional treatment without providing more details on the model/framework of integration are not regarded as true IM practice [92–94]. As an alternative medical model, IM combines two knowledge systems, using optimum evidence and optimum research methodology [58]. The theoretical background of the package of treatment can be considered by IM researchers and practitioners, if a thorough literature review is carried out. This needs to include information on the optimum packages of interventions for a specific condition (element F, Fig. 1) that integrates the best evidence of CAM and conventional interventions, and consider safety and effectiveness (elements A/E/G/I, Fig. 1), in a non-hierarchical, blended approach, tailored to the individual [57,68].

The conceptual and theoretical background of IM across and within countries has originated from different philosophies, beliefs, and educational systems [28]. Therefore, integration at the theoretical level may be the most difficult. Using conventional medical research methods to explore TCM theory such as essence of yin and yang theory, viscera theory, and meridians [63], it may not be sensible or appropriate to extend these into animal models or to laboratory studies, nor can it be used to explain the mechanism of TCM therapies [95–97]. The IM paradigm also needs to be considered for other health systems such as Ayurveda, homeopathy and Korean oriental medicine.

IM theoretical structures influence all aspects of clinical practice including diagnostic techniques, interventions and therapeutic effects.

Diagnostic level

Diagnostic integration can provide a comprehensive understanding of a condition by using both biomedical and traditional and complementary approaches. As a result, the etiology and pathology can be explored biomedically, but also taking into consideration the overall holistic response into the process and dynamics, thus in parallel guiding diagnosis [63]. Integration at a diagnostic level is comparably well implemented in those countries with an intact system of IM in terms of education, clinical practice, policy and regulation. In China, IM uses a 'disease-pattern' model, which involves both conventional diagnosis and TCM pattern differentiation; in India, Ayurveda and homeopathy have their own unique diagnostic framework. Other examples investigating, classifying and quantifying at a diagnostic level includes; tongue/pulse diagnosis which may highlight pathological changes and may be substantiated through morphology, cytology, biochemistry, blood rheology and optical methods, etc. [58], computerized tongue diagnosis [98] determining health status using pulse diagnosis [99–102].

Diagnostic techniques are closely linked to the practitioners' theoretical background, the nature of the clinical setting, and the close communication among the multidisciplinary team.

Therapeutic level

Integration at a therapeutic level is often the most implemented of these three levels [58]. In practice, developing a holistic understanding and relationship with patients (elements B/D, Fig. 1), and providing the intervention package in a regulated, systematic, integrative way (element J, Fig. 1) allows practitioners to guide patients more efficiently toward health and well-being using a holistic approach. Such treatment emphasizes the interactions with all aspects of lifestyle by considering the numerous factors that influence health, wellness and disease, including the physical, emotional, psychological and spiritual aspects of the individual and community [57,69,82].

There are many successful examples of clinical practice integrated at therapeutic level. There are apparently a limited number of trials on IM as there is usually inadequate information to determine whether the interventions were IM or not. There is a lack of evidence for IM which suggest that an IM approach may be beneficial for various conditions such as cancer, musculoskeletal disorders (MSDs); cardiovascular disease; gynecological conditions; insomnia; and some medically unexplained symptoms [103–106]. In addition evidence for IM provided in different clinical settings (e.g. pain centers, rehabilitation units, etc.) is limited.

Implications for research

As with conventional medicine, many definitions of IM emphasize the importance of effective treatment (element G, Fig. 1) which should be underpinned by an evidence-base (element E, Fig. 1). However, it can be difficult to conduct trials in IM; for example, blinding is a challenge for complex and non-pharmaceutical interventions such as IM [107]. Pragmatic randomized controlled trials or observational studies with nested qualitative approaches (with both practitioners and patients) are worth investigating. These would provide information on effectiveness and safety on IM in 'real world' situations and would mimic the complexity of health care provision [108].

There appear to be many research papers on IM, but clarification of whether they actually provided IM is usually impossible due to the inadequate information provided on key elements of

IM, e.g. whether or not the care was relationship-centered or whether it provided a holistic approach. In order to improve the quality of reporting in IM research, we are proposing a potential guideline which may help researchers and reviewers to develop reporting guidelines for IM and also facilitate carrying out systematic reviews on effectiveness. However, this is a preliminary recommendation which needs further discussion, expert consensus and input from other expert researchers in this field as well as experts in countries where different systems of medicine are used.

Limitations

Only selected definitions from resources in four countries have been considered. Other countries have other systems of medicine with different degrees of integration, i.e. Korean Oriental Medicine, Ayurveda/Unani, homeopathy, and various other indigenous healing systems. The potential reporting guideline for IM has been developed from the current literature, and based on individual authors' experiences and selected sources which may have missed some key elements of definitions used in other countries.

Conclusion

This paper identified thirteen key elements defining IM and provides the basis for a potential reporting checklist for future IM studies. This may benefit researchers who are designing clinical research or conducting systematic reviews on IM practice. It may also help reviewers and health practitioners to determine whether an intervention is really IM. Though the acceptability of the term IM and the elements determining the definition vary between countries, recommendations for reporting IM research may help standardize reporting and help in developing a recognized and standardized definition. This in turn would facilitate the evaluation of integrative practice, improve the quality and relevance of narrative and systematic reviews in IM, and stimulate further discussion.

Conflict of interest statement

There is no conflict of interest as there are no direct financial or other connections with other people or organizations or that can inappropriately influence our work. All research has done by the authors. There was no financial support and no conflict of interest and all authors contributed equally to the drafting of this article.

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Appendix 2 2 Systematic review published on integrative treatment for low back pain

EVIDENCE-BASED INTEGRATIVE MEDICINE

Integrative Treatment for Low Back Pain: An Exploratory Systematic Review and Meta-Analysis of Randomized Controlled Trials

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ABSTRACT **Objective**: Low back pain (LBP) is a common musculoskeletal condition often treated using integrative medicine (IM). Most reviews have focused on a single complementary and alternative medicine (CAM) therapy for LBP rather than evaluating wider integrative approaches. This exploratory systematic review aimed to identify randomized controlled trials (RCTs) and provide evidence on the effectiveness, cost effectiveness and adverse effects of integrative treatment for LBP. **Methods**: A literature search was conducted in 12 English and Chinese databases. RCTs evaluating an integrative treatment for musculoskeletal related LBP were included. Reporting, methodological quality and relevant clinical characteristics were assessed and appraised. Meta-analyses were performed for outcomes where trials were sufficiently homogenous. **Results**: Fifty-six RCTs were identified evaluating integrative treatment for LBP. Although reporting and methodological qualities were poor, meta-analysis showed a favourable effect for integrative treatment over conventional and CAM treatment for back pain and function at 3 months or less follow-up. Two trials investigated costs, reporting £5332 per quality adjusted life years with 6 Alexander technique lessons plus exercise at 12 months follow-up; and an increased total costs of $244 when giving an additional up to 15 sessions of CAM package of care at 12 weeks. Sixteen trials mentioned safety; no severe adverse effects were reported. **Conclusion**: Integrative treatment that combines CAM with conventional therapies appeared to have beneficial effects on pain and function. However, evidence is limited due to heterogeneity, the relatively small numbers available for subgroup analyses and the low methodological quality of the included trials. Identification of studies of true IM was not possible due to lack of reporting of the intervention details (registration No. CRD42013003916).

KEYWORDS integrative medicine, integrative treatment, low back pain, systematic review, meta-analysis, exploratory review

There is no international consensus on the definition of integrative medicine (IM).[1] It is not the same as complementary and alternative medicine (CAM),[2,3] nor is it simply a synonym for conventional medicine (CM) in addition to CAM.[4] IM can be defined and understood as a holistic approach that combines evidence based CAM with conventional medicine, and emphasizes the practitioner-patient relationship, the body's innate healing response, multidisciplinary teamwork; and integration at theoretical, diagnostic and therapeutic levels.[1]

The need for multi/inter-disciplinary teamwork in providing IM and the importance of complex interventions is understood by clinicians, researchers, as well as other stakeholders.[5,6] Previous studies have demonstrated positive results for IM in cancer, musculoskeletal disorders (MSDs), cardiovascular, gynaecological disease, insomnia; and some of the medically unexplained symptoms (MUS), i.e. dry mouth in hyperpyrexia after radiotherapy and chemotherapy, and other conditions.[7-10]

However, there are often no clear boundaries between CAM and CM, i.e. some of the pain management programmes in physiotherapy and rehabilitation clinics may include CAM treatment. Whether a trial evaluates IM or not, may depend on whether it reports the elements of IM as defined above.[1] Clinically, there are several interventions

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that are a combination in themselves, i.e. manual therapy[11] which includes acupoints, trigger point massage, or acupressure, and conventional/medical manipulation, which focus more on the mobilization or stabilization of spine, such as muscle energy technique.

We encountered difficulties in deciding whether a trial evaluated IM or not because there was often insufficient information to confirm whether the treatment used was indeed IM, for example whether it used a holistic approach, individualized treatment and included interaction between patients and practitioners.[1] IM needs to be further studied and this cannot be addressed unless there is standard guidance to inform the reporting of IM practice. Integrative treatment, which represents the combination of conventional treatment plus evidence-based CAM in an integrative setting (only as an inclusion criteria, rather a definition), was thoroughly explored in this review.

Low back pain (LBP) is one of the most common MSDs. It is difficult to treat and is a costly medical problem throughout the world.[12,13] Studies have tended to focus on a single CAM treatment such as acupuncture, which has been shown to be a potentially effective intervention for LBP.[14-16] Studies have reported that CAM treatment offers the modest health benefits with minimal extra cost, and may demonstrate cost effectiveness in the long term.[17,18] Apart from the clinical achievements identified from comparing a single CAM treatment with a single conventional treatment for LBP,[19-22] the current evidence for IM and LBP is mainly from non-systematic reviews.

This exploratory systematic review was therefore conducted to identify the clinical effectiveness, cost-effectiveness and safety of integrative treatment for LBP.

METHODS

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guideline was followed through all stages of the design, implementation, and reporting of this review.[23] The protocol for the review was registered and is available online (CRD42013003916).[24]

As IM is a complex intervention, with associated difficulties in identifying and synthesising trials, an exploratory review using broad search terms was conducted.[25] This review is part of a pragmatic study evaluating IM for MSDs.[26]

Data Sources

A literature search was carried out on English and Chinese databases: English databases: Pubmed, AMED, Embase, Cochrane Library resources, CINAHL, PsycINFO, ScienceDirect, Index to Theses (UK); and Chinese databases: China National Knowledge Infrastructure (CNKI), VIP, Wanfang, Chinese BioMedical (CBM). All databases were searched from inception to December 2012.

Inclusion Criteria

Fully published randomized controlled trials (RCTs) in English or Chinese evaluating outcomes of clinical effectiveness, cost effectiveness, or safety of integrative treatment for LBP were included.

Participants: Patients of all ages, with acute/sub-acute/chronic LBP (including pain in the lumbar or sacral regions, which may be associated with muscular-ligamentous sprains and strains; intervertebral disk displacement; and other conditions) were included. Only musculoskeletal related LBP was included. Internal/obstetrics and gynecology related LBP were excluded.

Interventions: Research evaluating integrative treatment (combined CAM and conventional interventions) in the same (group of) clinical settings were included, with no limitations regarding the duration of the treatment and no limitations regarding additional (routine) care. The decision as to whether an exercise intervention was CAM or CM was based on whether it potentially involved a mind-body interaction in the intervention process.

Comparisons: Interventions comparing integrative treatment with CM/CAM/usual care were included. Possible combinations were: CM+CAM (+usual care) *vs*. CM (+usual care); CM+CAM (+usual care) *vs*. CAM (+usual care); CM+CAM+usual care *vs*. usual care; CM+CAM (+usual care) *vs*. sham CM+CAM (+usual care); CM+CAM (+usual care) *vs*. CM+sham CAM (+usual care). CM may include a group of CM; CAM may include a group of CAM. Studies with more than two arms were also included.

Primary outcome: any form of pain measurement;

back pain functional status (i.e. Roland Morris Disability Questionnaire, Oswestry Disability Index). Secondary outcomes: quality of life; mental conditions (anxiety, depression, sleep conditions); adverse events; costs.

Data Selection and Collection

Three authors (Hu XY, Lorenc A and Robinson N) reviewed the search terms and strategies. Four reviewers (Hu XY, Chen NN, Yang GY, Chai QY; two in Chinese and two in English) screened and selected eligible papers. Disagreements were resolved through discussion with Lorenc A, Robinson N and Liu JP to achieve final consensus. None of the reviewers were blinded to the authors' affiliations, journal of publication, or trial results of the selected articles at this or any stage of the review.

Quality Analysis and Risk of Bias Assessment

The STandards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) were used with Consolidated Standards of Reporting Trials (CONSORT) for the selected RCTs on integrative treatment.[27,28] A score (yes=1, no=0, cannot tell/ partial/ not available=0.5) was given for each question for each study. A percentage (sum of the scores/ number of questions) was generated to show the overall reporting score combining CONSORT and STRICTA of the individual trials. Methodological quality was assessed using the 2009 updated method guidelines for systematic review from the Cochrane Back Review Group (CBRG).[29] Yes (Y) = low risk of bias, No (N) = high risk of bias, Unclear (U) = Insufficient information or rationale. Similarities of scores were checked among reviewers.

Selected trials were independently scored by Hu XY and Trevelyan E (English), and Hu XY, Chen NN, Yang GY, and Chai QY (Chinese). Disagreements were resolved by consensus with Lorenc A, Robinson N and Liu JP.

Data Extraction

A spreadsheet was developed to capture the extracted data: language, country, authors and publication year, the most successful terms (to find the paper), study design, sample size, condition of LBP (chronic/sub-acute/acute; specific/non-specific), when did the condition occur; treatment frequency and period, mentioning of the body's innate healing response, treatment providers' background, information on practitioner-patient relationship, organization/ setting providing treatment; whether multidisciplinary teamwork was involved, the level integrative treatment was provided (theoretical/diagnostic/therapeutic) follow-up period; outcome measures, outcome data, judgment of whether there was a holistic approach, and relevant *P*-values. Data extraction was independently completed by the same reviewers who conducted quality appraisal. Disagreements were resolved by discussion between Lorenc A, Robinson N and Liu JP.

Summary Measures and Synthesis of Results

Statistical analysis was conducted with Review Manager (version 5.2). Trials were classified and combined according to their control treatments, follow-up period, and outcome measures. Heterogeneity was assessed by the I^2 test, where I^2 values of 50% or more were considered to be highly heterogeneous.[30] As all target outcomes were continuous data, mean difference (MD) and 95% confidence intervals (CI) were calculated. Effect size was defined as 0.20 for small, 0.50 for medium, and 0.80 for large effects.[31] All relevant parameters were compared with sensitivity analysis if the data were adequate. For cases where there was missing data or the data were analyzed using an inappropriate test, the data were reported separately. As there were various combinations of treatments, if a meta-analysis could not be carried out, a narrative description of selected trials was reported.

RESULTS

Description of Trials

An initial search identified 1,470 English and 3,358 Chinese potentially relevant studies. After excluding ineligible studies by screening titles and abstracts, 218 English and 739 Chinese articles remained. By applying inclusion and exclusion criteria to full text articles, a final total of 56 RCTs consisting of 58 articles remained (Figure 1).[32-89] The Appendix 1 presents the detailed characteristics of the included trials. A total of 6,616 patients (ranging from 20 to 681 per study) were involved in the 56 RCTs. Four Chinese trials[38,66,85,88] used the term 'integrative traditional and Western medicine' [中西结合] and two English trials [83,86] used the term 'integrative'. The most common condition was lumbar disk herniation (LDH, 43/56, 77%). The duration of treatment varied from one off treatment to 3 months. For the trials published in Chinese, 21/47 (45%) were conducted in Western medical hospitals, 19/47 (40%) in Chinese

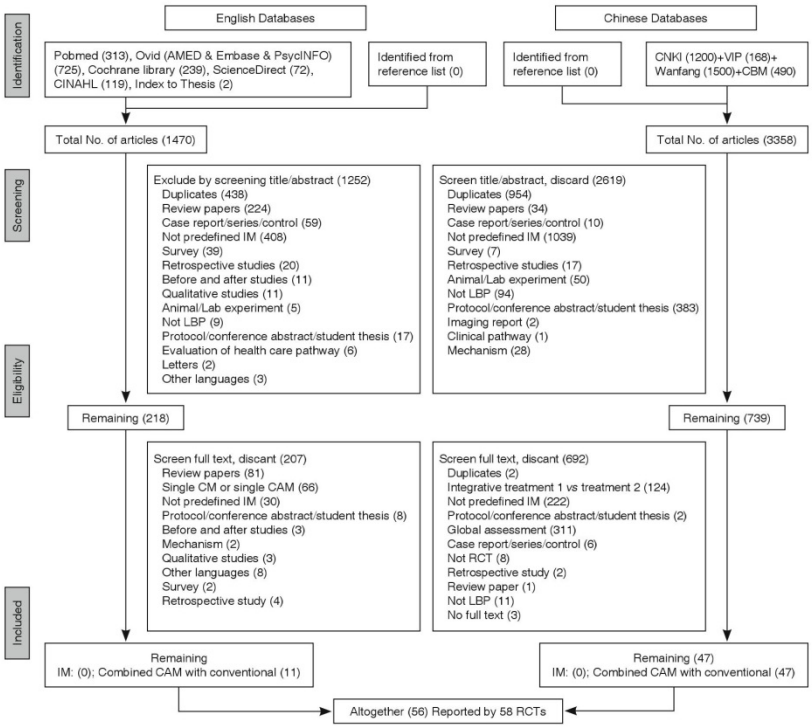

Figure 1. PRISMA 2009 Flow Diagram: Screening Process

medical hospitals. Most trials (6/9, 67%) conducted in other countries were carried out in government regulated organizations (primary care settings, a rehabilitation centre, or universities).[45-47,61,63,65] One trial was provided by multi-speciality group and CAM was provided in a private clinic.[82] One trial did not report where the treatments were provided.[44]

Range of Interventions

The most common integrative treatment was acupuncture plus traction (8/56, 14%), followed by a package of CAM treatment (7/56, 13%), Tuina plus epidural injection (6/56, 11%), and Chinese herbal medicine (CHM) plus traction (5/56, 9%). Details of the interventions are available in the Appendix 1.

Quality of the Selected Articles

Quality of reporting was accessed using STRICTA and CONSORT checklists. English trials reported more items compared with Chinese trials (STRICTA: 31%–69%, average 52%; CONSORT: 24%–74%, average: 49%).

The risk of bias varied across the included trials (Figures 2 and 3). Regarding random sequence generation, 8 trials used computer generated statistical software for randomization.[44-47,63,65,82,86] Fifteen trials reported using random number tables.[32-34,39-41,50,53,57,61,69,70,79,88,90] Six trials potentially had a high risk of bias as the randomization was generated sequentially by date of presentation.[59,60,66,67,74,85] Other trials (*n*=24) only mentioned 'patients were randomized' without any detailed information, thus an unclear risk of bias was given for those trials.

Regarding allocation concealment, apart from 6 trials[44,46,47,61,65,82] which had central control, and 1 trial[86] reported that the research coordinator was informed about the allocation and then enrolled the patient, none of the other trials provided details

Figure 2. Risk of Bias Summary: Review Authors' Judgments about Each Risk of Bias Item for Each Included Study

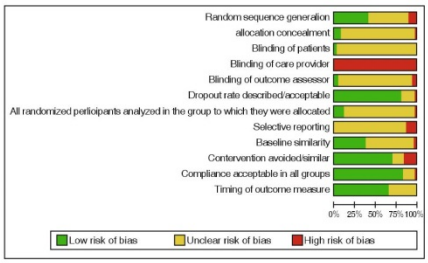

Figure 3. Risk of Bias Graph: Review Authors' Judgments about Each Risk of Bias Item Presented as Percentages across All Included Studies

regarding allocation concealment.

Regarding blinding, 2 trials reported using double blinding (both participants and examiner were blinded) in verum and sham acupuncture (by inserting needles superficially, outside meridians, with no 'Deqi').[45,47] Other trials did not give information on blinding, or reported that blinding was impossible in patients and practitioners.[46]

Effects of Interventions

For the meta analysis, two types of comparisons were considered: integrative treatment versus conventional treatment and integrative treatment versus CAM (≤3 months and >3 months respectively). Different comparisons with different outcome measures are discussed separately in the subgroup analyses.

Integrative Treatment *vs*. Conventional Treatment (short follow-up ≤3 months)

Pain Scale

Favourable effects were shown in integrative treatment over conventional treatment as measured by pain scales using visual analogue scale (VAS) and numerical rating scale (NRS) with MD −12.78, 95% CI [−14.07, −11.48], P=0.05, I^2=38% in 26 trials (Figure 4). Six trials favoured acupuncture plus traction over traction alone (n=450, MD −15.68, 95% CI [−17.61, −13.75], P=0.42, I^2=0%).[32-37] Four trials favoured acupuncture plus medication over medication alone (n=234, MD −10.57, 95% CI [−13.83, −7.31], P=0.32, I^2=14%)[41,44,84,85] (one study[88] was excluded from meta-analysis as it showed large heterogeneity I^2=95% if it was included). One study favoured acupuncture plus epidural injection (EI) over EI alone MD −6.00, 95% CI [−8.09, −3.91].[40] Although these presented positive

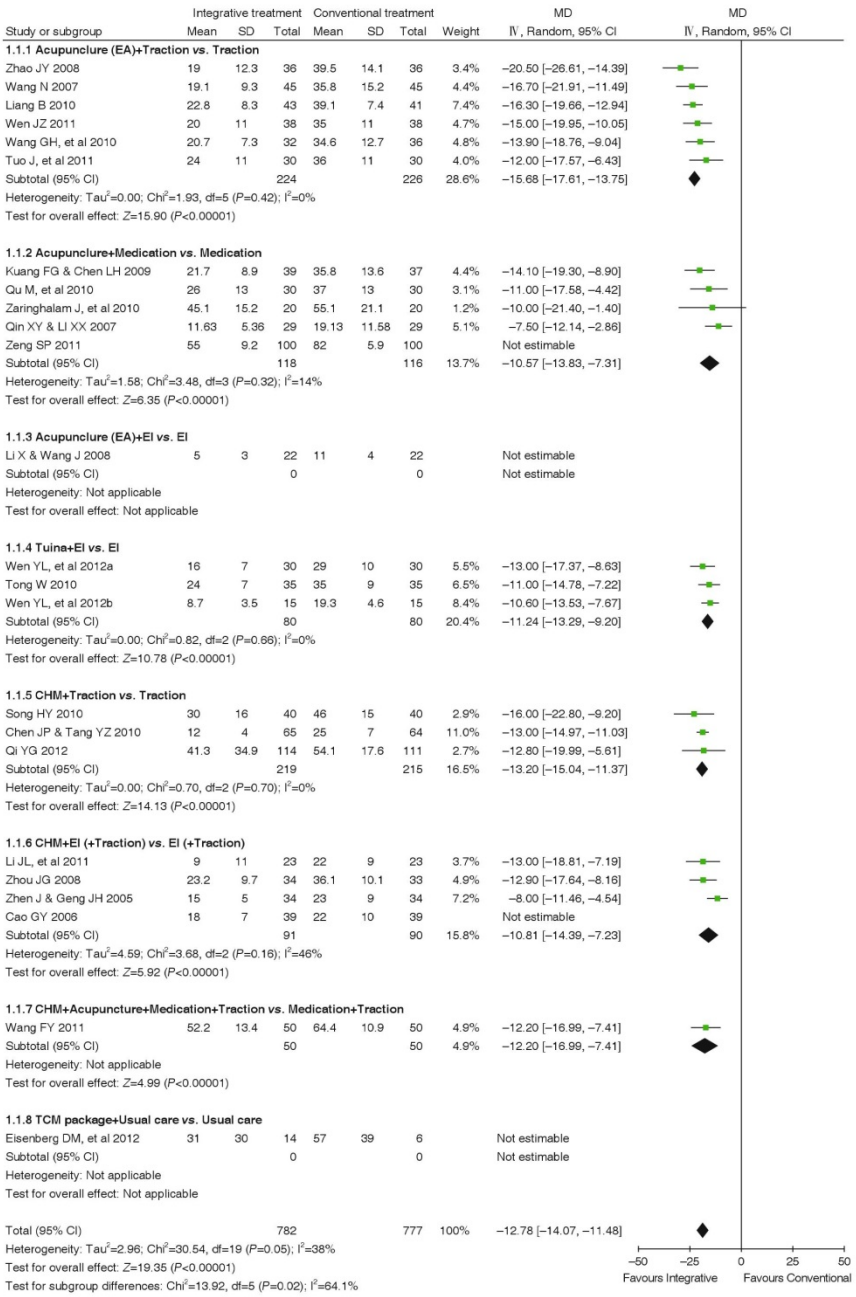

Figure 4. IM versus Conventional Treatment as Measured by Pain Scale

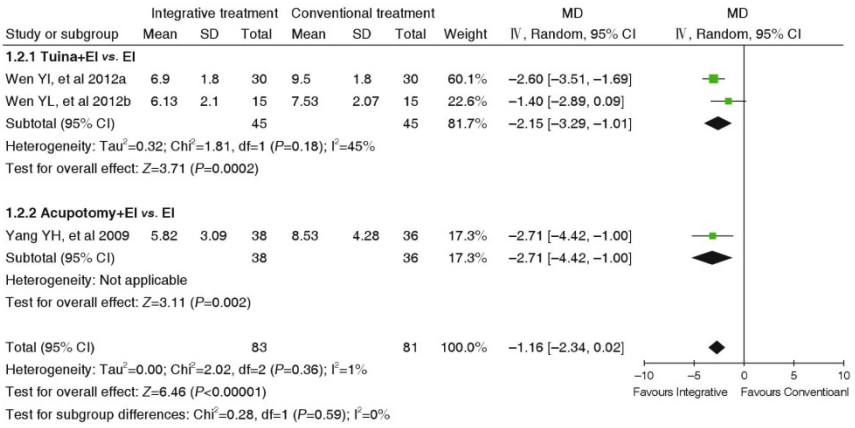

Figure 5. IM versus Conventional Treatment as Measured by mJOA2

results, due to insufficient data could be extracted from original data; results of 3 trials evaluating acupuncture plus usual care versus usual care alone were not synthesized in this analysis.[45-47]

Three trials favoured Tuina plus EI over EI (n=160, MD −11.24, 95% CI [−13.29, −9.20], P=0.66, I^2=0%);[52-54] but failed to show a favourable effect in Tuina plus traction.[56,57] Three trials favoured CHM plus traction over traction alone (n=434, MD −13.20, 95% CI [−15.04, −11.37], P=0.70, I^2=0%).[67-69] Three trials favoured CHM plus EI over EI alone (n=181, MD −10.81, 95% CI [−14.39, −7.23], P=0.16, I^2=46%)[72-74] (if included 1 study,[71] large heterogeneity I^2=73%). One study showed favourable improvement in CHM plus acupuncture, medication and traction over medication and traction MD −12.20, 95% CI [−16.99, −7.41]. Two trials evaluated Tuina plus traction versus Tuina alone MD −13.59, 95% CI [−33.77, 6.59][56,57] and one study on a package of care (includes Swedish massage, manipulative therapy, shiatsu, acupuncture, qigong) plus usual care versus usual care with MD −26.00, 95% CI [−60.94, 8.94] which failed to establish a favourable effect.[82]

Modified Japanese Orthopaedic Association (mJOA) Score

Favourable effects were shown in integrative treatment over conventional treatment as measured by mJOA with MD −2.35, 95% CI [−3.06, −1.63] in 3 trials (Figure 5): 2 trials favoured Tuina plus EI over EI (n=90, −2.15 [−3.29, −1.01], P=0.18, I^2=45%) and 1 study favoured acupotomy (a small needle-scalpel) plus EI over EI -2.71 [−4.42, −1.00].[78]

Integrative Treatment *vs*. CAM (short follow-up ⩽ 3 months)

Pain Scale

Favourable effects were shown in integrative treatment over CAM as measured by pain scales with MD −5.09, 95% CI [−7.65, −2.52] in 12 trials (Figure 6). Two trials favoured Tuina plus physiotherapy over Tuina alone (n=166, MD −6.87, 95% CI [−13.17, −0.57], P=0.10, I^2=67%).[59,60] Two trials favoured CHM plus usual care over CHM (n=220, MD −12.24, 95% CI [−18.43, −6.04], P=0.10, I^2=64%.[75,76] Two trials favoured acupotomy plus medication over acupotomy alone (n=180, MD −2.98, 95% CI [−5.34, −0.62], P=0.09, I^2=65%);[79,81] and one study showed a favourable improvement in acupotomy plus medication over acupotomy plus CHM MD −3.00, 95% CI [−5.25, −0.75].[80] Two trials evaluated acupuncture plus medication over medication alone and 3 trials evaluating Tuina plus EI over EI alone failed to show a favourable improvement in mJOA with effect size of MD −0.29, 95% CI [−6.70, 6.11][43,44] and −2.73 [−8.12, 2.65][49,53,54] separately.

mJOA Score

Two trials reported positive results when comparing Tuina plus EI with Tuina alone (−2.87 [−4.16, −1.58];[51] −1.80 [−3.18, −0.42].[54] One reported positive results when comparing CHM plus usual care with CHM alone as measured by JOA (7.20 [5.53,

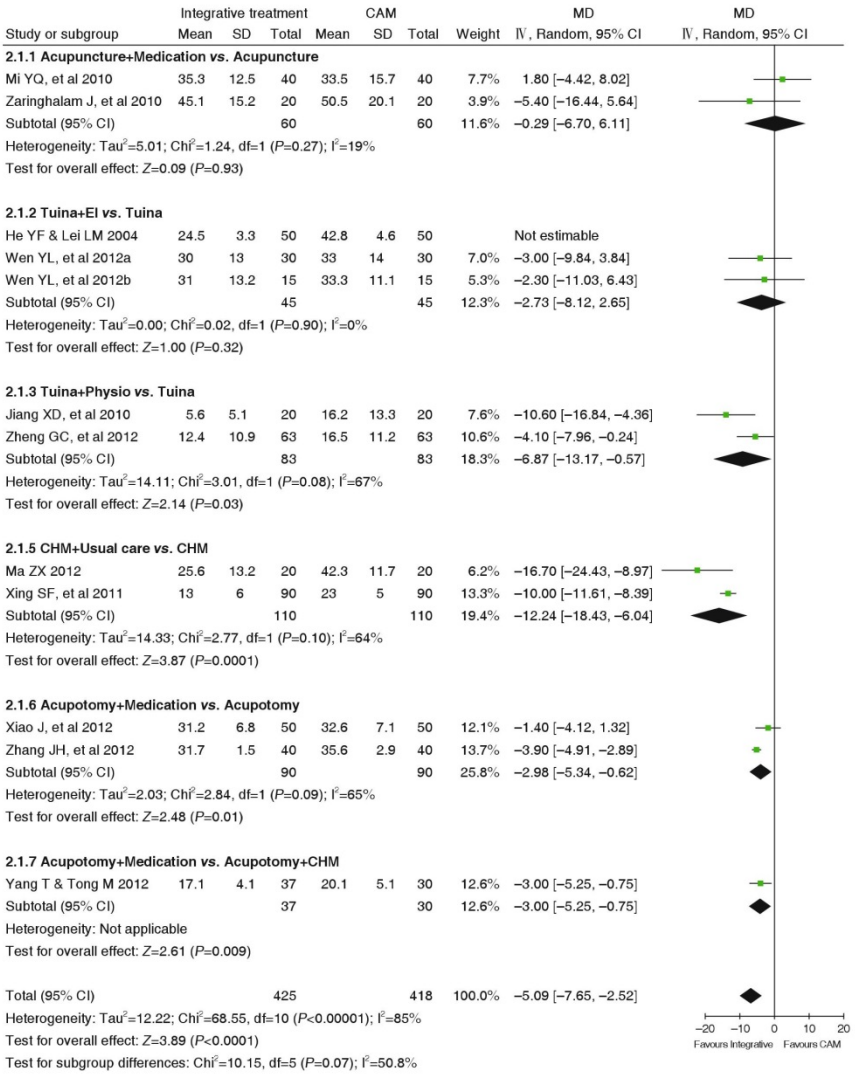

Figure 6. IM versus CAM as Measured by Pain Scales

8.87]).[77] Two failed to prove integrative treatments were superior to CAM.[53,55]

Integrative Treatment *vs*. CAM (long follow-up >3 months)

Ten trials had long follow-up of more than 3 months and 6 trials reported positive improvement with statistical significance: acupuncture plus medication versus medication at 6-month follow-up measured by Oswestry Pain Disability Index (ODI) with MD −1.10, 95% CI [−1.56, −0.63];[89] acupuncture plus usual care versus usual care at 3-month follow-up measured by VAS with MD −13.00, 95% CI [−20.64, −5.36];[47] at 6-month follow-up measured by VAS with MD −8.00,

95% CI [–16.03, 0.03], pain disability index (PDI) with MD –6.70, 95% CI [–11.53, –1.87], and Hospital Anxiety and Depression Scale (HADS) with MD –2.30, 95% CI [–4.48, –0.12];[45] EI plus Tuina versus EI at 3- and 6-month follow-up measured by VAS with MD –20.80, 95% CI [–30.49, –11.11] and MD –9.50, 95% CI [–18.85, –0.15], versus Tuina at 3- and 6-month follow-up measured by VAS with MD –21.50, 95% CI [–32.20, –10.80] and MD –24.10, 95% CI [v35.68, –12.52];[50] one study evaluated chiropractic plus physical modalities versus chiropractic alone at 6-, 12- and 18-month as measured by MD of NRS (most severe pain) with MD –0.15 , 95% CI [–0.85, 0.55], MD –0.34, 95% CI [–1.05, 0.36], and MD 0.25, 95% CI [–0.49, 0.98], NRS (average pain) with MD –0.26, 95% CI [–0.81, 0.29], MD –0.56, 95% CI [–1.13, 0.02], and MD 0.12, 95% CI [–0.46, 0.71], and Roland-Morris Disability score with MD 0.12, 95% CI [–1.15, 1.38], MD –0.92, 95% CI [–2.26, 0.42], and MD –0.01, 95% CI [–1.35, 1.32].[64,65]

One study evaluated Alexander technique plus exercise versus usual care with positive improvements only perceived when as measured by Roland-Morris Disability score (number of activities impaired by pain) with MD –1.29, 95% CI [–2.25, –0.34]; but not in Short-Form Health Survey 36 (SF36) (physical) with MD 1.9, 95% CI [–1.97, 5.79], and SF36 (mental) with MD 0.9, 95% CI [–2.8, 4.6].[62]

Two trials were unable to show statistical improvement: package of care (including swedish massage, manipulative therapy, shiatsu, acupuncture, qigong) plus usual care compared with usual care alone at 16-week follow-up as measured by SF36 bodily pain with MD 2.10, 95% CI [–7.99, 12.19] and NRS (disability) with MD –0.70, 95% CI [–2.13, 0.73];[86] integrative treatment package plus usual care versus usual care as measured by modified Roland Disability Questionnaire with MD –7.10, 95% CI [–14.73, 0.53], NRS (bothersomeness of worst symptom) with MD –4.30, 95% CI [–7.53, –1.07], SF12 (physical) with MD 5.80, 95% CI [–4.92, 16.52], and SF12 (mental) with MD 0.00, 95% CI [–11.65, 11.65]. The only positive result was obtained in NRS (pain) with MD –4.40, 95% CI [–7.43, –1.37].[83]

Cost Effects

Two trials reported cost information: Hollinghurst, et al[62] reported that 6 lessons of Alexander technique plus exercise were more cost effective than 12 lessons, with a gain of £5332 per quality adjusted life year. The second study by Eisenberg and colleagues reported that an additional package of CAM care, including a choice of adjunctive acupuncture, chiropractic or massage, increased total costs ($244) though reduction ($99) in the cost of usual care was observed at 12-week follow-up.[82]

Adverse Effects

Sixteen out of 57 articles (28%) reported information on adverse effects (AEs): acupuncture related AEs (6/14, 43%) included pain,[40,83,85] circulatory problems,[85] minor aching, bruising, light-headedness;[46] minor discomfort, and soreness.[82] One trial reported no adverse events during treatment.[41] Two trials reported that the acupuncture group experienced significantly fewer side effects.[45,46] CHM related AEs (1/14) included dizziness, nausea and vomiting.[74] Chiropractic and massage related AEs (1/14) included: minor discomfort and soreness.[82] Four trials (29%) reported that no AEs were experienced by participants.[41,65,68,76] One trial reported no severe AEs in patients who withdrew from the study.[86]

Sensitivity Analysis and Publication Bias

There was a high heterogeneity in the 7 subgroup comparisons, the results of which have been presented in a narrative. We were unable to conduct sensitivity analysis due to the insufficient number of trials in the subgroups (2/3 trials). Asymmetrical funnel plots suggested potential bias .

DISCUSSION

Summary of Evidence

Though RCTs evaluating integrative treatment for LBP were reviewed, identification of whether a trial used IM (as defined in our previous paper and above) was difficult due to the lack of reporting. We have previously proposed the defining elements of IM,[1] but these were not sufficiently well reported, particularly whether the interventions were provided using a holistic approach. It was also unclear whether a patient-practitioner relationship was considered, and whether it involved active communication. There were no trials with sufficient details to determine whether treatments were being explicitly provided as an IM approach.

The meta-analysis showed a favourable effect on integrative treatment over conventional treatment in back pain and back function measured by pain

intensity and mJOA at 3 months or less follow-up. It also showed favourable improvement on integrative treatment over CAM in back pain and back function measured by pain intensity. For the trials which investigated a longer follow-up period (>3 months), 60% reported statistically significant improvement in pain condition and back function. However, this evidence is limited because of the relatively small inclusion number and high heterogeneity for each subgroup analysis as measured by back function and the low methodological quality of the included trials.

Though most CAM therapies increase healthcare costs, there is some evidence that integrative treatment could reduce the health care costs of conventional treatment.[90,91] 'Non-invasive' CAM may help reduce the use of conventional treatment and alleviate the severity of adverse effects.[92,93] Many trials report AEs from CAM therapies but there is inadequate information on possible AEs resulting from the interaction of CAM and conventional treatment.

There are various differences in IM between China and most Western countries. Differences in policy regulation, registration and education/training result in differences in clinical practice. Lack of consensus on terminology and no standard definition of IM meant few papers published in English could be identified as IM either from their titles or from the key words. For example, in China, practitioners providing acupuncture treatment are mainly qualified doctors, with a biomedical background and at least 5 years of medical training.[94] An integrated approach is provided as they have access to both conventional and Chinese medicine in the same (group of) setting, and IM is provided in most hospitals and with insurance coverage.[94] For other CAM therapists in China e.g. reflexology (delivered in private clinics), there is limited, if any research. However, in some Western countries, acupuncture can be provided by practitioners without biomedical training. The 8 trials evaluating the combined effects of acupuncture and traction were all published in China, with most of them published in the recent 10 years. Though traction is no longer considered as an evidence-based intervention,[95] these trials represent the current practice situation in China.

Limitations

The most important limitation of this exploratory systematic review was the lack of a universal definition of IM. The trials conducted were poor in terms of reporting and methodological quality. Inadequate information on randomization, and the lack of allocation concealment may result in study bias. Many trials do not have a sham control design thus specific effects of treatment cannot be identified.

Chinese and English language databases were searched and the search was completed in December 2012. Another updated comprehensive search is required when clearer reporting guidance for IM is available and established in published trials. There are a few differences between the preset protocol and this review, inclusion criteria were tightened as there were abundant eligible trials with the preset criteria. Therefore, trials using global assessment/effect rate without any recognized/standard/validated outcome measurements were excluded, which largely reduced the amount of eligible trials.

As there has been limited attention given to CAM as an integrative treatment as part of conventional medicine in Western countries, there are few trials available evaluating the effectiveness of a package of IM. This restricted the papers that could be included in this review.

However, we feel this is an important area worth exploring. Apart from one systematic review which identified no LBP trials,[96] no previous reviews that investigated integrative treatment and compared it with single CAM or conventional treatment. Since LBP is a complex condition, an integrative approach is quite a common practice in both China, and other countries. The model in China and Korea using both traditional and Western medicine as a combined integrative treatment has shown potential patient benefit, and this deserves further explanation.[96,97]

Conclusion

Integrative treatment appears to be useful for relieving pain and improving function in LBP, though current trials have poor methodological and reporting quality. There is a need for standardizing the definition of IM and developing reporting guidelines for IM, therefore adding evidence for IM. More systematic reviews and RCTs evaluating IM for various conditions are needed. Adverse effects and economic evaluation exploring intervention packages, especially the interaction between/among interventions should be considered in future studies.

Electronic Supplementary Material: Supplementary material (Appendix 1) is available in the online version of this article at http://dx.doi.org/10.1007/s11655-015-2125-2

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Appendix 2 3 Definitions of integrative medicine identified from the mapping review

The practice of medicine that reaffirms the importance of the relationship between practitioner and patient, focuses on the whole person, is informed by evidence, and makes use of all appropriate therapeutic approaches, healthcare professionals and disciplines to achieve optimal health and healing…

Integrative Medicine is the practice of medicine that reaffirms the importance of the relationship between practitioner and patient, focuses on the whole person, is informed by evidence, and makes use of all appropriate therapeutic approaches, healthcare professionals and disciplines to achieve optimal health and healing.

(The Consortium of Academic Health Centers for Integrative Medicine, 2009)

Represents a higher-order of system of care that emphasizes wellness and healing of the entire person (bio-psycho-socio-spiritual dimensions) as primary goals, drawing on both conventional and CAM approaches in the context of a supportive and effective physician-patient relationship"

(Bell *et al.*, 2002b)

Integrated medicine brings together conventional medicine with safe and effective complimentary medicine. It emphasises the importance of the doctor-patient relationship and the use of all appropriate therapeutic approaches, healthcare professionals and disciplines to achieve healing and optimal health.

(Royal London Hospital for Integrated Medicine, 2015)

Integrative medicine combines mainstream medical therapies and CAM therapies for which there is some high-quality scientific evidence of safety and effectiveness… Involve bringing conventional and complementary approaches together in a coordinated way.

(National Center for Complementary and Alternative Medicine, 2015)

Integrative medicine is healing-oriented medicine that takes account of the whole person (body, mind, and spirit), including all aspects of lifestyle. It emphasizes the therapeutic relationship and makes use of all appropriate therapies, both conventional and alternative.

(The Bravewell Collaborative, 2015)

Integrative medicine is a new term that emphasizes the combination of both conventional and alternative approaches to address the biological, psychological, social and spiritual aspects of health and illness (MeSH term). It emphasizes respect for the human capacity for healing, the importance of the relationship between the practitioner and the patient, a collaborative approach to patient care among practitioners, and the practice of conventional, complementary, and alternative health care that is evidence-based.

(Osher Center for Integrative Medicine, 2015)

Integrative care is personalized, participatory, relationship-based care, promoting optimal health. It emphasizes healing of the whole person to achieve each individual's unique physical, emotional, mental, spiritual, and social health goals. The primary therapies used to achieve these goals are healthy habits (nutrition, activity, sleep, mindful self-care and fellowship) in a healthy habitat (social, natural and built environment). Integrative healthcare skillfully uses the best of both conventional and complementary strategies to attain patients' health goals.

(The Ohio State University, 2015)

Key concepts from the book cover (fromamazon.com) include: 1) combining complementary and conventional therapies; 2) evidence-based

(Lee and Kligler, 2004)

Integrative medicine is defined as healing-oriented medicine that takes account of the whole person, including all aspects of lifestyle. It emphasizes the therapeutic relationship

between practitioner and patient, is informed by evidence, and makes use of all appropriate therapies.

(Arizona center for Integrative Medicine, 2015)

Integrated medicine focus on health and healing rather than disease and treatment. It views patients as whole people with minds and spirits as well as bodies and includes these dimensions into diagnosis and treatment. It also involves patients and doctors working to maintain health by paying attention to life-style factors such as diet, exercise, quality of rest and sleep, and the nature of relationships.

(Rees and Weil, 2001)

Integrative medicine is healing oriented and emphasizes the centrality of the doctor-patient relationship. It focuses on the least invasive, least toxic, and least costly methods to help facilitate health by integrating both allopathic and complementary therapies. These are recommended based on an understanding of the physical, emotional, psychological, and spiritual aspects of the individual.

- *Provide relationship centered care*
- *Integrates conventional and complementary methods of treatment and prevention*
- *Involves removing barrier to activate the body's healing response*
- *Uses natural, less invasive intervention before costly, invasive ones when possible*
- *Engages mind, body, spirit, and community to facilitate healing*
- *Healing is always possible, even when cursing is not*

(Rakel, 2012b)

Referring to Andrew Weil's definition, *combining conventional and nonconventional therapies.*

(Sierpina, 2001)

Integrative medicine… contains elements of a) combining complementary and conventional; b) evidence-based; c) whole person, addressing mental, emotional, and spiritual as well as physical well-being

(Wisneski and Anderson, 2009)

Integrative Medicine combines conventional medicine with evidence-based complementary medicine, therapies and lifestyle interventions for optimal outcomes in health, healing and disease prevention with a supportive and empowering practitioner-patient relationship.

The practice of IM focuses on the whole person, is informed by evidence, and makes use of all appropriate therapeutic approaches, healthcare professionals and disciplines. IM takes into account the physical and psychological state of the person to help create overall health and wellbeing, now and in the future.

(National Institute of Integrative Medicine, 2015)

Integrative medicine is healing oriented and emphasizes the centrality of the doctor-patient relationship. It focuses on the least invasive, least toxic, and least costly methods to help facilitate health by integrating both allopathic and complementary therapies. These are recommended based on an understanding of the physical, emotional, psychological, and spiritual aspects of the individual.

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- *Healing is always possible, even when cursing is not*

(Rakel, 2012b)

"Integrative Medicine and the Health of the Public" from the prestigious Institute of Medicine, summarizing the 2009 summit by the same title (IOM Summit on Integrative Medicine and the Health of the Public), published by National Academies Press in 2009.

On page 5, in the Summary, there is a box listing themes from the summit:

- *Vision of Optimal Health as per the WHO, more than the absence of disease*
- *Conceptually inclusive across prevention, to treatment, to rehabilitation and recovery*
- *Lifespan perspective*
- *Person-centered*
- *Prevention-oriented*
- *Team-based*
- *Care integration across providers and institutions*
- *Science integration*
- *Integration of approach*
- *Policy opportunities*

Don Berwick offered 8 principles of IM (p11)

- *Place the individual at the center*
- *Individualize care*
- *Welcome family and loved ones*
- *Maximize healing influences within care*
- *Maximize healing influences outside of care*
- *Rely on sophisticated, disciplined evidence*
- *Use all relevant capacities – waste nothing*
- *Connect helping influences with each other*

Harvey Fineberg, President of the IOM, listed 5 critical dimensions of integrative care (p.27-28)

- *Broad definition of health – more than absence of disease; physical, mental, emotional, and spiritual well-being*
- *Wide range of interventions – prevention, treatment, rehabilitation and recovery*
- *Coordination of care*
- *Patient-centered care*
- *Variety of modalities- complementary and conventional*

(Institute of Medicine, 2009)

将传统的中医中药知识和方法与西医西药的知识和方法结合起来，在提高临床疗效的基础上，阐明机理进而获得新的医学认识的一种途径。中西医结合是中华人民共和国建立后政府长期实行的方针。中西医结合是中、西医学的交叉领域，也是中国医疗卫生事业的一项工作方针。中西医结合发轫于临床实践，以后逐渐演进为有明确发展目标和独特方法论的学术体系。

中西医结合的方式和途径有以下几个主要方面：结合疾病的诊治、结合中西医诊断方法的研究、结合中医治法治则的研究、结合中医学基础理论的研究。

IM in China always refer to integration of Chinese and Western medicine [中西结合医学]. It combines TCM and CHM knowledge and methods with western medicine, in order to improve clinical efficacy, explain mechanisms and to develop new understandings of medicine. IM is a long term policy in China ever since the establishment of the government.
It emphasises the integration in several levels, included integration in theoretical, diagnostic, and therapeutic levels.

(Baidu Baike, 2015)

中西医结合医学是综合运用中、西医药学理论方法，以及在中、西医药学相互交叉、综合运用中产生的新理论、新方法，研究人体系统结构与功能、人体系统与环境系统（自然与社会）关系等，探索并解决人类健康、疾病及生命问题的科学。中西医结合就是综合统一中、西医药学知识，创造新医药学。结合医学是综合运用传统医学与现代医学理论、知识和方法，以及在其综合运用中创造的新理论、新方法，研究人体系统结构与功能、人体系统与环境系统（自然与社会）关系等，探索并解决人类生命、健康和疾病防治问题的一门科学。

Integrative medicine emphasises:

- *TCM & western medicine methodology*
- *New theory/method (discipline)*
- *To explore body structure/function/system/environment (holistic)*
- *To address health issues & diseases*

(Chen, 2005)

Appendix 2 4 Detailed search terms and search strategy of the systematic review

	MeSH terms	Non MeSH terms	Chinese Databases
LBP	Low back pain	Low back pain, OR lumbago, OR low backache, OR lumbar herniation, OR lumbar muscle strain, OR sciatica	腰(脊)痛，腰痹，腰突症，腰肌劳损,坐骨神经痛
AND			
IM	Integrative medicine, OR *Complementary therapies	Integrative/integrative/complex/combined, OR Medicine/treatment/therapy/intervention, OR Acupuncture/electrotherapy/massage/herbal medicine/homeopathy/complementary medications, OR Medication/surgery/injections/traction treatment/physiotherapy/rehabilitation/pain management/exercise/nutrition/diet advice	（中西）结合，联合，合并，配合
*Alternative therapy, Acupuncture Therapy, Anthroposophy, Auriculotherapy, Diffuse Noxious Inhibitory Control, Holistic Health, Homeopathy, Horticultural Therapy, Medicine, Traditional, Mesotherapy, Mind-Body Therapies, Musculoskeletal Manipulations, Naturopathy, Organotherapy, Phytotherapy, Reflexotherapy, Rejuvenation, Sensory Art Therapies, Speleotherapy (salt therapy) and Spiritual Therapies are under this category.			

1 – Medline via Pubmed search strategy (searched Mesh Terms, 1st Jan 1980 – 2nd Dec 2012)

Integrative medicine [MeSH Terms] OR Complementary therapy [MeSH Terms] (162961)

Low back pain [MeSH Terms] (12485)

1 AND 2 (728)

3 Filters: Meta-Analysis; Systematic Reviews; Clinical Trial; Humans; Chinese; English (313)

2 – AMED (1985 – Dec 2012), Embase (1947 – Dec 2012), PsycINFO (1806 to Dec 2012) using Ovid

("Integrative medicine" OR "integrative treatment" OR "integrative therapy" OR "integrative healthcare" OR "integrative medicine" OR "integrative treatment" OR "integrative therapy" OR "integrative healthcare" OR "complementary medicine" OR "complementary treatment" OR "complementary therapy" OR "alternative medicine" OR "alternative treatment" OR "alternative therapy" OR "complex intervention" OR "complex treatment" OR "complex therapy" OR "combined therapy" OR "combined treatment").mp. [mp=ab, hw, ti, sh, tn, ot, dm, mf, dv, kw, nm, ps, rs, an, ui] (105599)

("low back pain" OR "lumbago" OR "low backache" OR "sciatica").mp. [mp=ab, hw, ti, sh, tn, ot, dm, mf, dv, kw, nm, ps, rs, an, ui] (49422)

1 AND 2 (725)

3 – Cochrane library (inception to Dec 2012)

Integrative medicine [MeSH Terms] explode all trees (33)

Complementary therapy [MeSH Terms] (11882)

Low back pain [MeSH Terms] (1699)

(1 OR 2) AND 3 (239)

4 – ScienceDirect (1823 – Dec 2012, all journals, all books, all source, Include Articles in Press, Limit by document type: articles)

TITLE-ABSTR-KEY (("Integrative medicine" OR "integrative treatment" OR "integrative therapy" OR "integrative medicine" OR "integrative treatment" OR "integrative therapy" OR "complementary medicine" OR "complementary treatment" OR "complementary therapy" OR "alternative medicine" OR "alternative treatment" OR "alternative therapy" OR "complex intervention" OR "complex treatment" OR "complex therapy" OR "combined therapy" OR "combined treatment") AND ("low back pain" OR "lumbago" OR "low backache" OR "sciatica")) (72)

5 – CINAHL Plus via EBSCO (all years, searched abstract, Suggest Subject Terms)

AB ((Integrative medicine or integrative treatment or integrative therapy or integrative healthcare or integrative medicine or integrative treatment or integrative therapy or integrative healthcare or complementary medicine or complementary treatment or complementary therapy or alternative medicine or alternative treatment or alternative therapy or complex intervention or complex treatment or complex therapy or combined therapy or combined treatment) AND (low back pain OR lumbago OR low backache OR sciatica)) (119)

6 – Index to Thesis (inception to Dec 2012)

AB ((Integrative medicine or integrative treatment or integrative therapy or integrative healthcare or integrative medicine or integrative treatment or integrative therapy or integrative healthcare or complementary medicine or complementary treatment or complementary therapy or alternative medicine or alternative treatment or alternative therapy or complex intervention or complex treatment or complex therapy or combined therapy or combined treatment) AND (low back pain OR lumbago OR low backache OR sciatica)) (2)

7 – CNKI (Jan 1915 – Dec 2012; key word; vague search terms)

主题= 中英文扩展（腰痛）(精确匹配)（21031）

1 AND ((关键词=中英文扩展(结合) 或者(关键词=中英文扩展(联合) 或者 (关键词=中英文扩展(合并) 或者(关键词=中英文扩展(配合) (精确匹配))（179）

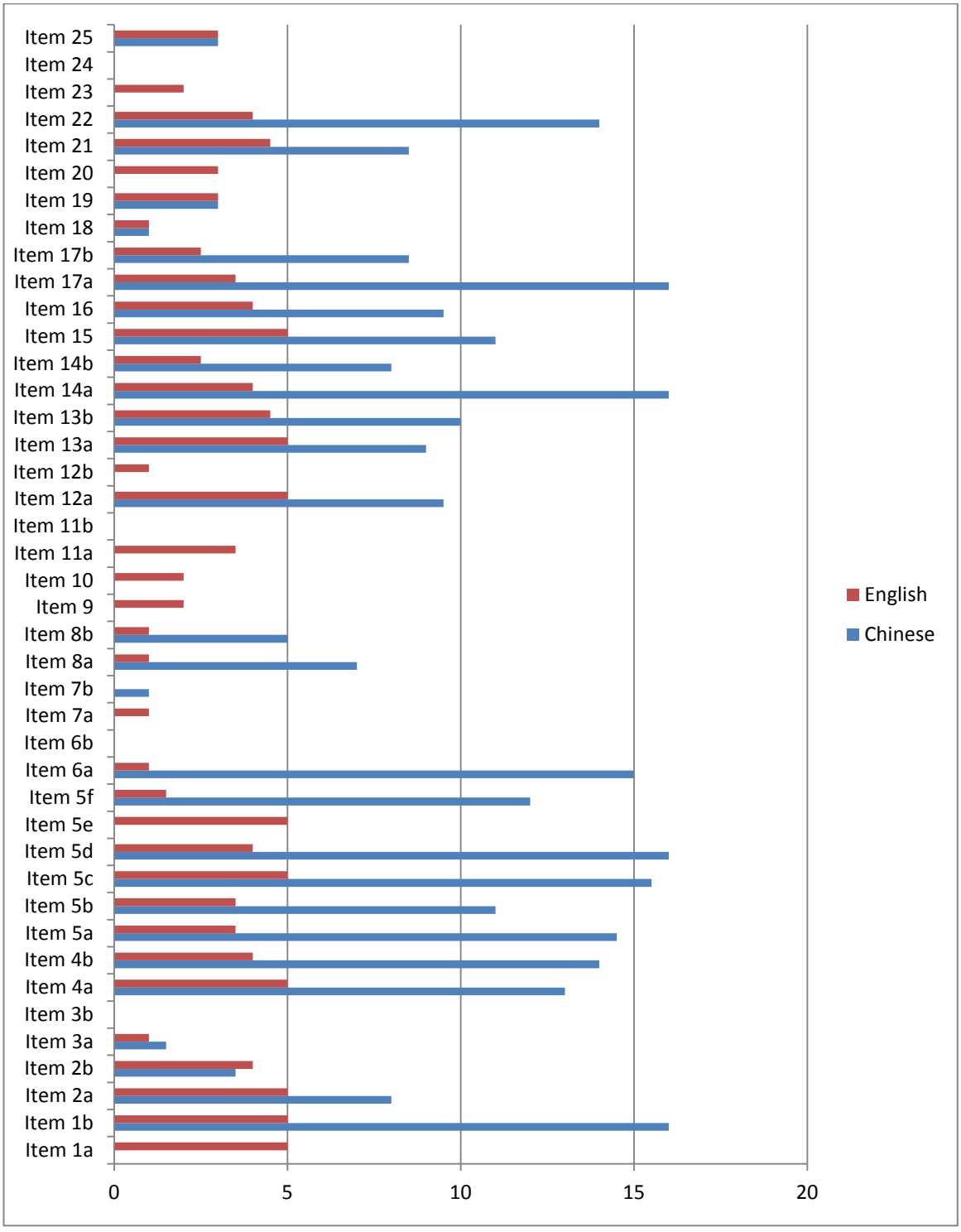
2 filters: 不包含=进展或者综述或者述评（114）

8 – VIP (1989 - Dec 2012, Title and key words)

(题名或关键词=腰痛或者腰痹) (4676)

(题名或关键词= 结合) 或者(题名或关键词=联合) 或者 (题名或关键词=合并) 或者(题名或关键词=配合) (751842) 1 AND 2 (329)

Appendix 2 5 Reporting scores for CONSORT and STRICTA items in systematic review



Appendix 2 6 Clinical characteristics of selected studies in the systematic review

Study ID	Labelled as 'IM'	Sample size and *Condition	Hospital, Department and healthcare provider	Comparisons	Treatment Regimen and notes	Outcome Measure	※ End point
Liang B (2010)	Y [结合]	84 LDH 15 days-3 years	MH Acu outpatient and surgery inpatient Dr	Acu+T vs. T	Acu/ T: 30 min, q.d., 7 days/ session, 2 sessions	VAS	1 day (T)
Tuo J (2011)	Y [配合]	60 LDH A/SA/C	MH N/A Dr	EA+T vs. T	EA: 20 min, once daily, 6 days / session; T: 30 min, q.d. , 6 days /sessions	VAS	6 days (T)
Wang N (2007)	Y [结合]	90 LDH N/A	MH Acu inpatient Dr	Acu+T vs. T	Acu/ T: 30 min, q.d., 6 days / session, 1 day rest between sessions, 4 sessions	VAS	28 days (T)
Wang GH (2010)	Y [结合]	68 LDH A/SA/C	MH Acu Dr	Acu+T vs. T	Acu: 30 min, q.d., 15 treatments/session, 2 sessions; T: 30 min, q.d., 10 treatments/session, 2 sessions	VAS	1 month(T)
Wen JZ (2011)	Y [联合]	76 LDH 0.2-35.2 month	TCMH N/A Dr	Acu+T vs. T	T: 30 min, q.d.; 10 days / session, 5 days rest between every 3 weeks; not specified how long the treatments were	VAS	1 week (F)
Zhao JY (2008)	Y [综合]	108 LDH A/SA/C	MH N/A Dr	EA+T vs. EA vs. T	EA/ T: 30 min, q.d., 14 days	VAS	14 days (T)
Yuan L (2012)	Y [中西结合]	60 LDH C	Community health center N/A N/A	EA+T(+TT) vs. T	T: 20 min, q.d., 20 treatments/ session; Acu(+TT): 15-40 min, q.a.d, 10 treatments/session	m-JOA	40 days (T)
Zhong MY	Y	66 LDH	MH Physiotherapy	Acu+T vs. T	Acu: 30 min, T: 20 min; q.a.d., 5 treatments	JOA	10 days

Study ID	Labelled as 'IM'	Sample size and *Condition	Hospital, Department and healthcare provider	Comparisons	Treatment Regimen and notes	Outcome Measure	※ End point
(2013)	[结合]	N/A	Dr				(T)
Li X (2008)	Y [结合]	88 LDH C	TCMH N/A Dr	Acu+EI vs. Acu vs. EI	EI: one off treatment; Acu: q.d., 1 week	VAS	7 days (T)
Qu M (2010)	Y [结合]	90 LDH SA/C	MH Rehabilitation and Pain management Dr	EA(+RT)+NB vs. EA(+RT) vs. NB	EA/ RT: 30 min, q.a.d., 12 treatments; NB: once the other 2 weeks, 3 treatments NB: 2-3 mL 2% lidocaine; 1 mL diprospan; 7 mg betamethasone; 0.5 mg cobamamide, together with 0.9% sodium chloride (IV)	VAS	14 days (T)
Zhao ZH (2011)	Y [结合]	94 LDH N/A	TCMH N/A Dr	EA+EI vs. EI	EA: 20 min, q.d., 21 days a session, one session; EI: 3 off, 7 days rest between each treatment	JOA	21 days (T)
Mi YQ (2010)	Y [联合]	120 LDH A	MH N/A Dr	EA+M1 vs. EA+M2 vs. EA	EA: 20 min, q.d., 10 days/ session, 2 sessions; M1: q.d., 3 d; M2: q.d., 10 days M1: 10 mg dexamethasone in 0.9% sodium chloride 500 mL, 250 mL mannitol (IV); M2: 7.5 mg meloxicam, p.o.	VAS	25 days (T)
Zaringhalam J (2010)	Y [Combined]	84 NS C	N/A N/A Certified acpuncturist	Acu+M vs. Acu vs. M/ No treatment control	Acu: twice/w, 5 weeks; M: 15 mg, twice daily, 5w M: 15 mg baclofen, p.o.	VAS	1 week (T)
Leibing E (2002)	N [and/with]	131 non-radiating C	University Orthopaedics out-patient Dr	Acu+Physio vs. Sham Acu+Physio vs. Physio	Physio: 30 min, 26 sessions over 12 weeks; Acu: 30 min, 20 sessions over 12 weeks	VAS; PDI; HADS	12 weeks (T); 9 months (T)
Meng	N	55	A group of	Acu+Standardca	Acu: twice/week, 5 weeks	RMDQ	1

Study ID	Labelled as 'IM'	Sample size and *Condition	Hospital, Department and healthcare provider	Comparisons	Treatment Regimen and notes	Outcome Measure	※ End point
CF (2003)	[and]	NS C	orthopaedic centers N/A Anaesthetists certified in acupuncture	re vs. Standard care	Standard care: NSAIDs, muscle relaxant, paracetamol, back exercises	; VAS	week (F); 5 weeks (F)
Molsberger AF (2002)	N [Pain management]	174 NS C	Rehabilitation H In-patient Dr	Acu+COT vs. Sham Acu+COT vs. COT	Acu (sham Acu): 30 min, 3 treatments/week,4 weeks; COT: conventional COT includes physiotherapy, physical exercise, back school, mud packs, and infrared heat therapy.	VAS	4 weeks (T); 3 months (F)
Tang ZZ (2012)	Y [综合/结合]	120 LDH N/A	TCMH Rehabilitation Dr	Acu+Rehb vs. Rehb	Acu: 20 min, q.d., 10 days / session, 3 sessions	sf-JOA	2 months (F)
He YF (2004)	Y [结合]	100 LDH NR	TCMH NR Dr	TN+EI vs. TN	TN: q.d., 7 treatments/session; EI: once every 10 days, 3 days rest between each treatments, 1-3 treatments	VAS	T
Li DJ (2011)(LI *et al.*, 2011)	Y [联合]	180 LDH SA/C	MH Rehabilitation Dr	TN+EI vs. EI vs. TN	TN: once every 10 days, 2 treatments; EI: once every 5 days, 4 treatments	Pain intensity	3 months 6 months (F)
Sun K (2003)	Y [结合]	73 LDH A/SA/C	TCMH Acupuncture Dr	TN+EI vs. TN	TN: 20 min, q.d., 10 treatments/session; EI: one off	mJOA	T

Study ID	Labelled as 'IM'	Sample size and *Condition	Hospital, Department and healthcare provider	Comparisons	Treatment Regimen and notes	Outcome Measure	※ End point
Tong W (2010)	Y [结合]	70 LDH A/SA/C	TCMH Orthopaedics Dr	TN+EI vs. EI	EI: once/week, 3 treatments/session; TN/T: 30 min, q.d., 20 treatment/session	VAS	T
Wen YL (2012a)	Y [联合]	120 NS A	MH Rehabilitation Dr	TN+EI vs. EI vs. TN	EI: one off; TN:3-4 days rest between 2 treatments;	VAS mJOA	T 1 week (F)
Wen YL (2012b)	Y [配合]	45 LDH C	MH Rehabilitation outpatient and Orthopaedic inpatient Dr	TN+EI vs. EI vs. TN	EI: q.a.d., 3 treatments/week, 2 weeks; TN: 20 min, q.a.d., 3 treatments/week, 2 weeks	VAS mJOA	T 1 week/ 2weeks (F)
Gu F (2007)	Y [配合]	68 LDH A/SA	Integrated Hospital TN Dr	TN+T vs. TN	TN: 20 min, q.d.; EI (with TN): once every 2-month, 1 week rest between treatments; T: 20 min, once every 5 days; TN/T: 10 days /session, 2-4 sessions	JOA	T
Heng DQ (2011)	Y [配合]	120 LDH C	TCMH Orthopaedics Dr	TN+T vs. T	TN: 15-20 min, b.i.d-q.d., 10 treatments/session, 2-3 sessions; T: 20-60min, b.i.d.-q.d., 10 treatments/session, 2-3 sessions	VAS	T
Zhang PT (2012)	Y [结合]	100 LDH C	Community Health Center Orthopaedics Dr	TN+T vs. T	TN/T: 30 min (at the same time), q.d., 1-2 days rest in 15 days treatment	VAS	T
Zhu J (2005)	Y [配合]	120 LDH A/SA/C	MH Rehabilitation Dr	TN+T vs. T	T: 30 min, q.d., 20 treatments/session; TN: once the other day, 10 treatments/session	JOA	T
Jiang XD (2010)	Y [配合]	40 LDH NR	N/A NR Dr	TN+Physio(RT+TENS+T) vs. TN	TN: 40 min; TENS: 15 min; T: 20 min; RT: 15 min; all approaches: q.d., 21 treatments	VAS	T
Zheng	Y	126	TCMH	TN+Physio vs.	T: q.d., 10 treatments/session; TN: q.a.d., 10 days	VAS	T

Study ID	Labelled as 'IM'	Sample size and *Condition	Hospital, Department and healthcare provider	Comparisons	Treatment Regimen and notes	Outcome Measure	※ End point
GC (2012)	[联合]	LDH C	NR Dr	physio	/session; M: q.d., 5-7 continuous days	JOA	
Grunnesjo MI (2011)	Y [in addition to]	160 N/A A/SA	9 primary health care centres N/A A/SA orthopaedic surgeons, GPs, and physiotherapists - trained in manual therapy	Manual package + injections vs. manual package	Individualized manual therapies with no standardized treatment protocol but with a concept of 'stay active'; Injection: steroid injectionsin the pelvic area	Well being score; Complaint score	10 weeks (F)
Hollinghurst S (2008) Little P (2008)	N [and]	579 N/A C	GP N/A local Alexander technique teachers, therapists, doctor and nurse	6/12 session Alexander technique+exercise vs. usual care	For 6-session Alex: 2 lessons a week for 2 weeks then 1 lesson a week for 2 weeks; 12-s Alex: 22 lessons over 5 months, 1 revision lesson at 7 months and 1 at 9 months; exercise: 6w. Usual care: normal primary care for LBP	RMDQ; SF36; QALY gain; NHS cost	3/12 months
Hurwitz EL (2006/2002)	N [with and without]	681 N/A N/A	primary care center N/A physical therapist	Chiropractic+physical modalities vs. chiropractic care	Individualized 'Frequency of chiropractic/physical therapy visits was at the discretion of the chiropractor/supervising physical therapist'	NRS; mRMDQ	2/6/26/52/78w (F)
Cai YZ (2011)	Y [中西医结合]	108 LDH A/SA/C	MH TCM Rehabilitation Dr	CHM+T vs. T	T: 30min, q.d. (6 treatments/week), 2 weeks/session, 2 sessions; CHM: b.i.d., 7 treatment/session, 4 sessions	JOA	T
Chen JP	Y [结合]	129 LDH	TCMH Orthopaedics	CHM+T vs. T	CHM/T: q.d., 7 treatments/session, 2 sessions	VAS	T

Study ID	Labelled as 'IM'	Sample size and *Condition	Hospital, Department and healthcare provider	Comparisons	Treatment Regimen and notes	Outcome Measure	※ End point
(2012)		A/SA/C	Dr				
Qi YG (2012)	Y [联合]	225 LDH NR	MH Orthopaedics Dr	CHM+T vs. T	CHM: t.i.d., 60 days; T: 30min, q.a.d., 30 days	VAS	T
Song HY (2010)	Y [配合]	80 LDH C	TCMH Orthopaedics Dr	CHM+T vs. T	CHM: b.i.d., 2 weeks/session, 2 sessions; T: 45-90 min, 1-2 treatments/day, 2 weeks/session, 2 sessions	VAS	T
Zhu G et al. (2012)	Y [联合]	62 LDH C	TCMH NR Dr	CHM+T vs. T	CHM: q.d.; T: 2-3 treatments; other in N/A	Pain intensity	T
Cao GY (2006)	Y [综合]	78 LDH A/SA/C	TCMH Orthopaedics Dr	CHM+EIvs.EI	CHM: twice, 1 month a session; EI: QWK, 3 times/session, 1 session (typical cases could have 2 sessions)	VAS	T
Li JL (2011)	Y [联合]	46 LDH SA/C	MH NR Dr	CHM +EI(+Ex) vs. EI	EI: 7-10 days rest between each treatment, 4 treatments; CHM: once 2-3 days, 35 days /session, 3-month rest between each session, 3 sessions/y; Ex: 15 min, twice, 1 year	VAS	T
Zhen J (2005)	Y [联合]	68 LDH A/SA/C	MH Rehabilitation and Pain Dr	CHM+EIvs. EI	EI: once/week, 4 treatments/session; CHM: b.i.d.-q.d., 1 month	VAS	T
Zhou JG (2008)	Y [配合]	67 LDH A/SA/C	MH Orthopaedics/Anorectal Dr	CHM+EI+T vs. EI+T	CHM: NR; EI followed by T, q.d., 5 treatments/session, 1 week rest between sessions; T: 20-30 min	VAS	T
Ma ZX (2012)	N [配合 (not for IM)]	40 NS C	Sport University affiliated hospital NR N/A	CHM + Physio (WT) vs. CHM	CHM: t.i.d., 30 days /session, 2 sessions; exercise in water: 45-60 min, q.a.d.	VAS	T

Study ID	Labelled as 'IM'	Sample size and *Condition	Hospital, Department and healthcare provider	Comparisons	Treatment Regimen and notes	Outcome Measure	※ End point
Xing SF (2011)	Y [配合]	180 LDH A/SA/C	MH Orthopaedics/Anorectal Dr	CHM+usual care (Physio+M) vs. usual care	CHM: q.d.; M: q.d.; Other info N/A; all treatments: 3 weeks	VAS	T
Yang DJ (2012)	Y [配合]	75 NS C	TCMH NR Dr	CHM+usual care vs. CHM	CHM: twice daily, 7 days; Physio (electromagnetic): b.i.d., 7 days	JOA ODI	15 days (F)
Yang YH (2009)	Y [联合]	74 LDH NR	TCMH Acu Dr	Acupotomy+EI vs. EI	Acup/EI: 7 days rest between each treatment, 3 treatments altogether	m-JOA	T
Xiao J (2012)	Y [联合]	100 NS C	TCMH Orthopedics/Anorectal Dr	Acupotomy(+TT)+M vs. Acupotomy(+TT)	Acup: 7 days rest between 2 treatments; TT: 20 min; M: Oxycodone and acetaminophen tablets, p.o., 1 pill before Acupotomy, 2 pills altogether	VAS ODI	During inserting 1 h/ 2 months (F)
Yang T (2012)	Y [配合]	102 LDH SA/C	TCMH Orthopedics/Anorectal Dr	Acupotomy+M vs. CHM	NR	VAS	T
Zhang JH (2012)	Y [联合]	80 3rd LTPS A/SA/C	MH Anesthesia Dr	Acupotomy+M vs. Acupotomy	NR	VAS	T
Eisenberg DM (2007)	Y [addition]	444 N/A A	CT: multi-speciality group practice; CAM: private offices	(Acu/msg/chiro) +usual care + vs. usual care	CAM: up to 10 sessions over 5 weeks and up to 5 additional sessions at 50% co-pay; U: N/A	NRS; mRMDQ;	2/5/12/26/52

Study ID	Labelled as 'IM'	Sample size and *Condition	Hospital, Department and healthcare provider	Comparisons	Treatment Regimen and notes	Outcome Measure	※ End point
			N/A CAM practitioners		Usual care includes: NSAIDS, muscle relaxants, limited bed rest, education, activity alteration	SF12	weeks (F)
Eisenberg DM (2012)	Y [integrative care]	20 N/A A/SA	multi-speciality group practice and Brigham, Women's Hospital occupational health Dr and trained multidisciplinary team	IC+Usual carevs. usual care	up to 2 treatments a week with up to 2 treatment modalities per session for up to 12 weeks IC: following services if needed - acupuncture, chiropractic, internal medicine consultation and referral as appropriate, massage therapy, occupational therapy, physical therapy, mind body techiniques, neurology consultation, nutritional counselling, orthopaedics consultation, and psychiatry and rheumatology consultation and referrals as appropriate) Usual care: nonsteroidal anti-inflammatory drugs, muscle relaxants, as-needed referrals to physical therapy, limited bed rest, education, and activity alterations	NRS; mRMDQ; SF12	5/12 weeks (F)
Kuang FG (2009)	Y [结合]	76 LDH SA/C	MH Acu Dr	(Acu+Cupping+Bleeding+Moxa)+M vs. M	M: 20 mg β-sodium aescinate in 0.9% sodium chloride, IV, q.d.,14 days; Acu/moxa: 20 min, q.d., 7 days /session, 2 sessions; Bleeding/cupping: once the other 2 days, for 14 days altogether	VAS	14 days (T)
Qin XY (2007)	Y [中西结合]	90 LDH A	MH N/A Dr	(CHM+Acu+Cupping+AA)+M vs. CHM+Acu+Cupping+AA vs. M	CHM: twice daily, 10 days / session, 3-5 days rest between sessions; Acu: 30 min; Cupping: 20 min; AA: 1 h, q.d., 10 days / session, 10 days rest between sessions; 30 days M: 100 mg ketoprofen (IM), b.i.d.	VAS	7 days (T)
Sundberg T (2009)	Y [IM]	80 NS A/SA/C	Primary care units N/A GP, certified CT providers	CAM package + usual care vs. usual care	Pragmatic/individualized Package: Swedish massage, manipulative therapy, shiatsu, acupuncture, qigong	SF36; NRS	16 weeks (F)
Wang FY	Y [配合]	50 LDH	TCMH Orthopaedics	(CHM+Acu)+M+T vs. M+T	M: NR; T: 20 min, q.d., 4 weeks; CHM: t.i.d., 4 weeks; Acu: 20-30 min, 1 day, 4 weeks	VAS	14/28 days

Study ID	Labelled as 'IM'	Sample size and *Condition	Hospital, Department and healthcare provider	Comparisons	Treatment Regimen and notes	Outcome Measure	※ End point
(2011)		NR	Dr		M: NR		(F)
Zeng SP (2011)	Y [中西结合]	200 LDH A	MH TCM Dr	(Acu+CHM+TN) +M+T vs. M	M: q.d., 3w; CHM: p.o., b.i.d., Acu: 30 min; 7 days / session, 3 sessions; (Not given how many sessions should be given. But outcome measures assessed by the end of the 3rd week)M: 20% mannitol 125 mL, 5% glucose 250 mL + dexamethasone 10 mg, 10% glucose 200 mL + Salvia 20 mL (IV); vitamin B1 100 mg and vitamin B12 500 μg (IM)	VAS	3 days (F)
Zheng D (2012)	N [加]	82 S C	TCMH Orthopeadic Dr	(Acu+TN)+M vs. M	M: q.d., 10-14 days; Acu: 30 min, b.i.d., 28 days M: mannitol 250 mL+ dexamethasone 5 mg, after 3 days, changed the intervention to: 0.9% sodium Chloride 250 mL added aescin 20 mg + 0.9% sodium chloride 100 mL added Neurotropin + 5% glucose 250 mL add Danhong (Chinese herb) 30 mL (IV)	ODI	28 days (T) 6 months (F)

Notes: *Condition 1 (LDH: Lumbar disk herniation, 3rd LTPS: Third lumbar transverse process syndrome, NS: Non-specific); Condition 2 (A: Acute - < 6 weeks, SA: Subacute - 6-12 weeks, C: Chronic - > 12 weeks); N: no, Y: yes; ※End point: T-after treatment, F-after completion of treatment;

NR: not reported, min: minute(s), MH: medical hospital;

Acu: acupuncture, Acup: acupotomy, physio: physiotherapy, TN: Tuina, Rehb: rehabilitation, M: medication, AA: auricular acupuncture, CHM: Chinese herbal medicine, T: traction, EI: epidural injection, TT: thermal therapy, NB: nerve block, EA: electroacupuncture, RT: radiotherapy, COT: conventional orthopeadic treatment, TCMH: traditional Chinese medicine hospital, IC: integrative care;

q.a.d.: every other day, q.d.: once daily, b.i.d.: twice daily, t.i.d.: three times a day, QWK: every week;

p.o.: by mouth or orally, IV: intravenous, IM: intramuscular (with respect to injections);

VAS: visual analogue scale, JOA: Japanese Orthopeadic Association, mJOA: modified Japanese orthopeadic Association, sf-JOA: short form Japanese Orthopeadic Association, PDI: Pain disability index, HADS: hospital anxiety and depression scale, ODI: Oswestry pain disability index, (m)RMQD: (modified) Roland Morris Disability Questionnaire

Appendix 3 1 Patient information sheet

London South Bank University

NHS
University College London Hospitals
NHS Foundation Trust
Royal London Hospital for Integrated Medicine

Participant Information Leaflet

Feasibility study of integrated treatment on musculoskeletal disorders (FIT)

(Questionnaire and Interview)

Patient Information – please read carefully and ask if you have any questions.

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

1. What is the purpose of the study?

Musculoskeletal disorders are a major cause of illness and disability in the UK, and have a substantial influence on patients' health and quality of life. The Royal London Hospital for Integrated Medicine (RLHIM) is the largest public sector provider of integrated medicine in Europe. Integrated medicine brings together conventional and complementary medicine, providing pathways with different care options. Patients receive integrated packages of care at this hospital.

This study aims to determine the feasibility to evaluate integrated treatments for musculoskeletal disorders at the RLHIM; and to explore your perceptions of the acceptability of the study design and research process.

2. Why have I been invited?

You have been chosen because you have been referred to the RLHIM for musculoskeletal disorders. We are inviting all eligible patients attending RLHIM over a 12 month period to take part in the study.

3. Do I have to take part?

It is up to you to decide whether to participate in the study. If you decide to take part you will be asked to sign a consent form which is enclosed with this letter. If you decide to take part you are still free to withdraw from the study at any time during the study, without giving a reason. This will not affect the standard of care you receive.

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NHS Foundation Trust
Royal London Hospital for Integrated Medicine

London South Bank University

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

Your decision to take part in the study will not affect your treatment at the RLHIM. You will receive exactly the same treatment whether you participate or not. If you decide to take part you will be asked to complete various questionnaires so we can explore the feasibility of conducting a further full trial. We would ask you to complete these questionnaires before your first treatment appointment (face to face with study researcher's guidance), (another one before the treatment if you are on a waiting list), and then 4, 8 or 12 months after your first treatment when they would be posted to you. We will also ask you for some information about yourself, including your age, education employment and ethnic background (although it is ok for you to choose not to complete these questions).

Except the first questionnaire which will be completed face to face, we will be asking you to return completed questionnaires to us using postage paid envelopes. We would like to contact you with reminders, either by a letter, text message or by phone.

If you agree to take part in the study we may also ask you to take part in an interview although it is ok if you choose not to do this. The aim of the interview is to explore your perceptions of the acceptability of the study design and research process. Interviews will take no longer than 60 minutes, and can take place at a time and location convenient for you.

5. What are the possible benefits to taking part?

The information we get from this study may help us to design future research studies to see how we could better treat musculoskeletal problems for future hospital patients. At the end of the study, you will be provided with a copy of the findings, and invited to attend a presentation meeting to discuss the findings in person with the researchers.

6. What are the possible risks of taking part?

You will receive the same treatments from the Royal London Hospital for Integrated Medicine whether you participate in the study or not. There are no risks from taking part in the study. Also, the interview discussions are completely non-invasive, and no sensitive topics will be discussed.

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NHS Foundation Trust
Royal London Hospital for Integrated Medicine

7. Will my taking part in this study remain confidential?

If you consent to take part in this study, your medical records may be looked at by the researchers. Your name, however will not be disclosed outside the hospital. All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital will not have your name and address attached and will not be associated with you.

8. What will happen to the results of the research study?

The results will be summarised and presented both at medical conferences and through scientific publications in medical/nursing journals, so health professionals can learn more about the results of our study. At the end of the study you will be provided with a copy of the findings, and invited to attend a presentation meeting to discuss the findings in person with us. You will not be identified in any report/publication.

9. What will happen if I do not want to carry on with the study?

You are free to withdraw from the study at any time during the study. You can still receive your treatment at the hospital if you withdraw.

10. Who is organising the study?

The study is being organised by London South Bank University and the Royal London Hospital for Integrated Medicine.

11. Who has reviewed the study?

This study was given a favourable ethical opinion for conduct in the NHS by NRES Committee London – City & East (Ref No. 12/LO/1341).

12. To take part or for further information

If you would like to take part, or would like specific information about this research project, please contact the study's principle investigator (Mio Hu, Tel: 020 78158350, 07411175772; Email: hux2@lsbu.ac.uk).

Thank you for reading this information. This information sheet is for you to keep. If you decide to participate you will also be given a consent form to sign.

London South Bank University

NHS
University College London Hospitals
NHS Foundation Trust
Royal London Hospital for Integrated Medicine

Participant Information Leaflet

Feasibility study of integrated treatment on musculoskeletal disorders (FIT)

(Interview/Focus group)

Patient Information – please read carefully and ask if you have any questions.

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

1. What is the purpose of the study?

Musculoskeletal disorders are a major cause of illness and disability in the UK, and have a substantial influence on patients' health and quality of life. The Royal London Hospital for Integrated Medicine (RLHIM) is the largest public sector provider of integrated medicine in Europe. Integrated medicine brings together conventional and complementary medicine, providing pathways with different care options. Patients receive integrated packages of care at this hospital.

This study aims to explore your experiences in receiving treatment at RLHIM and your perceptions of the acceptability of the study design and research process.

2. Why have I been invited?

You have been chosen because you recently took part in a study of integrated medicine for musculoskeletal disorders at the RLHIM. We are planning to recruit about 30 patients enrolled in the study.

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NHS Foundation Trust
Royal London Hospital for Integrated Medicine

3. Do I have to take part?

It is up to you to decide whether to participate in the study. If you decide to take part you will be asked to sign a consent form which is enclosed with this letter. If you decide to take part you are still free to withdraw from the study at any time during the study, without giving a reason.

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

We would ask you to take part in an interview or focus group. The interviews will take approximately 30-60 minutes, and can take place at a time and location convenient for you.

5. What are the possible benefits to taking part?

The information we get from this study may help us to design future research studies to see how we could better treat musculoskeletal problems for future hospital patients. You may also benefit from group discussions. At the end of the study, you will be provided with a copy of the findings, and invited to attend a presentation meeting to discuss the findings in person with the researchers.

6. What are the possible risks of taking part?

There are no risks from taking part in the study. The interview/focus group discussions are completely non-invasive, and no sensitive topics will be discussed.

7. Will my taking part in this study remain confidential?

All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised from it.

London South Bank University

NHS
University College London Hospitals
NHS Foundation Trust
Royal London Hospital for Integrated Medicine

8. What will happen to the results of the research study?

The results will be summarised and presented both at medical conferences and through scientific publications in medical/nursing journals, so health professionals can learn more about the results of our study. At the end of the study you will be provided with a copy of the findings, and invited to attend a presentation meeting to discuss the findings in person with us. You will not be identified in any report/publication.

9. What will happen if I do not want to carry on with the

You are free to withdraw from the study at any time during the study. You can still receive your treatment at the hospital if you withdraw.

10. Who is organising the study?

The study is being organised by London South Bank University and the Royal London Hospital for Integrated Medicine.

11. Who has reviewed the study?

This study was given a favourable ethical opinion for conduct in the NHS by NRES Committee London – City & East (Ref No. 12/LO/1341).

12. To take part or for further information

If you would like to take part, or would like specific information about this research project, please contact the study's principle investigator (Mio Hu, Email: hux2@lsbu.ac.uk).

Thank you for reading this information. This information sheet is for you to keep. If you decide to participate you will also be given a consent form to sign.

Appendix 3 2 Consent forms

London South Bank University

NHS University College London Hospitals NHS Foundation Trust

Royal London Hospital for Integrated Medicine

CONSENT FORM FOR RESEARCH STUDY

Questionnaire

Official use only	
Study Number:	Patient Identification Number for this trial:

Title of Project:
Feasibility study of integrated treatment on musculoskeletal disorders (FIT)

Please tick to confirm

I confirm that I have read and understand the information sheet version 2, 24-10-2012 for the above study. ☐

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reasons, without my medical care or legal rights being affected. ☐

I am aware that my contact information and relevant sections of my medical notes and data collected during the study may be looked at by responsible individuals from RLHIM's research team, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records ☐

I agree to take part in the questionnaire phase of the study. ☐

I agree that my healthcare practitioner at RLHIM is informed about my participation in this study. ☐

Name of Patient	Date	Signature

Researcher	Date	Signature

1 copy for patient, 1 copy for researcher site file, 1 to be kept in medical notes.

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CONSENT FORM FOR RESEARCH STUDY

1st Interview

Official use only	
Study Number:	Patient Identification Number for this trial:

Title of Project:
Feasibility study of integrated treatment on musculoskeletal disorders (FIT)

Please tick to confirm

I confirm that I have read and understand the information sheet version 2, 24-10-2012 for the above study.	☐
I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reasons, without my medical care or legal rights being affected.	☐
I am aware that my contact information and relevant sections of my medical notes and data collected during the study may be looked at by responsible individuals from RLHIM's research team, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	☐
I agree to take part in an interview/focus group as part of the study and I agree that my interview can be audio taped.	☐
I agree that my healthcare practitioner at RLHIM is informed about my participation in this study.	☐

Name of Patient	Date	Signature
Researcher	Date	Signature

1 copy for patient, 1 copy for researcher site file, 1 to be kept in medical notes.

London South Bank University

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CONSENT FORM FOR RESEARCH STUDY

2nd Interview/Focus group

Official use only Study Number:	Patient Identification Number for this trial:

Title of Project:
Feasibility study of integrated treatment on musculoskeletal disorders (FIT)

Please tick to confirm

I confirm that I have read and understand the information sheet version 3; 06.03.2013 for the above study.	☐
I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reasons, without my medical care or legal rights being affected.	☐
I am aware that my contact information and relevant sections of my medical notes and data collected during the study may be looked at by responsible individuals from RLHIM's research team, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	☐
I agree to take part in an interview/focus group as part of the study and I agree that my interview can be audio taped.	☐
I agree that my healthcare practitioner at RLHIM is informed about my participation in this study.	☐

_____	_____	_____
Name of Patient	Date	Signature
_____	_____	_____
Researcher	Date	Signature

1 copy for patient, 1 copy for researcher site file, 1 to be kept in medical notes.

Appendix 3 3 The questionnaire pack

Feasibility study of Integrated Treatment on musculoskeletal disorders

Information Booklet

Research Group:
Mio (Xiaoyang Hu), John Hughes, Peter Fisher, Ava Lorenc, Rachel Purtell, A-La Park, Nicola Robinson

Mio's Contact details:
020 7815 8350, 07411175772, hux2@lsbu.ac.uk

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Sociodemographics

Official use only
Patient study code: ……..
Today's date: ……

Some Information about Yourself

Please complete all the questions below:

1. **Month and year of birth:** _____

2. **Gender:** Female ☐ Male ☐

3. **Marital Status:** Single ☐ Married ☐
   Divorced/Separated ☐ Widowed ☐
   Living with partner ☐

4. **Educational Level:**
   Primary School ☐ Secondary School ☐ College/diploma ☐
   University/Degree ☐ Postgraduate ☐

5. **Occupational status:**
   Employed full-time ☐ Employed part-time ☐ Retired ☐
   Unemployed ☐ Casual worker ☐ Not working due to ill health ☐
   Homemaker ☐ Other ☐

6. **Occupational group:**
   Professional ☐ Managerial & Technical ☐ Skilled non manual ☐
   Skilled manual ☐ Unskilled ☐ Not applicable ☐

7. **Mother Tongue:**
   Is English your first language? Yes ☐ No ☐

If no, what is your first language? _____

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8. Ethnic Origin:

A. White

White British ☐ White Irish ☐

White other (please write in) _____

B. Mixed

White and Black Caribbean ☐ White and Black African ☐

White and Asian ☐

Any other mixed background (please write in) _____

C. Asian

Asian or Asian British Pakistani ☐ Asian or Asian British ☐

Bangladeshi ☐

Indian ☐

Any other Asian background (please write in) _____

D. Black

Black or Black British Caribbean ☐ Black or Black British African ☐

Any other Black background (please write in) _____

E. Chinese ☐ Japanese ☐

Prefer not to say ☐

If other, please state _____

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9. Religious affiliation:

Christian	☐	Hindu	☐	Jewish	☐
Buddhist	☐	Muslim	☐		
No beliefs/ prefer not to say	☐				

If other, please state_____

10. Lifestyle:

Do you smoke regularly? Yes ☐ No ☐

if yes,how many cigarettes do you smoke **each week**?

_____Cigarettes

Do you drink alcohol regularly? Yes ☐ No ☐

if yes, how much do you drink **each week** (according to the guide showed below)?

_____ Units

Guide to units of alcohol

Thank you for completing this questionnaire

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Royal London Hospital for Integrated Medicine

Patient Expectation Questionnaire

Official use only
Patient study code: ……
Today's date: ……

Please circle the relevant number below:

How much do you believe that the treatment you will receive at the Royal London Hospital for Integrated Medicine will make your condition better?

0 1 2 3 4 5 6 7 8 9 10
Not at all — Will help me a lot

How much faith do you have in complementary therapies in general?

0 1 2 3 4 5 6 7 8 9 10
Not at all — Complete faith in them

Thank you for completing this questionnaire

University College London Hospitals
NHS Foundation Trust
Royal London Hospital for Integrated Medicine

London South Bank University

Brief Pain Inventory (Short Form)

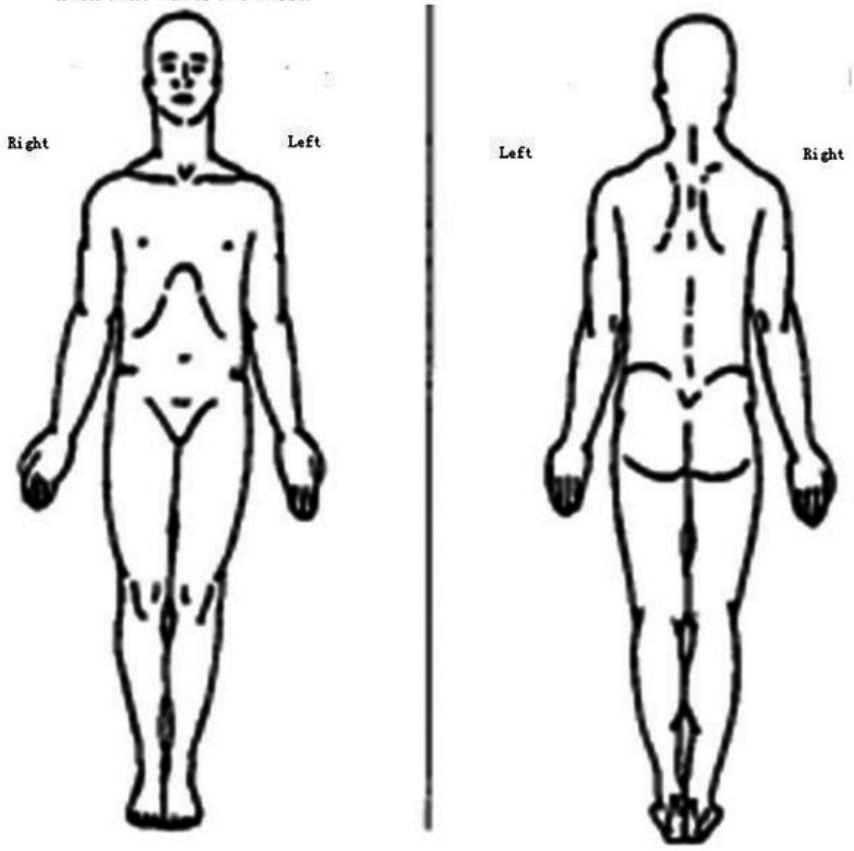
Official use only
Patient study code: ……
Today's date: ……

Please complete questions:

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?**

Yes ☐ **No** ☐

2. **On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.**



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3. Please rate your pain by circling 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
No Pain										Pain as bad as you can imagine

4. Please rate your pain by circling 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
No Pain										Pain as bad as you can imagine

5. Please rate your pain by circling one number that best describes your pain on the average.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

6. Please rate your pain by circling one number that tells how much pain you have right now.

0	1	2	3	4	5	6	7	8	9	10
No Pain										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

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9. Circle the 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

Thank you for completing this questionnaire

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Modified Client Service Receipt Inventory

Official use only
Patient study code: ……..
Today's date: ……

Musculoskeletal problems can affect peoples' lives in many ways. The following questions will help us to understand the effect they can have on you and on the services you have.

All your answers will remain completely confidential

1. **In the last 3 months, have you used any of the NHS or social services below because of your musculoskeletal disorder(s)?**

Please tick 'yes' or 'no' for each line. If you answer 'yes' to any, please tell us how many times you used the service. If you report anything in this section, please do not report it again in another section.

Services at your local GP surgery/health centre	**No**	**Yes**		**Total contacts in last 3 months**
Seen GP at the surgery	☐	☐	Number of visits	
Seen GP at home	☐	☐	Number of visits	
Phoned GP for advice	☐	☐	Number of calls	
Seen practice nurse at the surgery	☐	☐	Number of visits	
Phoned practice nurse for advice	☐	☐	Number of calls	
Got a repeat prescription (without seeing doctor)	☐	☐	Number of times	

Physiotherapist (do not include private visits)	**No**	**Yes**		
Seen at a hospital	☐	☐	Number of visits	
Seen at home	☐	☐	Number of home visits	
Seen at the GP surgery	☐	☐	Number of visits	
Seen elsewhere (do not include private visits)	☐	☐	Number of visits	

Occupational therapist (do not include private visits)	**No**	**Yes**		
Seen at a hospital	☐	☐	Number of visits	
Seen at home	☐	☐	Number of home visits	
Seen at the GP surgery	☐	☐	Number of visits	
Seen elsewhere (do not include private visits)	☐	☐	Number of visits	

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Services at a hospital	**No**	**Yes**	
Been to accident and emergency (A&E/casualty)	☐	☐	Number of visits
Stayed in hospital overnight	☐	☐	Number of nights
Had a hospital outpatient appointment	☐	☐	Number of appointments

Social services	**No**	**Yes**	
Got meals on wheels	☐	☐	Number of meals
Home help visited	☐	☐	Number of home visits
Seen social worker	☐	☐	Number of visits
Spoke to social worker on telephone	☐	☐	Number of calls

Other health or social services	**No**	**Yes**	
Please describe……	☐	☐	Number of contacts
Please describe……	☐	☐	Number of contacts

Any hospital tests	**No**	**Yes**		**Total no. of tests in last 3 months**
Magnetic Resonance Image (MRI)	☐	☐	Number of tests	
CT / CAT scan	☐	☐	Number of tests	
Ultrasound	☐	☐	Number of tests	
X-ray	☐	☐	Number of tests	
Electroencephalogram (EEG)	☐	☐	Number of tests	
Other (please describe) ……..				

2. **Do you have private health insurance?** No ☐ Yes ☐

3. **Have you had any private healthcare consultations in the last 3 months?**

Type of practice	How many consultations	Cost of each consultation

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4. **In the last 3 months, have you used any of the complementary medicine services below?**

No ☐ **Yes** ☐

	Service cost per treatment (If it was provided by NHS, please put £0)	**Number of visits**	**Travel cost**
Acupuncture			
Alexander Technique			
Aromatherapy			
Autogenic training			
Chiropractic			
Craniosacral therapy (CST)			
Healing/Reiki			
Herbal			
Homeopathy			
Hydro-/balneo therapy			
Hypnotherapy			
Mediation/Imagery (visualization)			
Massage			
Osteopath			
Shiatsu			
Tai Chi			
Other (please specify)			

5. **Do you pay for your NHS prescriptions?** **No** ☐ **Yes** ☐
6. **In the last 3 months, what prescribed medicines did you use?**
   Please only include medicines that were prescribed to you by a doctor (in other words, do not include any that you bought over the counter without a prescription). If you report anything in this section, please do not report it again in another section.

Name of medication e.g. NSAIDS, Painkillers, Topical applications (deep heat), etc	**Dose** *State quantity and the measurement unit if you know it e.g. 10 mg)*	**How often do you take it?** *Use these codes:* *1 = 6 times daily* *2 = 5 times daily* *3 = 4 times daily* *4 = 3 times daily* *5 = 2 times daily* *6 = Once daily* *7 = 4 times a week* *8 = 3 times a week* *9 = 2 times a week* *10 = Once a week* *11 = Every 3 weeks* *12 = Every 2 weeks* *13 = Monthly* *If other, specify below*	**How many days have you taken it in the last 3 months?** *If one month, write '30'* *If 2 months, write '60'* *If 3 months, write '90'* *For any other duration, please work out the days as best as you can*

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7. **In the last 3 months, what over the counter medicines did you use?**

Name of medication e.g. Aspirin, Paracetamol, Ibuprofen, Sleeping pills, etc	**Dose** *State quantity and the measurement unit if you know it e.g. 10 mg)*	**How often do you take it?** *Use these codes:* *1 = 6 times daily* *2 = 5 times daily* *3 = 4 times daily* *4 = 3 times daily* *5 = 2 times daily* *6 = Once daily* *7 = 4 times a week* *8 = 3 times a week* *9 = 2 times a week* *10 = Once a week* *11 = Every 3 weeks* *12 = Every 2 weeks* *13 = Monthly* *If other, specify below*	**How many days have you taken it in the last 3 months?** *If one month, write '30'* *If 2 months, write '60'* *If 3 months, write '90'* *For any other duration, please work out the days as best as you can*

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8. **In the last 3 months, what Complementary and Alternative medicine and/or self-care help have you used?**

Name of medication and reasons for using **e.g.** Herbal medicine (Chilli, Devil's claw, willow), Supplements: fish oil (omega-3 fatty acids), glucosamine, chondroitin, SAM-e, vitamins etc.), Bathing/hydro therapy/heat therapy, etc e.g. For knee pain, low back pain, etc	**Dose** *State quantity and the measurement unit if you know it e.g. 10 mg)*	**How often do you take it?** *Use these codes:* *1 = 6 times daily* *2 = 5 times daily* *3 = 4 times daily* *4 = 3 times daily* *5 = 2 times daily* *6 = Once daily* *7 = 4 times a week* *8 = 3 times a week* *9 = 2 times a week* *10 = Once a week* *11 = Every 3 weeks* *12 = Every 2 weeks* *13 = Monthly* *If other, specify below*	**How many days have you taken it in the last 3 months?** *If one month, write '30'* *If 2 months, write '60'* *If 3 months, write '90'* *For any other duration, please work out the days as best as you can*

9. **In the last 3 months, have you participated in regular physical activity?** No ☐ Yes ☐

Type of exercise	**Time per session**	**How often did you exercise?** *Use these codes:* *1 = once per week* *2 = 2 times/ week* *3 = 3 times /week* *4= 4 times/week* *5= 5 times/week* *6= 6 times /week* *7=7 times/ week* *If other, specify below*	**How many days have you exercised in the last 3 months?** *please work out the days as best as you can*

10. **In the last 3 months, have you used any other medicine/services for other conditions?**

Type of medicine/ services	**Dose/ session** *State quantity and the measurement unit if you know it e.g. 10 mg; 4 hours/session, 2 sessions)*	**How often do you take it?** *Use these codes:* *1 = once per week* *2 = 2 times/ week* *3 = 3 times /week* *4= 4 times/week* *5= 5 times/week* *6= 6 times /week* *7=7 times/ week* *If other, specify below*	**How many days have you taken it in the last 3 months?** *please work out the days as best as you can*

London South Bank University

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11. **In the last 3 months, have NHS or social services paid for any of the following because of any illness?**

Please tick 'yes' or 'no' for each line and tell us how much it cost (if you know). If you report anything in this section, please do not mention it again in another section.

	No	Yes	Who paid for this? NHS	Social services	How much has this cost altogether in the last 3 months?
Transport to get to health care appointments *(e.g. to go to your GP surgery or hospital)*	☐	☐	☐	☐	
Special equipment *(e.g. kitchen equipment)*	☐	☐	☐	☐	
Changes to your home *(e.g. hand rail, stair lift)*	☐	☐	☐	☐	
Any other help (e.g. cleaning, shopping, childcare etc.).....	☐	☐	☐	☐	
Any other help	☐	☐	☐	☐	

12. **If you are currently employed, have you taken any time off work in the last 3 months because of any illness?**

Include any time taken off because you were ill or using any health services such as those listed in question 1.

Yes ☐ ***If yes:*** *Please give details below*

No ☐ ***If no:*** *Please go straight to question 13*

I have not been employed in the last 3 months ☐ ***If not employed:*** *Please go straight to question 13*

*Please tell us **either** the number of days **or** the number of hours you took off in the last 3 months*

	No	Yes	Number of whole working days	Or Number of hours
Took sick leave from work	☐	☐		
Used your paid holiday time from work	☐	☐		
Took unpaid leave from work	☐	☐		
Just made up the time at work	☐	☐		
Other arrangement *(please describe below)*	☐	☐		

.....

Have you lost any pay because of this time off work?

Yes ☐

No ☐

If yes: **How much gross income (i.e. before tax) have you lost in the last 3 months?** £

13. **In the last 3 months, have friends and relatives stayed off work to help you because of any illness?**

Please include any time they took off to look after you, take you to health care appointments or visit you in hospital.

Yes ☐

No ☐

If yes: **How many whole days or hours did they take off work in the last 3 months?** days / or hours

14. **Do you receive any state benefits?**

Yes ☐ ***If yes:*** *Please tick below which benefits you get and tell us how much you get altogether*

No ☐ ***If no:*** *Please go straight to question 15*

Attendance allowance	☐	Jobseeker's allowance	☐
Disability living allowance	☐	Severe disablement allowance	☐
Council tax benefit	☐	Statutory sick pay	☐
Housing benefit	☐	Working tax credit	☐
Incapacity benefit	☐	Jobseeker's allowance	☐
Income support	☐	Others (please describe)	☐

……

How much do you receive altogether in benefits each week? £

Please exclude housing benefit from this total.

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Now please tell us something about yourself

15. **Which of the following best describes your <u>current</u> situation?**
Please read the whole list first and then write '1' in the box that applies. If other categories apply, write '2', '3' etc. to indicate the order that best describes your situation.

Retired	
Unable to work due to MSD	
Unable to work due to other illness	
Unable to work for other reasons	
Made redundant/took early retirement due to MSD	
Made redundant/took early retirement due to other illness	
Made redundant/took early retirement for other reasons	
Working full time (30 hours or more per week)	
Working part time (less than 30 hours per week)	
Unemployed and looking for work	
Student	
Volunteer worker	
Job training/apprentice	
At home and not looking for work (e.g. looking after home/family)	
Other (*Please describe below)*	

.....

Thank you for completing this questionnaire

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SF-36® Health Survey

Official use only
Patient study code: ……..
Today's date: ……..

This questionnaire asks for your views about your health. This information will help us to keep track of how you feel and how well you are able to do your usual activities.

Answer every question by ticking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

---

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
☐	☐	☐	☐	☐

---

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
☐	☐	☐	☐	☐

---

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	Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	☐	☐	☐
b	Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐	☐	☐
c	Lifting or carrying groceries	☐	☐	☐

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d	Climbing several flights of stairs	☐	☐	☐
e	Climbing one flight of stairs	☐	☐	☐
f	Bending, kneeling, or stooping	☐	☐	☐
g	Walking more than a mile	☐	☐	☐
h	Walking several blocks	☐	☐	☐
i	Walking one block	☐	☐	☐
j	Bathing or dressing yourself	☐	☐	☐

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

		No	Yes
a	Cut down on the amount of time you spent on work or other activities	☐	☐
b	Accomplished less than you would like	☐	☐
c	Were limited in the kind of work or other activities	☐	☐
d	Had difficulty performing the work or other activities (for example, it took extra effort)	☐	☐

5. During the past 4 weeks, 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)?

		No	Yes
a	Cut down on the amount of time you spent on work or other activities	☐	☐
b	Accomplished less than you would like	☐	☐
c	Did work or other activities less carefully than usual	☐	☐

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6. During the <u>past 4 weeks</u>, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

Not at all	Slightly	Moderately	Quite a bit	Extremely
☐	☐	☐	☐	☐

7. How much <u>bodily</u> pain have you had during the <u>past 4 weeks</u>?

None	Very mild	Mild	Moderate	Severe	Very severe
☐	☐	☐	☐	☐	☐

8. During the <u>past 4 weeks</u>, how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐	☐	☐	☐	☐

9. These questions are about how you feel and how things have been with you during the <u>past 4 weeks</u>. 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 <u>past 4 weeks</u>...

	All of the time	*Most of the time*	*A good bit of the time*	*Some of the time*	*A little of the time*	*None of the time*
a. Did you feel full of pep?	☐	☐	☐	☐	☐	☐
b. Have you been a very nervous person?	☐	☐	☐	☐	☐	☐
c. Have you felt so down in the dumps that nothing could cheer you up?	☐	☐	☐	☐	☐	☐
d. Have you felt calm and peaceful?	☐	☐	☐	☐	☐	☐
e. Did you have a lot of energy?	☐	☐	☐	☐	☐	☐
f. Have you felt downhearted and blue?	☐	☐	☐	☐	☐	☐
g. Did you feel worn out?	☐	☐	☐	☐	☐	☐
h. Have you been a happy person?	☐	☐	☐	☐	☐	☐
i. Did you feel tired?	☐	☐	☐	☐	☐	☐

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10. During the <u>past 4 weeks</u>, how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

11. How TRUE or FALSE is <u>each</u> of the following statements for you?

	Definitely true	*Mostly true*	*Don't know*	*Mostly false*	*Definitely false*
a. I seem to get sick a little easier than other people	☐	☐	☐	☐	☐
b. I am as healthy as anybody I know	☐	☐	☐	☐	☐
c. I expect my health to get worse	☐	☐	☐	☐	☐
d. My health is excellent	☐	☐	☐	☐	☐

Thank you for completing this questionnaire

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Official use only
Patient study code: .....
Today's date: .....

Visual Analogue Scale

Please place a vertical mark on the scale below to indicate how you bad you feel your pain today:

No Pain Worst Pain

Here is an example of how to complete the question:

No Pain Worst Pain

Thank you for completing this questionnaire

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Additional Notes

Your Email Address:

Anything you would like to add:

Appendix 3 4 QUAL topic guide for pre-treatment interviews and follow-up interviews and focus groups

Topic guide for the pre-treatment interviews

Questions	Probes
1. Can you tell me what do you feel about taking part in the study?	Do you think taking part will effect/affect your treatment in the RLHIM, what is the main worry of taking part in the study?
2. Can you tell me about the condition which you have been referred to the hospital for?	When and how this developed, how they feel emotionally, symptoms, concomitant conditions.
3. How does your condition affect your daily life?	Has this condition has impacted on work, ability to perform everyday activities, their relationships with family/friends, their social life.
4. What treatments/self help measures have you used to try to improve your condition?	Any use of conventional and unconventional treatments (including CAM).
5. Can you tell me how you came to be referred to the Royal London Hospital for Integrated Medicine?	Own initiative or health practitioners recommendation; any barrier to accessing; perceptions of referring health practitioner/family/friends.
6. Can you tell me what your expectations are for your treatment at the hospital?	Expectations of benefit/adverse effects; what do they think the experience will be like.
7. What are your expectations of being involved in the study?	What they perceive it's like taking part in research.
OTHER PROBES AS DICTATED BY THE EMERGING CATEGORIES AND THEMES	

Topic guide for the follow-up interviews and focus groups

Questions	Probes
What is your experience of taking part in this study?	How did you find the process of taking part in the study? Why you decided to take part in the study in the first place? How did you find the recruitment process? Do you feel the information we provided was sufficient to make an informed decision to take part [PIS, verbal communication] and if not how could it have been improved? Did you complete all the questionnaires? If not, why not? How did you find completing the questionnaires [too long, had to complete on specified days etc] (show them copies)? Was there anything you did not understand? Which questionnaire do you think best explained your conditions? What do you think of having such an assessment included in the future study? Is there anything else we should have asked you? Were there anything/changes/symptoms we didn't capture? [If not why not]? Did you have any problems taking part in the study? Do you feel taking part in this study is affected your treatment at RLHIM? Is there anything which you feel could have improved your experience of taking part? What do you think about the length of time you were in the study? Do you think you benefited from taking part in this study? Is there anything else you think we could have done differently?
Can you tell me the treatment you received at the RLHIM and about the experiences you have had during the treatment?	Did you attend all your treatment sessions? If not, why not? How did you feel during your treatment? (Emotionally, kinds of symptoms, concomitant conditions). Were there any barriers, adverse effects, new problems that emerged?What was it like receiving a package of care?
Has the treatment changed your symptoms, wellbeing and quality of daily life? If so, how?	Has the treatment changed the severity of the pain, sleeping, work, ability to perform everyday activities, their relationships with family/friends, their social life, did it meet your expectations.

OTHER PROBES AS DICTATED BY THE EMERGING CATEGORIES AND THEMES

Appendix 3 5 Follow-up reminder letter to participants

London South Bank University

NHS University College London Hospitals NHS Foundation Trust
Royal London Hospital for Integrated Medicine

Dear _____,

Thank you for taking part in the FIT study at the Royal London Hospital for Integrated Medicine. This is a follow up questionnaire (_____ round).

We sincerely appreciate your participation in helping the research and hope you could finish the questionnaire and send it back with the prepaid envelope which you could find in this letter, within two weeks.

Please do not hesitate to contact Mio if there is anything not clear (hux@lsbu.ac.uk)

Thank you very much.

Best wishes,

Research Group: Mio Hu, John Hughes, Peter Fisher, Ava Lorenc, Rachel Purtell, A-La Park, Nicola Robinson

FIT Feasibility study of Integrated Treatment on musculoskeletal disorders

Appendix 3 6 Practitioner treatment log

London South Bank University

NHS University College London Hospitals NHS Foundation Trust

Royal London Hospital for Integrated Medicine

Dear colleague,

This patient has been recruited to a study being carried out at the Royal National Hospital for Integrated Medicine. Please complete this table during the study each time the patient has a consultation. Thank you very much.

	Date	Diagnosis or ICD codes i.e. M54.2 for neck pain, M54.5 for low back pain http://apps.who.int/classifications/icd10/	Today's treatment provided	Treatment Provider (Initials)	Patient's progress since last appointment +4 Cured /Back to normal +3 Major Improvement +2 Moderate improvement, affecting daily living +1 Slight improvement, no effect on daily living 0 No change/Unsure -1 Slight deterioration, no effect on daily living -2 Moderate deterioration, affecting daily living -3 Major deterioration -4 Disastrous deterioration
1					N/A
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					

PTO

Appendix 3.6 Practitioner treatment log

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Royal London Hospital for Integrated Medicine

	Date	Diagnosis or ICD codes i.e. M54.2 for neck pain, M54.5 for low back pain http://apps.who.int/classifications/icd10/	Today's treatment provided	Treatment Provider (Initials)	Patient's progress since last appointment +4 Cured /Back to normal +3 Major Improvement +2 Moderate improvement, affecting daily living +1 Slight improvement, no effect on daily living 0 No change/Unsure -1 Slight deterioration, no effect on daily living -2 Moderate deterioration, affecting daily living -3 Major deterioration -4 Disastrous deterioration
17					
18					
19					
20					
21					
22					
23					
24					
25					
26					
27					
28					
29					
30					
31					
32					
33					
34					

Appendix 3 7 Framework analysis memo in Nvivo (partial)

Examples of Ava's codes identified from the follow-up interviews and focus groups

27th Feb 2015

MSD	TREATMENT/EXPERIENCE AT THE RLHIM	PATHWAY TO TREATMENT	PREVIOUS TREATMENT EXPERIENCE
Diagnosis/condition	Course of treatment	Access to treatment (physical/practical)	western medicine (not effective)
(chronic) pain	effect of treatment (improvement/it work	referral/pathway to treatment	NHS treatment
experience of disease	integration (works)	NHS organisation issues	physio
symptom	acupuncture		GP
diagnosis (CAM)	western medicine	NHS funding	consultant
complex condition	long term effect (lack of)	Mechanism of action?	practitioner NHS
diagnostic tests	maintaining the effect	CCGs or funding	private treatment
effect (pain/daily life)	cost effectiveness	NHS cuts	hydroptherapy
seriousness of condition	side effects		previous experience CAM
complex life	experience of treatment	Reason for coming to RLHIM	trust in profession
mental health	duration of treatment	decision making to come to RLHIM	avoid WM
patient understanding of condition	individualised effect	reason for seeking treatment	GP advice/opinion
problems with diagnosis	enjoyment?		
impact of condition/pain	good experience	patient understanding of treatment pathway	**EXPECTATION/HOPE**
emotional impact	TCM vs. western acupuncture (effectiveness, mechanism)		individualised
things which impact condition	mechanism		belief in CAM (lack of)
	homeopathy	**RESEACH DESIGN**	expectation
	consultation (length/booking/phone)	questionnaire	hope
	holistic	outcome measures	expectation
	advice	sf BPI	often disapointed/not satisfied/has very high expectation
	comparing WM and CAM	SF36	patient demand
	acupressure	CSRI	treatment met expectation/satisfied
	disappointment	VAS	hopeful
	RLHIM process	Difficulty to score (confusing/easy/varies/recall)	expectation of effect

Examples of Nicky's codes identified from the follow-up interviews and focus groups

41	FG2	40	9
Multiple morbidity	Multi MSD morbidities	Extent of pain and severity	Access to treatment
Other health problems/issues	Reason for referral	Type of pain	Outcomes of integrated care
Knee pain prior	Treatment at hospital	Frequency of pain	Post RLHIM (continuity of care)
Carpal tunnel TMD	Satisfaction with consultation	Triggers	Self-help
Mental affect	Change in attitude as a result of treatment	Access to other treatment	Outcome of complex intervention
Coping with pain	Treatment details	Living with pain	Access to treatment in other NHS location
Attitude to understanding own pain	Experience of RLHIM treatment	Treatment package	Need for continuing care for pain relief
Wish for alternatives	Experience of acupuncture treatment at RLHIM	Other health problem	Complex MSD
Barriers to exercise	Amount of treatment	Individual RLHIM treatment	Access to other sources of help
Attitude to healthcare (another hospital)	Experience of practitioner	Perceived improvement	(difficult to get) Access due to costs of treatment
Reason for coming to RLHIM	Time allocated for treatment	Length of consultation	Prior use of CAM
Doctor's approach (Dr. RLHIM1 referred the patient to Dr. RLHIM2)	Time allocated for consultation	Satisfaction with consultation	Rationing of health care (referrals)
Previous experience of western drugs	Frequency of contact	Satisfaction with health care practitioner and consultation	Expectation of increased costs and health outcomes
IM treatment given	Provision + amount of time for treatment	Patient satisfaction with treatment	Satisfaction with CAM
Getting to travelling to appointment	Referral results (difficulties in getting re-referred)	Request for alternative treatment	Acupuncture as part of complex intervention
Accessibility changing appointment	Attitudes of GPs	Previous use of CAM	Side effect of acupuncture
Time taking to get an appointment	Time to access to treatment	Side effect of previous treatment	Individualization of intervention
Patients' perception of docs attitudes	Patient need	Other hospital treatment	Consultation experience of hospital and barriers
Attitude to western medicine	Use of services ? hospital	Expectation for other care	Experience of consultations
Beliefs in alternative (doctors views)?	Time to treatment (time waited interim treatment)	Experience of acupuncture	Waiting time
Treatment received (at the RLHIM)	Wish for additional treatment at hospital	Experience of treatment	Reception
Consultation content	Use of conventional medicine	Type of acupuncture	Positive outcome
Treatment externally received	Practitioner delivered integrated care	Consultation practitioner input	Side effects of intervention
Wish to seeking other approaches	Seeking treatment	Patient explanation of treatment	Complexity of care
Other therapies patient would like	Access to (RLHIM) care	Explanation given to patient on effect of treatment	Needed to treat pain
Other self-care treatment used	Provider of info	Patient searching for information	Side effects
Coping with pain	Diet	Satisfaction with treatment	Hospital environment
Other treatment received from hospital (not sure if this is RLHIM)	Relationship with practitioner	Experience after completion of treatment	Problems accessing to services
Use of other treatment option	Provision of care	Outcome of treatment	Amount of treatment alleviate
Attitude to treatment offered	Advice from practitioner	Expectation after initial consultation	Problems of access
Outcome of treatment used	Intervention experience	Dissatisfaction with RLHIM care	Attitude of pain
Expectation	Patient control of intervention	Communication with GP	Limited/reduced access to care
Status of daily activities	Understanding the intervention	Access further care	Costs
Self-help	Referral	Geographical location of patient	Importance of complex care package
Attitudes to use of other treatments	Intervention outcomes	RLHIM service	Effect of acupuncture care package
Doctor's attitude	Provision? of self-help advice	Satisfaction with reception services	effect of acupuncture
Belief in whether having integrative treatment	Treatment provided	Appointment waiting time	integrated care package
Self-care	Patients perception of doctors	Consultation at the RLHIM	other effects of treatment
Needs (on treatment)	Adverse effect of intervention (acupuncture)	Problems on questionnaire completion	process of care
Access to RLHIM services (care pathway)	Adverse effect of treatment	Acceptability of questionnaire	need for complex intervention
Patient control? (Extended treatment)	Adverse effect of treatment (osteopathy)	Affect of treatment on sleep	previous use and accessing acupuncture elsewhere
Discharge process at RLHIM or satisfaction? with care	Doctors explanation of intervention	Problems of completing CSRI	limited other access of treatment

Framework version 1 for the follow-up interviews and focus groups (partially), developed on the 25th March 2015

This version framework was developed on the 25th March 2015, after coding 009/040/041/FG2/FG3 (with 9/30 participants)				
Living with MSDs	**Previous Experiences**	**Access to Treatment**	**Patient Expectations**	**Self-management**
History of MSDs	Previous CM experiences	Decision making process to come to the RLHIM	Participants' understanding of their expectation (e.g. Lack of expectation, avoid having expectation)	Coping with pain/condition
MSDs symptoms	Previous CAM/IM experiences	Access to treatment	Expectations and hope for type of treatment (e.g. often disapointed/not satisfied/has very high expectation)	Understanding of (Importance of) self-help
Impact of MSDs	Lack of CAM/IM experiences	Access to treatment - physical (e.g. Getting to travelling to appointment; Dealing with costs)	Hopes/needs/wishes for CAM/IM treatment (e.g. continuing/additional treastment/seek for other approaches)	Exercise
Self-management		Access to treatment - practical (e.g. time waited interim treatment)	Hopes from the practitioner	Things which impact condition
CAM Diagnosis		Mechanism of action/RLHIM changes	Hopes for future NHS CAM/IM access	Self-directed integrative treatment
Diagnostic tests		Patient understanding of treatment pathway/rationing of healthcare referrals (e.g. different approach for different patients etc)	Treatment met expectation/satisfied	
Patient understanding of MSDs e.g. mechanism, how knowledge on health is found)			Worries of being treated	Stress/Emotional management?

N.B
Texts in brown represent same coding as the prior treatment qualitative study;
Texts in black represent new categoris and codes generated from the post treatment qualitative study;
Texts in red represent where changes were made, with comments explaining what changes have been made and why;
Texts in green represent where codes were deleted;
Text in blue represent newly added codes

Framework version 3 for the follow-up interviews and focus groups (partially), developed on the 25th March 2015

This version framework was developed on the 1st Apr 2015, after coding 30/30 participants				
Living with MSDs	**Previous Experiences**	**Access to Treatment**	**Patient Expectations**	**Self-management**
History of MSDs	Previous CM experiences	Decision making process to come to the RLHIM	Participants' understanding of their expectation (e.g. Lack of expectation, avoid having expectation)	Coping with pain/condition
MSDs symptoms	Previous CAM/IM experiences	Access to treatment	Expectations and hope for type of treatment (e.g. often disapointed/not satisfied/has very high expectation)	Understanding of (Importance of) self-help
Impact of MSDs	Lack of CAM/IM experiences	Access to treatment - physical (e.g. Getting to travelling to appointment; Dealing with costs)	Hopes/needs/wishes for CAM/IM treatment (e.g. continuing/additional treastment/seek for other approaches)	Exercise
Impact of non-MSDs		Access to treatment - practical (Referal Pathway) (e.g. time waited interim treatment; limited treatment available at the hospital etc))	Hopes from the practitioner	Things which impact condition
Self-management		Mechanism of action (e.g. not being addresse because they are not in certain scheme)	Hopes for future NHS CAM/IM access	Self-directed integrative treatment
CAM Diagnosis		Rationing of healthcare referrals/mechanism of action (e.g. different approach/scheme for different patients etc)	Treatment met expectation/satisfied	Information seeking
Diagnostic tests		Awareness of Strain in NHS Resources	Worries of being treated	Stress/Emotional management?

The research student's charting reflections (partially)

23rd Apr 2015

Difference in using Excel and Nvivo framework matrix function:

1. If wanted to make any changes in transcripts when coding/developing framework/charting/interpretation, one can easily do that and the whole project will be automatically updated
2. Can re-code or un code nodes while charting: sometimes while charting, Mio found certain quotes were not belong to a code, it is easy to change it to another code or delete it when charting in framework matrix in Nvivo.
3. Several tabs: easy to record memo and reflections as memo can be linked to the transcripts/framework/framework matrix etc
4. If content was not clear, can easily get access to the whole transcripts and read and add stuff.

Changes in codes while charting:

Some codes were combined in the charting process of the follow-up interview analysis: for example, code 'MSDs symptoms' was combined with code 'history of MSDs' because much fewer quotes were on their MSD history and symptoms is part of medical history.

24th Apr 2015

While charting, Mio copied some of the quotes she likes to a separate word document.

Language used in charting:

There might be sentences difficult for supervisors to understand but Mio wrote down the sentences that she can best understand the content, as this is only for her interpretation.

Category 1: Living with MSDs

Most of the words Mio used to summarize or describe participants' history of MSDs and MSDs symptoms (1.1 &1.2) were their own words because it is what they believed they had.

28th Apr 2015

Mio found it is difficult not to interpret during charting. Mio must be descriptive and use the participants' own words as much as possible. There is no harm having a long summary for a quote.

01st May 2015

While charting, Mio have written down the ideas of possible themes and copied good quotes to a separate word file.

In summary:

There are altogether 3 versions of framework before finalizing the final framework. Details of the how codes were changed and reasons of them are available in memo: Framework v1-v3 and excel file: final framework.

Version 1: developed on the 25th Jan 2015, after coding 009/040/041/FG2/FG3 (with 9/30 participants)

Version 2: developed on the 1st Feb 2015, after coding

021/013/044/022/007/034/009/040/041/FG2/FG3 (with 13/30 participants)
Version 3: developed on the 1st Apr 2015, after coding 30/30 participants

24th Feb 2015

Data saturation:

Today I started working on drafting my framework as I feel no more new data is generating from the interviews (n=16). So far, I have transcribed 22 interviews altogether;

- I kept all the categories and codes I had from the first part qualitative study when I started drafting my framework. I also feel this might help with identifying which are the extra/missing codes compared with the part one qualitative study;
- I started from the interview No.41 as I remember this participant was quite active;

There were a few mistakes in transcribing so I revised them in Nvivo directly as I think Nvivo will help me organizing my final data, including emails and texts that I will import later.

26th Feb 2015

Inter-rater coding reflections:

Framework developed by five interviews

Nicky: 041, FG2 (010, 014) – received on the 16th March 2015

040 and 009 – received on the 19th March 2015

Ava: 009, 040, FG3 (027, 031, 058, 041)

Nicky suggested Mio not to lead the question and not to give advice; Mio acknowledged these.

What Mio did:

1. Copy the codes given by Nicky, Ava and herself; all codes were only recorded once for each coder;
2. Add in explanations by reading relevant quotes if the codes did not stand themselves;
3. Grouped the codes and add category titles using track changes;
4. Discuss with Nicky and Ava

Copied categories and codes from the pre-intervention interview; added/deleted/grouped;

Reasons (go to in method):

Although research questions of the follow-up interview are focusing on participants' treatment experiences and their experiences in participating in the research study, the researcher anticipated participants would explain their MSD experiences

many similar categories and codes, e.g. codes under 'living with MSDs' and ''

Limitation: I sometimes need to make decision whether participants were talking about the treatment in the RLHIM, or they were talking about services in hospital in general? Also need to make decision on whether they are treatments received at the time of interview, or treatments received before.

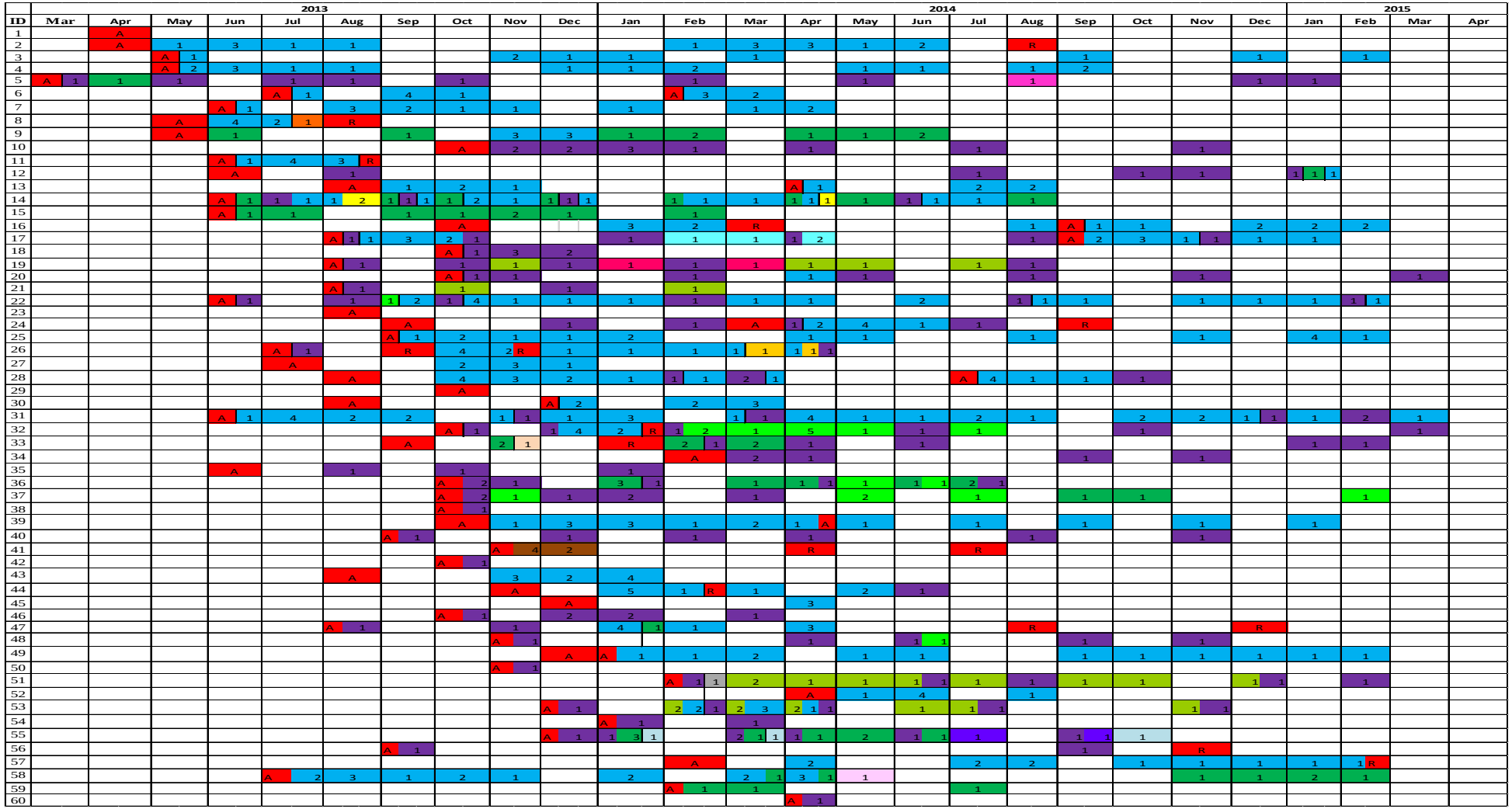
Some useful information was wasted, e.g. a participant received acupuncture treatment (the treatment she really wanted to get but didn't) after talking with other participants in focus group.

Why not using 'kappa' to check similarity/trustness: it works well for researchers who have experiences in working on the same project before?
What I found difficult: codes or themes?
Difficulties in separate/group CM and CAM
Ideas on theme (partially)

24th Apr 2015
Living with MSDs
1.1 History of MSDs
A Variety of Musculoskeletal Disorders
Long term conditions
Complex or multifactorial conditions
Unclear diagnosis
A hidden disability
Fluctuating pain
Stiffness and restrictions in movement
Fatigue
Accepting the truth
Consistent pain
Underlying pain all the time with severe flare-ups

1.2 Impact of MSDs
Affect all aspect of life
Compromise doing things
Feel all different when in pain
Changed how they do things - self-management?
Feel of dependent?
Change the ways of doing things

Appendix 4 1 Complexity of the frequency of treatments received by participants



Appendix 7 1 Ethical approval

NHS
Health Research Authority

NRES Committee London - City & East
Bristol Research Ethics Committee Centre
Whitefriars
Level 3, Block B
Lewins Mead
Bristol
BS1 2NT

Telephone: 01173421386
Facsimile: 01173420445

24 October 2012

Miss Xiaoyang Hu
Faculty of Health and Social Care
London South Bank University
103 Borough Road, London
SE1 0AA

Dear Miss Hu,

Study title:	**A pragmatic observational longitudinal study of integrated treatment for musculoskeletal disorders (POINT)**
REC reference:	**12/LO/1341**

Thank you for your letter of 02 October 2012, 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 lead reviewer.

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).

Non-NHS sites

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

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).

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

Document	*Version*	*Date*
Covering Letter	email	19 July 2012
Covering Letter		02 October 2012
Evidence of insurance or indemnity		14 July 2012
Evidence of insurance or indemnity		01 August 2012
Investigator CV		06 June 2012
Letter from Sponsor		11 June 2012
Letter of invitation to participant	2	26 September 2012
Other: Academic Supervisor CV: N Robinson		
Other: Academic Supervisor CV: A Lorenc		
Other: Treatment Log	2	25 September 2012
Other: Instructions for CT and PSD		
Other: Topic Guide for 1st Interview	2	09 October 2012
Other: Topic Guide for 2nd Interview	2	09 October 2012
Participant Consent Form: Consent Form (1st Interview)	2	25 September 2012
Participant Consent Form: Consent Form (2nd Interview)	2	25 September 2012
Participant Consent Form: Consent Form (Questionnaire)	2	25 September 2012
Participant Information Sheet: Participant Information Leaflet (Interview/Focus Groups)	2	25 September 2012
Participant Information Sheet: Participant Information Leaflet (Questionnaire and Interview)	2	25 September 2012
Protocol	2	09 October 2012
Questionnaire: SF-36		
Questionnaire: BPI-short form		
Questionnaire: Sociodemographics		
Questionnaire: Patient expectation		
Questionnaire: Pain Visual Analogue scale		
Questionnaire: Client Service Inventory		
REC application		19 July 2012
Referees or other scientific critique report - Ricky Banarsee		
Response to Request for Further Information		02 October 2012

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.

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

12/LO/1341	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

Yours sincerely

pp Dr Arthur T. Tucker
Chair

Email: Ubh-tr.CityandEastREC@nhs.net

Enclosures: "After ethical review – guidance for researchers"

Copy to: *Nicola Crichton, London South Bank University*
Mr Philip Diamond, University College London Hospitals NHS Foundation Trust

Appendix 7 2 First ethical amendment approval

National Research Ethics Service

NHS Health Research Authority

NOTICE OF SUBSTANTIAL AMENDMENT (non-CTIMP)

For use in the case of all research other than clinical trials of investigational medicinal products (CTIMPs). For substantial amendments to CTIMPs, please use the EU-approved notice of amendment form (Annex 2 to ENTR/CT1) available in the Integrated Research Application System (IRAS) at http://www.myresearchproject.org.uk or on the EudraCT website at https://eudract.ema.europa.eu/document.html.

To be completed in typescript by the Chief Investigator in language comprehensible to a lay person and submitted to the Research Ethics Committee that gave a favourable opinion of the research ("the main REC"). In the case of multi-site studies, there is no need to send copies to other RECs unless specifically required by the main REC.

Further guidance is available at http://www.nres.nhs.uk/applications/after-ethical-review/notification-of-amendments/.

Details of Chief Investigator:

Name: Xiaoyang Hu
Address:
Faculty of Health and Social Care
London South Bank University
103 Borough Road
London
Postcode: SE1 OAA
Telephone: 020 7815 8350
Email:Hux2@lsbu.ac.uk
Fax:

Full title of study:	Feasibility study of integrated treatment on musculoskeletal disorders (FIT)
Lead sponsor:	London South Bank University
Name of REC:	City and East
REC reference number:	12/LO/1341
Name of lead R&D office:	UCLH R&D
Date study commenced:	9th January 2013

Protocol reference *(if applicable)*, current version and date:	V2, 09.10.2012
Amendment number and date:	V3, 06.03.2013

Type of amendment (indicate all that apply in bold)

(a) Amendment to information previously given on the REC Application Form

Yes (No)

If yes, please refer to relevant sections of the REC application in the "summary of changes" below.

(b) Amendment to the protocol

Yes (No)

If yes, please submit either the revised protocol with a new version number and date, highlighting changes in bold, or a document listing the changes and giving both the previous and revised text.

(c) Amendment to the information sheet(s) and consent form(s) for participants, or to any other supporting documentation for the study

(Yes) *No*

If yes, please submit all revised documents with new version numbers and dates, highlighting new text in bold.

Is this a modified version of an amendment previously notified to the REC and given an unfavourable opinion?

Yes (No)

Summary of changes

Briefly summarise the main changes proposed in this amendment using language comprehensible to a lay person. Explain the purpose of the changes and their significance for the study.

If this is a modified amendment, please explain how the modifications address concerns raised previously by the ethics committee.

If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained.

1. Letters of invitation to participant

The letter of invitation to participant was re-written so that the language is more user-friendly and easier to understand by a lay person. This is mainly aiming to improve recruitment rate at the hospital.

2. Patient information sheet
Study title " Feasibility study of integrated treatment on musculoskeletal disorders (FIT)" to 2 patient information sheets in order to ensure that patients understand that it is a research study and that it links directly to the information sheets.

Any other relevant information

Applicants may indicate any specific ethical issues relating to the amendment, on which the opinion of the REC is sought.

N/A

Appendix 7.2 First ethical amendment approval

List of enclosed documents

Document	*Version*	*Date*
Revised 2.Letters of invitation to participant	3	06.03.2013
Revised 3.Patient Information Sheet_Interview&Focus group	3	06.03.2013
Revised 3.Patient Information Sheet_Questionnaire&Interview	3	06.03.2013

Declaration by Chief Investigator

- I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.
- I consider that it would be reasonable for the proposed amendment to be implemented.

Signature of Chief Investigator:

Print name: .....Xiaoyang...Hu.....

Date of submission: .....

Notice of substantial amendment (non-CTIMP), version 4.0 November 2011 4

Appendix 7.2 First ethical amendment approval

Declaration by the sponsor's representative

The sponsor of an approved study is responsible for all amendments made during its conduct.

The person authorising the declaration should be authorised to do so. There is no requirement for a particular level of seniority; the sponsor's rules about delegated authority should be adhered to.

- I confirm the sponsor's support for this substantial amendment.

Signature of sponsor's representative:

Print name: Nicola Crichton .....

Post: Pro Dean Research .....

Organisation: London South Bank University .....

Date: 15 March 2013 .....

Appendix 7 3 Second ethical amendment approval

NHS
Health Research Authority

NRES Committee London - City & East
Bristol Research Ethics Committee Centre
Whitefriars
Level 3, Block B
Lewins Mead
Bristol
BS1 2NT

Tel: 01173421386
Fax: 01173420445

07 May 2013

Miss Xiaoyang Hu
Faculty of Health and Social Care
London South Bank University
103 Borough Road, London
SE1 0AA

Dear Miss Hu

Study title:	**A pragmatic observational longitudinal study of integrated treatment for musculoskeletal disorders (POINT)**
REC reference:	**12/LO/1341**
Amendment number:	**AM02 Substnatial amendment V3, 09.04.2013**
Amendment date:	**10 April 2013**
IRAS project ID:	**97747**

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

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
Protocol	2	09 October 2012
Notice of Substantial Amendment (non-CTIMPs)	AM02 Substantial Amendment V3, 09.04.2013	10 April 2013
Covering Letter		10 April 2013
Protocol	3	10 April 2013

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Appendix 7.3 Second ethic amendment approval

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/

12/LO/1341:	**Please quote this number on all correspondence**

Yours sincerely

pp Dr Arthur T. Tucker
Chair

E-mail: nrescommittee.london-cityandeast@nhs.net

Enclosures: *List of names and professions of members who took part in the review*

Copy to: *Mr Philip Diamond, University College London Hospitals NHS Foundation Trust*
Nicola Crichton, London South Bank University

Appendix 7.3 Second ethic amendment approval

NRES Committee London - City & East

Attendance at Sub-Committee of the REC meeting on 29 April 2013

Name	*Profession*	*Capacity*
Mr Roger Maran		Lay Plus
Dr Arthur T. Tucker	Principal Clinical Scientist & Honorary Reader, (REC Chairman)	Expert

Also in attendance:

Name	*Position (or reason for attending)*
Mr Rajat Khullar	Committee Coordinator

Glossary of Terms

Terms listed in this glossary are categorised into three groups: philosophy terms, research methodology terms, and definitions of other terms. Most of the definitions of philosophy terms were referenced from the SAGE research methods dictionary and the Oxford dictionary, references are provided when the definition was not from the stated two sources.

PHILOSOPHY TERMS	
Confucianism	Also known as Ruism, an ethical and philosophical system, developed from the teachings of the Chinese philosopher Confucius (551-479 BCE); characterised with five concepts: "Jen" (benevolence), "Yi" (righteousness), "Chung" (loyalty), "Hsia" (filial piety), and "Te" (virtue) (Allinson, 1989).
Constructivism/ empiricism/nat uralism	A research paradigm which believes truth is relative, values individual influences on what counts as knowledge and values subjective human experience over objectivity.
Epistemology	"Theory of knowledge". The branch of philosophy that studies the nature, origin, concerns criteria of knowledge.
Interpretivism	A philosophical concept in social science that opposes the positivism of natural science. A belief that someone can study qualitatively in inquiry in social science and related disciplines.
Objectivism	The belief that objective science is possible, often refers to research paradigm based on quantitative methods.
Ontology	The theory of the nature of being and existence.
Paradigm	Paradigms allow researchers to summarise their beliefs about how knowledge is created and allow for frameworks for research design, measurement, analysis and personal involvement. Paradigm is essential to provide world view and social contexts, guide actions, and allow framework for research design (Morgan 2007).
Positivism	"Empirical study of phenomena"; the term was introduced by Auguste Comte (1798–1857). The most common way of interpreting it nowadays refers it to a belief that held by someone can study scientifically and/or quantitatively.
Pragmatism	A philosophical concept seeking the middle ground between (post) positivism/objectivism on which pure quantitative approaches are based and interpretivism/constructivism on which pure qualitative approaches are based (Johnson and Onwuegbuzie, 2004), emphasising resolving the problem as the priority, using the best philosophical or methodology approach to answer a research question (Mackenzie and Knipe, 2005).
Taoism	Tao means way; major idea of Taoism was described as "Man models himself on earth, earth on heaven, heaven on the way, and the way on that which is naturally so" (Chen, 1996).

RESEARCH METHODOLOGY TERMS	
Adverse events	Adverse events or adverse experience refer to any unfavourable or unintended sign or symptom, which may not necessary be caused by the intervention(s) taken.
Bowen's feasibility framework	A framework to guide design, evaluation, interpretation and prioritizes interventions for feasibility research (Bowen et al., 2009).
Ceiling/floor effect	Ceiling effect occurs when a measure possesses a distinct upper limit for potential responses and a large concentration of participants score at or near this limit (the opposite of a floor effect).
Complex intervention	Complex interventions are treatments that comprise of several interaction components. In this research study, integrative medicine is considered as a complex intervention as it may involve a variety of therapies or diagnostic approaches, and it may also involve components such as holistic lifestyle advice and patient-practitioner relationship (Campbell et al., 2000; Craig et al., 2008).
Data saturation	Data saturation in this research study refers to the point in qualitative data collection when no new theme emerges. This is a point which the theory appears to be robust thus no more data need to be collected.
Deductive/Inductive/Abductive	Deductive research begins with a hypothesis and which it seeks to confirm/falsify, while an inductive approach generates theory from the data (Lincoln and Guba 1985). Typical examples of deductive and inductive research are experimental trial and qualitative research. Abductive moves back and forth between induction and deduction and typical example is pragmatic research (Morgan 2007).
Effect size	Effect size is "the degree to which the null hypothesis is false". In this research study, Cohen's d was used to reflect difference in outcome for the average at different time points. It also reflects the measure of practical significance and provides statistical power.
Feasibility study	Feasibility research is a crucial stage of evaluating complex intervention as suggested by the MRC. It is often conducted to provide recommendations on whether efficacy/effectiveness testing should be performed for an intervention, to fill gaps in the literature, and to provide details in recruitment, study timelines, and to provide new criteria and suggesting measures to evaluate relevant outcomes (Glasgow et al., 2006).
Framework analysis	Framework analysis is a highly structured approach of qualitative data analysis, containing five stages included; data familiarization, identifying a thematic framework, indexing, charting, mapping and interpreting (Ritchie and Spencer, 1994).
Homogeneous sampling	The process of selecting a group of participants with same features or consisting similar parts.
Homoscedasticity	Homoscedasticity is a statistical term refers to the assumption that equal levels of variability between quantitative dependent variables across a range of independent variables that are either continuous or categorical.
Intensity sampling	A form of non-probability sampling, by researcher selecting rich or excellent examples of the phenomenon of interest.

Limited outcome testing	This is a term adapted from the "limited efficacy" in Bowen's feasibility framework. The framework recommended feasibility trial to report findings in efficacy, which are limited due to a feasibility design but can be used in the future definitive trial. Since this research study is a mixed methods feasibility study, quantitative and qualitative outcomes were tested (Bowen et al., 2009).
Mapping review	Mapping reviews often include a search which the completeness depending on time and scope, with no quality assessment required. By categorising or characterising key features of the target topic, this type of review often aims to commission further reviews or to identify gaps in literature (Grant and Booth, 2009).
Mixed methods research	Research that combines elements of both qualitative and quantitative research approaches, with an aim of exploring broad purposes of breadth and depth of understanding.
Mixed methods review/Integrative review	These terms refer to reviews that involve a combination of methods, e.g. reviews on both quantitative and qualitative literature, or reviews on outcome with process studies etc. (Whittemore, 2005; Grant and Booth, 2009).
Narrative review	Narrative review presented in this research study refers to a common literature review on qualitative literature, which explored published qualitative materials of recent or current literature. In this narrative review, there was no restriction on levels of completeness and comprehensiveness, with systematic search and quality appraisal not included (Grant and Booth, 2009).
Observational study	Non-experimental research that describes the health status of populations and generate evidence about determinants of health outcomes.
Process evaluation	Mostly in health services (not exclusively), refers to qualitative investigations conducted in parallel with quantitative evaluations in policy and practice interventions. Process evaluation always answers the question why an intervention has been successful or not.
Publication bias	Statistically significant findings are likely to be published, therefore, when performing meta-analysis, there might be more for meta-analysis. This potentially arises publication bias.
Purposive sampling	A form of non-probability sampling, by researcher making decision on which individuals to be included in the sample based on a variety of criteria.
Qualitative research	Research that is predominantly conducted in an inductively, using an interpretive approach under a subjective view.
Quantitative research	Research that is mainly conducted in a deductive approach, using statistical analysis under an objective view.
Reflexivity	Reflexivity entails the researchers being aware of the fact that it is impossible to remain "outside" as their personal effects may have an influence on the process and outcomes of research.
Reliability	The consistency of the outcome measures utilised in producing reproducible results.

Self-awareness	As defined by the Oxford dictionary, self-awareness represents "conscious knowledge of one's own character, feelings, motives, and desires". In the context of this research study, the process of understanding and accepting MSDs can be painful but it might leads to greater self-awareness.
Self-reflection	As defined by the Oxford dictionaries, self-reflection represents "serious thought about one's character and actions". In the context of this research study, patients benefited in improved self-reflection by participating in the research.
Side-by-side table	Utilised to compare and triangulate quantitative and qualitative findings in a convergent mixed methods design (Creswell & Clark, 2011).
Sphericity assumption	The sphericity assumption is a statistical priority of using univariate or mixed model analysis of variance in a within-subject design. In this research study, it assumes the variance of any linear combination of the measures over different time points is identical.
Systematic review	Systematic reviews often include an exhaustive and comprehensive search, quality appraisal, aiming to provide evidence by synthesising current available data (Grant and Booth, 2009).
Triangulation	Triangulation in this research study refers to the use of multiple methods, namely quantitative and qualitative research methodologies, with a purpose of compensating any single element by the strengths of the other.
Trustworthiness	Equivalent to rigour of research methods in qualitative research. In this research study, four aspects were considered for trustworthiness of the qualitative research, they are credibility, confirmability, dependability and transferability (Lincoln and Guba 1985).
Validity	Internal validity is always associated with experiment research, aiming to show the extent of results that can be attributed to the treatment in an ideal research setting; External validity (generalisability) indicates the extent of how the findings can be generalised to settings beyond those in the study.

OTHER DEFINITIONS	
Acupotomy	The name of acupotomy comes from words "acupoint" and "anatomy". It is a non-invasive surgery using a small needle scalpel into acupoint.
Alexander technique	A method of manual treatment that often provided for musculoskeletal conditions, to improved posture and movement, relax tensions in muscle.
Autogenic training	A form of relaxation technique involving engagement in mind and body and reversing the stress response.
Complementary and alternative medicine	Complementary and alternative medicine refers to a broad set of healthcare practices that country's own tradition and are not integrated into the dominant health care system. It refers to different practices to health systems in different countries (WHO Collaborating Centres for Traditional Medicine, 2015).
Dorsopathies	A medical term for back pain or neck pain.
Evidence based medicine	The GMC Good Medical Practice guidelines described evidence based medicine as "provide effective treatments based on the best available evidence". Evidence based medicine is not only used in research, it also incorporates clinical expertise and patient values (General Medical Council 2006; Sackett et al. 2000).
Holistic	A holistic approach in clinical practice refers to whole person care considering physical, mental and social factors.
Horizontal integration	Horizontal integration at the RLHIM refers to interactions with other hospitals and departments within the Trust (RLHIM, 2015).
Integrative medicine	Findings of this research study suggested integrative medicine is the optimum treatment that considered the use of both complementary and conventional interventions; emphasises individualised holistic approach, patient-practitioner communication and expectation management, with interprofessional/multidisciplinary, collaborative. Teamwork.
Musculoskeletal disorders	As defined by the Centre for Disease Control and Prevention, MSDs are "injuries or disorders of the muscles, nerves, tendons, joints, cartilage, and disorders of the nerves, tendons, muscles and supporting structures of the upper and lower limbs, neck, and lower back that are caused, precipitated or exacerbated by sudden exertion or prolonged exposure to physical factors such as repetition, force, vibration, or awkward posture". The identification of musculoskeletal disorders were based on the international classification of diseases version 10 (Chapter XIII Diseases of the musculoskeletal system and connective tissue (M00-M99) (Centers for Disease Control and Prevention, 2012; ICD-10, 2010).
Nutraceuticals	Nutraceuticals refer to nutrition products that are believed to provide health related therapeutic or preventive benefits.
Prolotherapy	A method of injection irritant of an irritant solution to joint, ligament, or tendon to relieve pain.
Self-care	People who give themselves a diagnosis, treat their ill health themselves, or adopt health seeking behaviours (Terry 2002).
Speleotherapy	A method of treatment involving staying in underground environments, e.g. respiratory therapy infused air of caves or mines.
Tuina	Originated from China, tuina is a method of manual therapy nowadays commonly practiced over the world, with an aim of treating various conditions and enhancing people's general health.
Vertical integration	Vertical integration at the RLHIM refers to interactions between hospital, primary and self-care (RLHIM, 2015).

Glossary