IMPLEMENTATION AND EVALUATION OF PHYSIOTHERAPIST INDEPENDENT PRESCRIBING: A MIXED MULTI-METHODS ANALYSIS

by

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ABSTRACT

This research presents novel knowledge and insight into the effective implementation and utilisation of non-medical prescribing (NMP) across professions internationally. It will inform safe and effective implementation of physiotherapy independent prescribing across clinical specialities, settings and jurisdictions.

Individual studies (systematic reviews, surveys, feasibility trial) were designed using rigorous mixed methods, addressing specific pre-determined aims and objectives generated from gaps in the literature.

Rigorous evaluation established that the benefit of NMP to the health economy remains unclear and limited evidence exists evaluating its clinical effectiveness across professions and clinical settings. Internationally, physiotherapists support the introduction of physiotherapist prescribing. Physiotherapists surveyed in Australia perceived potential benefits across the population, within a multimodal-physiotherapeutic context. Barriers and facilitators of the implementation/utilisation of NMP demonstrate multifactorial context specific variables. The resulting implementation framework may be useful to aid safe and successful implementation/utilisation of NMP.

Low risk of bias trials are required to evaluate the clinical and cost-effectiveness of physiotherapist prescribing across a range of clinical specialities and settings. High-quality feasibility trial data demonstrates that with minor modifications, a low risk of bias trial to evaluate clinical and cost-effectiveness of physiotherapist independent prescribing for low back pain in primary care is feasible, suitable and acceptable.

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List of Abbreviations

ACP	Advanced Clinical Practice
AHPRA	Australian Health Practitioner Regulation Agency
APA	Australian Physiotherapy Association
APC	Australian Physiotherapy Council
APP	Advanced Physiotherapy Practitioner
CPDANZ	Council of Physiotherapy Deans Australia and New Zealand
CSP	Chartered Society of Physiotherapy
DOH	Department of Health
FCP	First Contact Practitioner
GP	General Practitioner
HEE	Health Education England
HPPP	Health Professions Prescribing Pathway
iNMP	Independent Non-medical Prescribing
LBP	Low Back Pain
MDT	Multi-Disciplinary Team
MSK	Musculoskeletal
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NMP	Non-medical Prescribing
PPI	Patient and Public Involvement
RCT	Randomised Controlled Trial
SWcRCT	Stepped Wedge Cluster Randomised Controlled Trial
WCPT	World Confederation for Physical Therapy

CHAPTER 1: BACKGROUND

Chapter overview:

This is the first research to evaluate the use of non-medical prescribing (NMP) globally, to inform the safe, high-quality and successful embedding of physiotherapy independent prescribing into physiotherapy scope of practice. This chapter introduces key terminology and describes the current landscape both in the United Kingdom (UK) and internationally, setting out the rationale and value of this research. The explicit aims and objectives of this thesis are presented, and the thesis structure outlined.

Sections of this chapter are taken verbatim from the introduction and background sections of publications for which I am principal author. Publications are detailed below:

Noblet T, Marriott J, Graham-Clarke E, Rushton A. Barriers to and facilitators of independent non-medical prescribing in clinical practice: a mixed methods systematic review. Journal of Physiotherapy 2017;63(4):221-34. doi: https://doi.org/10.1016/j.jphys.2017.09.001

Noblet T, Marriott J, Graham-Clarke E, Shirley D, Rushton A. Clinical and cost-effectiveness of non-medical prescribing: A systematic review of randomised controlled trials. PLOS ONE 2018;13(3): e0193286. doi: 10.1371/journal.pone.0193286

Noblet T, Marriott J, Jones T, Dean C, Rushton A. Views and perceptions of Australian physiotherapists and physiotherapy students about the potential implementation of physiotherapist prescribing in Australia: a survey protocol. BMC Health Services Research 2018;18(1):472. doi: 10.1186/s12913-018-3300-x

Noblet T, Marriott J, Jones T, Dean C, Rushton A. Perceptions about the implementation of physiotherapist prescribing in Australia: a national survey of Australian physiotherapists. BMJ open 2019;9(5): e024991

Noblet T, Marriott J, Jones T, Dean C, Rushton A. Perceptions of Australian physiotherapy students about the potential implementation of physiotherapist prescribing in Australia: a national survey. BMJ open 2019;9(5): e026327

Noblet T, Marriott J, Rushton A. Independent prescribing by advanced physiotherapists for patients with low back pain in primary care: protocol for a feasibility trial with an embedded qualitative component. BMJ open 2019;9(4): e027745

1.0 INTRODUCTION

1.1 The evolution of non-medical prescribing

NMP is the umbrella term describing the prescription of medication(s) by a registered health professional who is not a medical practitioner or dentist [1 2]. NMP first originated in the 1960s, with nurse prescribing introduced in the United States of America (USA) [3 4]. Over the next 60 years NMP developed across the world and is currently used in 7 countries: Australia, Canada, Ireland, New Zealand, Sweden, the UK and the USA. The professions now using NMP within their scope of practice include nursing, optometry, pharmacy, physiotherapy, podiatry, radiography and most recently, paramedicine [1 2]. In addition, discussions and consultation regarding the use of NMP by dieticians and physicians associates are ongoing due to debates around clinical need, public safety and professional regulation for these professions [1 2].

1.1.2 NMP in the UK

The UK's National Health Service (NHS) was established in 1948 to provide free healthcare to all [5]. Traditionally in the UK, prescribing authority was given to medical professionals and dentists. Extending prescribing authority within the UK has been driven by a variety of factors including clinical research, economic factors and political interest [2]. Originally, the adoption of NMP in the UK aimed to increase patient choice, improve access to medication and promote evidence-based practice [6-8]. More recently, shortages in medical staffing and NHS funding constraints have caused a shift in motivation for using NMP [2]. This has led to the introduction of contemporary advanced clinical practice (ACP) roles which mandate

the use of NMP to help drive efficiency across health services; replacing traditional medical roles where there are limited staff budgets or limited availability of medical practitioners.

In the 1980s the Cumberlege Report forged the path for limited use of NMP by health visitors and district nurses, with the Crown Report in the late 1990s recommending that prescribing rights be extended across healthcare professions working within the NHS [9-13]. Following the Crown Report, in 2000, the Department of Health (DOH) published a white paper 'The NHS Plan', which outlined proposed modernisation of the NHS. The NHS Plan recommended the breakdown of traditional health professional boundaries to improve the patient experience by optimising clinical skills, improving capacity and reducing patient waiting times [14]. Subsequently, consultation commenced regarding the introduction of nurse and pharmacist supplementary prescribing, with enabling legislation enacted in 2002.

Supplementary prescribing is a partnership entered into voluntarily by a registered supplementary prescriber, an independent prescriber (medical practitioner or dentist) and a patient. The supplementary prescriber is only authorised to prescribe medication listed on a 'clinical management plan' written and agreed by the partnership for the individual patient. The supplementary prescriber takes responsibility for managing the patient's health needs as well as prescribing the associated medication(s) [15]. This method of prescribing was quickly recognised for its benefits in the management of complex and chronic conditions by a close working multidisciplinary team (MDT). However, restrictions in scope of practice were thought to limit use in acute healthcare scenarios or where an independent prescriber was not readily available for consultation and planning [2 15].

In 2005, further national consultation led to the expansion of nurse and pharmacist prescribing to include independent prescribing; enacted in 2006 [15] [16]. Independent prescribers are accountable for the assessment, diagnosis and prescribing processes [16]. Consequently, this method of NMP enables the expert clinician to prescribe within their professional scope of practice and individual competence, thus it is more flexible and responsive to individual patient need [2]. Following the precedent set by the nursing and pharmacy professions, physiotherapy, podiatry, optometry, radiography and paramedicine have successfully introduced supplementary prescribing into their scope of practice. Independent non-medical prescribing (iNMP) has now been extended to optometrists, physiotherapists, podiatrists and therapeutic radiographers. All registered independent non-medical prescribers (prescribers) undertake accredited educational programmes meeting the standards set by the UK prescribing competency framework [17], qualifying to prescribe generically [18]. Explicit profession specific formularies are defined to restrict prescribing where it would not be clinically appropriate and can be viewed by the public on the National Institute for Health and Care Excellence (NICE) website [18].

1.2 Advanced physiotherapy and physiotherapist prescribing

1.2.1 Advanced physiotherapy and physiotherapist prescribing in the UK

Advanced musculoskeletal physiotherapy roles have existed in the UK for over 30 years, playing an integral part within the delivery of health services nationally [19]. Advanced practice was initially recognised through the adoption of physiotherapists into orthopaedic and neurosurgical services where the availability of medical and/or surgical practitioners did not meet the demands of a local community [20] [21]. By utilising full and extended scopes

of practice (including physiotherapist prescribing and requesting/interpreting of diagnostic investigations such as blood tests, nerve conduction studies and imaging), Advanced Physiotherapy Practitioners (APPs) have been shown to be clinically and cost-effective across musculoskeletal (MSK), neurological and cardio-respiratory patient pathways, working in a diversity of settings such as neurology, respiratory, emergency, rheumatology, persistent pain, paediatric and therapies departments, as well as in primary care as first contact practitioners (FCPs) and in MSK secondary care interface services [20 22 23].

Physiotherapists in the UK have been able to complete post-registration educational programmes and register as supplementary prescribers since 2005. Since August 2013, physiotherapists in England have been able to qualify and register as both supplementary and independent prescribers [24]. The other home nations quickly followed, with legislation reform enacted in Scotland in May 2014, Northern Ireland in July 2014 and Wales in September 2014 [18]. In 2016, a report commissioned by the UK DOH, evaluating physiotherapist and podiatry independent prescribing, concluded that patients were positive about the use of physiotherapist independent prescribing. Perceived benefits included the streamlining of clinical pathways, reduction in General Practitioner (GP) appointments for medicine review, physiotherapists' enhanced knowledge and clarity around the law regarding medicines management activity [25].

Physiotherapist independent prescribers are able to prescribe any medication (including those unlicensed), within their individual competence, scope and expertise, for any healthcare problem. The scope of physiotherapist independent prescribing includes the prescribing and administration (or direction for the administration) of schedule 2,3,4 and

5 controlled drugs [18 24]. The controlled drugs currently within the UK physiotherapist independent prescribing formulary are listed in Figure 1 [18 24].

Figure 1: Controlled drugs currently prescribed by independent physiotherapist prescribers

Controlled Drugs:
Oral or injectable morphine (schedule 2), transdermal fentanyl (schedule 2), oral diazepam (schedule 4), dihydrocodeine tartrate (schedule 5), lorazepam (schedule 4), oxycodone hydrochloride (schedule 2) and temazepam (schedule 3).

The emergence of advanced practice roles entailing the use of NMP, within the fast-developing NHS and the ongoing evolution of physiotherapy scope of practice (including the introduction of physiotherapist prescribing), has led to the development and implementation of education and training programmes to better prepare and future-proof the workforce within the UK. Health Education England (HEE) (the section of the DOH tasked with the coordination of health education and training in England) in collaboration with NHS England have published a multi-professional framework defining advanced clinical practice in England [26]. It has been proposed that recognition of a clinician's capabilities at an advanced level across the four pillars of advanced practice (clinical practice, facilitating learning, leadership and evidence, research and development) will lead to accreditation as an Advanced Clinical Practitioner with the Academy for Advancing Practice [26]. This may be achieved by completion of an accredited master's level university programme or through a recognised equivalence route.

1.2.2 The MSK First Contact Practitioner

In England, NHS England has mandated the introduction of 'new ACP roles', in order to modernise the delivery of healthcare services [27-29]. By placing specialist clinicians, such as APPs, in MSK First Contact Practitioner (FCP) roles at the front of the patient pathway, it is anticipated that waiting times in primary care will be reduced, alleviating pressures placed on GPs and enabling comprehensive management of MSK conditions outside of secondary care, in the local community [28 30].

Annually in the UK, more than 30 million working days are lost due to MSK conditions [31]. Low back pain (LBP) is the most prevalent MSK condition in the UK, with 58-84% of the population experiencing LBP in their lifetime [32-34]. Approximately 20% of those with LBP seek care from their GP [32], with 7% of all GP consultations being due to LBP [34 35]. The NHS spent £17.4 billion on prescription medications in 2016-17, with prescribing of analgesia for MSK pain significantly increased compared to the previous decade [36]. APPs that are registered non-medical prescribers are well positioned to ensure that the right analgesics are used at the right time, alongside other helpful treatments such as exercise, psychological interventions and manual therapy [37 38].

The 'essential' capabilities of FCP clinicians are described by HEE in the 'Musculoskeletal Core Capabilities Framework for First Point of Contact Practitioners' [29]. It is proposed that numerous 'clinical capabilities' set out in the 'multi-professional framework for advanced clinical practice in England' may be demonstrated by fulfilment of the capability framework. Capability 8 details specific knowledge required in pharmacotherapy. This explicit capability is currently demonstrated by completion of post-registration iNMP master's level programmes. With the number of FCP roles across England rapidly increasing

due to government policy [30], it is anticipated that the number of physiotherapists working in the MSK speciality, registered as independent prescribers will significantly increase over the next 5 years [27-29].

1.2.3 Physiotherapist prescribing: a global perspective

Following the introduction of physiotherapist independent prescribing in the UK in 2012, the international physiotherapy community has expressed interest in the integration of NMP into the profession. The World Confederation of Physical Therapy (WCPT) describes the scope of physiotherapy as 'dynamic' within the context of each individual country's legal and regulatory framework. Based on national need and the readiness of physiotherapists to undertake prescribing education, Australia is the only country currently pursuing physiotherapist prescribing responsibilities [39-41].

Few member nations of the WCPT have formally commenced evaluation of the potential use of physiotherapist prescribing [39-44]. Researchers in Nigeria and South Africa have completed studies evaluating potential use of physiotherapist prescribing to manage deficits in healthcare provision. Findings showed that the majority of physiotherapists would want to increase their knowledge of pharmacology and proceed to undertaking further education which would enable them to prescribe medicines [42-44]. The benefits to the local populations were identified as improved access to medicines when required and an improved combined approach to the management of health issues managed by the physiotherapists in these countries [42-44]. Although 7 nations have adopted the use of NMP within their health services (consistently across nursing, with pharmacist and optometrist prescribing adopted by some nations), due to the absolute nature of law and regulation within individual states, no formal proposals have been submitted to governments across

Africa, Asia, mainland Europe, North America or South America to seek changes in law that would enable NMP by physiotherapists.

1.2.3.1 Physiotherapist prescribing in Australia

The Australian federal government has introduced strategy and legislation to provide the setting for reform of the current prescribing pathway, presenting a means to address the challenges facing the country's healthcare system [6]. Reforms began in 2013, with the aim to streamline services, reduce duplication and red tape, and improve the efficiency of the health economy [39]. The Australian Physiotherapy Association (APA) in collaboration with the Australia Physiotherapy Council and Council of Physiotherapy Deans Australia and New Zealand have commenced national processes to evaluate the potential clinical need for physiotherapist prescribing and the associated quality and safety issues [39]. These processes are based on the Health Professions Prescribing Pathway (HPPP); a model for all health professions to prescribe under the 'National Registration and Accreditation Scheme' developed by Health Workforce Australia [45]. The policies were endorsed by the Australian state and federal Health Ministers in November 2013 but are yet to be implemented and tested [46].

The anticipated implementation of physiotherapist prescribing in Australia will require the whole physiotherapy profession (including both registered and student physiotherapists), alongside politicians, policy makers and healthcare managers, to welcome change within national and local healthcare systems [1 39 47 48]. In July 2015, the APA formally submitted a proposal for the endorsement of registered physiotherapists as autonomous prescribers (prescribers endorsed to use supplementary and or independent prescribing), to the

Physiotherapy Board of Australia [39]. The case for reform centred around meeting the healthcare needs of the modern Australian population. Inequality in access to medicines for people living in rural and remote Australia was recognised as a key driver for the introduction of physiotherapy prescribing. Further, it was suggested that physiotherapy prescribing may also help resolve health inequalities between Aboriginal and Torres Strait Islander peoples and other minority groups by increased access to medicines via non-medical prescribers in the local communities [39].

1.3 Rationale underpinning the thesis research

With the ever-increasing financial challenges faced by health services across the world, in part due to ageing populations and rising levels of chronic disease, the potential financial efficiencies gained through the use of NMP are of paramount importance [1 39]. A range of robust studies utilising survey designs have concluded that NMP practice is both safe and appropriate, exhibiting good patient satisfaction [15 49-52].

Nevertheless, the implementation of NMP in the UK remains at a relatively slow pace [1]. Although the reasons for this are unclear, it is argued that this is caused by a lack of persuasive high quality evidence demonstrating the clinical and economic benefits of NMP in comparison to current models of healthcare [1]. As demand for healthcare increases, it is likely that policy makers and healthcare departments will become increasingly interested in optimising the skills of all health professionals to streamline patient care [1]. Employing physiotherapist independent prescribers across healthcare services has potential benefits to the health economy, providing holistic patient management within a multimodal treatment approach [1 39 53]. To enable the successful implementation of physiotherapist

independent prescribing across clinical specialities, lessons learnt from the experiences of other professions about the implementation of NMP should be acknowledged and barriers to implementation navigated. Factors facilitating quality and safety should be exploited and best practice shared [47 48]. Establishing an evidence base regarding the use iNMP is required for successful acceptance and quality implementation and utilisation of physiotherapist independent prescribing in the UK. The introduction of MSK FCP roles in primary care has been mandated across England [27 28]. It is anticipated that MSK APPs working in these roles will use physiotherapist independent prescribing within a multimodal management plan where indicated [29 54 55]. Evaluation of the clinical and cost-effectiveness of the use of prescribing, particularly for the most prevalent, disabling and costly conditions such as LBP, will be essential to ensure quality and safety.

Internationally, a range of views regarding the implementation of physiotherapist prescribing and current physiotherapeutic pharmacological knowledge have been acknowledged via national evaluations in Nigeria, South Africa and the UK [42-44 56]. Data from these evaluations has been used to impact national physiotherapy policy in Australia, resulting in the submission of a proposal from the profession to the Physiotherapy Board of Australia recommending that they enact procedures that aim to change federal and state laws and regulation, enabling physiotherapist prescribing [44 56]. However, full consultation across the Australian physiotherapy community was not completed prior to proposal submission. Acceptance and support for prescribing by the Australian physiotherapy profession, including both current registered physiotherapist and student physiotherapists ('the physiotherapists of tomorrow') will be required for successful implementation into local and national health systems [1 39 47 48]. It is therefore important that the views of Australian physiotherapists and physiotherapy students are understood

in order to inform key stakeholders and decision-makers about redefining the scope of physiotherapy to include NMP in Australia.

Owing to the contemporary nature of physiotherapist independent prescribing, research is required to evaluate the use of NMP both internationally and in the UK to inform the safe, quality and successful embedding of physiotherapy independent prescribing into physiotherapy scope of practice.

1.4 Aims and objectives of the thesis

1.4.1 Aim

To evaluate the effective implementation and utilisation of NMP across professions internationally, to inform the successful, safe and effective implementation of physiotherapy independent prescribing across clinical specialities, settings and jurisdictions.

1.4.2 Objectives:

I. To evaluate the clinical and cost-effectiveness of NMP internationally across NMP professions (Chapter 2).

II. To evaluate the barriers to and facilitators of iNMP internationally across NMP professions (Chapter 3).

III. To explore the views of Australian physiotherapists and physiotherapy students regarding NMP by physiotherapists in Australia (Chapter 4).

IV. To evaluate the feasibility, suitability and acceptability of the methods required for completing a future definitive trial to evaluate the clinical and cost-effectiveness of physiotherapist independent prescribing (Chapter 5).

V. To propose future research priorities relating to the implementation and evaluation of physiotherapist independent prescribing in the UK (Chapter 6).

1.5 Thesis structure

In order to investigate the thesis aim, Chapters 2-6 address each objective sequentially through a series of studies. Each chapter uses the evidence determined from prior chapters to inform the specific study's research questions and objectives.

Chapter 2 presents a systematic review of the literature aiming to establish what is known about the clinical and cost-effectiveness of NMP within and across professional groups.

Chapter 3 evaluates the barriers and facilitators to the implementation and utilisation of NMP. Contemporary, quality and rigorous mixed methods are used to systematically review the literature across professions internationally.

Chapter 4 explores the views of the physiotherapy community in Australia. Survey methods are used to evaluate thoughts and perceptions of registered physiotherapists and physiotherapy students about the potential use and implementation of physiotherapist prescribing in Australia. Similarities and differences between qualified physiotherapists and student physiotherapists are interrogated and discussed, with differences in opinion due to clinical speciality, healthcare sector and geographical location investigated.

Chapter 5 presents a feasibility trial evaluating methods for a future definitive trial. This chapter responds to the conclusions from the prior chapters that acknowledge the need for timely, appropriate and quality evaluation of physiotherapist independent prescribing.

Chapter 6 discusses the aims and objectives of the thesis and the development of new knowledge. Future research priorities relating to the implementation and successful, safe utilisation of physiotherapist independent prescribing in the UK are proposed.

Chapter 7 presents the thesis' conclusions.

1.6 Patient and public involvement

Patient and public involvement (PPI) was informed by the principles detailed in the National Standards for Public Involvement, 'INVOLVE' [57]. Representatives from the patient and public populations were part of the research team and co-investigators throughout all stages of the research presented within this thesis. The patient perspective is central to all healthcare research. Throughout all stages of the research presented, PPI representatives were co-opted to both the Study Management Groups and Study Steering Groups, to ensure that patients and the public were involved at all steps in the research process.

PPI representatives reviewed study protocols and contributed to the development of documentation such as the questionnaires, interview and focus group questions, participant information sheets, consent forms; and importantly to the processes of data analysis and interpretation and the production of lay summary of findings.

CHAPTER 2: CLINICAL AND COST-EFFECTIVENESS OF NON-MEDICAL PRESCRIBING: A SYSTEMATIC REVIEW OF RANDOMISED CONTROLLED TRIALS

Chapter overview:

This chapter presents a systematic review of randomised controlled trials evaluating the clinical and cost-effectiveness of NMP, addressing thesis objective 1. Data from randomised controlled trials from two countries were included (n=932 participants) across primary and tertiary care settings. Data are analysed, synthesised and discussed in view of the current NMP landscape and evidence base.

The majority of this chapter is taken verbatim from the following publication for which I am principal author:

Noblet T, Marriott J, Graham-Clarke E, Shirley D, Rushton A. Clinical and cost-effectiveness of non-medical prescribing: A systematic review of randomised controlled trials. PLOS ONE 2018;13(3): e0193286. doi: 10.1371/journal.pone.0193286

To ensure the reader has a clear understanding as to why methodological decisions were made, the methods section of the published protocol article has been extended for clarity and transparency. For example, this chapter additionally describes the reasoning behind the selection of the risk of bias tool used and the process of generating eligibility criteria and expands on the strengths and weaknesses of the study.

Details of authors' contributions to the published paper (as acknowledged in the article):

TN is a PhD candidate at the University of Birmingham (UK). AR is a reader in musculoskeletal rehabilitation sciences and lead supervisor. JM is a professor of clinical pharmacy and co-supervisor. Both supervisors ensured the rigour of methods and analyses. EGC is a consultant pharmacist and non-medical prescribing lead within the NHS. EGC acted as second reviewer for this systematic review. DS is a senior lecturer in physiotherapy at Sydney University (Australia) and was co-opted onto the study steering group as an international expert. TN wrote the first draft of this article and led on subsequent drafts with feedback from supervisors and experts.

2.0 BACKGROUND

NMP contributes to the effective management of both acute and chronic conditions which require prescription of appropriate medication in a timely manner, without the service users' needs being affected by health services' staffing deficiencies, financial concerns or geographical location [58]. It is utilised by a range of professions, with limited consistency regarding definition and terminology internationally [3]. In recent years, the UK government has expanded the scope of NMP that now includes nursing, pharmacy, podiatry, radiography, optometry, physiotherapy, dietetics and paramedicine [1]. Although administration of drugs and the prescribing of medicines by physiotherapists in the UK is now considered an integral part of practice, this is not reflected within the profession internationally [59]. In the UK, the evolution of physiotherapist prescribing has been driven by political healthcare reform [2], while in other areas of the world, the potential benefits to extending scope of practice are recognised predominantly from within the profession.

Change is therefore driven internally by motivated clinicians, physiotherapy service managers and professional associations. This 'bottom- up' scenario requires efficacious evidence to convince health bureaucrats that change is required and will be of benefit to both the healthcare industry and to its users.

With the ever-increasing financial challenges faced by health services, in part due to ageing populations and rising levels of chronic disease, the potential financial efficiencies gained through the use of NMP are of paramount importance [1 39]. A range of robust studies utilising survey designs have concluded that NMP practice is both safe and appropriate, exhibiting good patient satisfaction [15 49-52]. Despite this, the implementation of NMP in the UK remains at a relatively slow pace [1]. Although the reasons for this are unclear, it is argued that this is caused by a lack of persuasive high quality evidence demonstrating the clinical and economic benefits of NMP in comparison to current models of healthcare [1]. As demand for healthcare increases, it is likely that policy makers and healthcare departments will become increasingly interested in optimising the skills of all health professionals to streamline patient care [1]. Employing non-medical prescribers within healthcare services has the potential to make savings across a range of health specialities, providing more holistic patient care within an individual profession's scope of practice [1 39 53].

For NMP to become more widely accepted, healthcare managers, clinical care quality and safety agencies, as well as the general public require evidence of the overall value of NMP; through the implementation of services that are patient-centred, improving the quality and safety of patient care, while simultaneously reducing costs and improving efficiency of treatment and patient-outcomes [1 60]. A robust evaluation of NMP is imperative to ensure quality implementation and effective utilisation [61]. The advantages, although anecdotal,

are evident in results from case studies and clinical audits which demonstrate that NMP has a good safety record and benefits both patients and clinical services [1 15]. A recent Cochrane review compared resource utilisation and assessed for non-inferiority in clinical outcome measures and patient reported outcomes of NMP to medical prescribing, concluding that non-medical prescribers provide comparable care across a range of clinical specialities [62]. This systematic review included high risk of bias evidence from controlled trials (randomised controlled trials (RCTs), cluster-RCTs, controlled before-and-after studies and interrupted time series analysis). The future development of NMP across professions internationally is dependent on low risk of bias evidence regarding clinical and cost-effectiveness; without which, it is difficult to demonstrate that NMP should be utilised by health services, offering quality care and patient safety [1]. To date, no systematic review has synthesised this existing evidence.

Research Question:

Is supplementary/independent NMP clinically effective and in what way does it benefit the health economy?

Objective:

To evaluate the clinical and cost-effectiveness of NMP.

2.1 METHODS

A systematic review was conducted according to a pre-defined protocol with pre-specified eligibility criteria, in order to identify and analyse empirical research relating to the study's objective [63]. This research method was selected as it endeavours to evaluate all relevant literature associated with a specific research question, allowing for the development of a reliable estimate concerning an intervention's effectiveness. It was envisaged that the synthesised evidence may be used by 'decision makers' to inform policy and procedural choices, with any deficits in knowledge used to inform future research planning [64].

In an effort to maximise the reliability of findings and minimise bias, a clear and overt protocol was informed by the Cochrane handbook [63-66]. The Cochrane handbook aims facilitate the completion of quality systematic reviews by providing recommendations regarding appropriate methodological decision-making informed by empirical evidence [63]. The systematic review is reported in accordance with the PRISMA statement for clarity and transparency (PRISMA Checklist is found in Appendix 1) [66 67]. The PRISMA statement (Preferred Reporting Items for Systematic Reviews and Meta-analyses) was developed by an international group of methodologists and authors to provide a gold standard for the reporting of systematic reviews, following the publication of a literature base which frequently excluded key information about the included studies [67 68].

2.1.1 Protocol and Registration

The systematic review protocol was registered with PROSPERO (CRD42015017212), a register of anticipated health and social care systematic reviews held by the University of York Centre for Reviews and Dissemination. Registration ensured transparency, reducing

bias caused by potential selective outcome reporting and was essential to avoid duplication [64] [68]. No changes were made to the original protocol registered. Following completion of the study the record was closed as per register policy.

2.1.2 Eligibility Criteria

PICOS ((P) patient population or the disease being addressed, (I) interventions or exposure, (C) comparator/control group, (O) outcome or endpoint, (S) study design) was utilised to inform eligibility criteria as advised by the Cochrane Handbook [63]. PICOS is a framework that enables specific elements of clinical evidence to be identified in a systematic review [63] [69]. All included studies satisfied the eligibility criteria set out in Figure 2.

Figure 2: Chapter 2 Eligibility Criteria

Inclusion criteria:

Participants: Health service users receiving treatment from non-medical prescribers from any professional group with appropriate authority to prescribe medicines via supplementary or independent prescribing mechanisms [70].
Intervention: Non-medical prescribing provided by a professional group with appropriate authority to prescribe medicines via supplementary or independent prescribing mechanisms [70]
Comparators: Inter- or intra-profession comparisons of clinical and cost effectiveness, pre and post intervention comparisons of clinical outcomes [63] [71].
Outcome Measures: Measurements reported on one or more outcome of: pain, functional impairment, disability, health, social impact, patient safety, associated costs analysis, quality adjusted life years (QALYs), patient satisfaction, clinician perception of clinical and functional outcomes [63].
Studies: Randomised controlled trials (RCTs) or pilot RCTs that evaluated the clinical or cost-effectiveness of NMP.

Exclusion criteria: studies not written in English [67].

2.1.3 Information Sources

The literature search employed sensitive topic-based strategies designed for each of the sources identified in Figure 3. The specific databases searched were selected following discussion with subject matter experts, methodologists and advice from specialist librarians at the University of Birmingham (UK). The information resources accessed were thought to ensure that a fully holistic literature search was achieved [63 64 71]. The search period was January 1994- May 2015. The date of 1994 onwards reflects the time period since the introduction of the first iNMP globally across all prescribing professions (initially the UK with piloting of independent prescribing for community nurses from an extended nurse formulary) [58 72].

Figure 3: Information Sources

Databases searched:

CINAHL, EMBASE, MEDLINE, AMED, NHS Economic Evaluation database, NICE, Medicines Complete

Cochrane Central Register of Controlled Trials

Selected internet sites:
PUBMED, Turning Research into Practice, Current Controlled Trials website (York), Google Scholar, the Royal College of Nursing, Royal Pharmaceutical Society, King's Fund, National Institute of Clinical Excellence, Department of Health, National Prescribing Centre, Chartered Society of Physiotherapy, Society of Chiropodists and Podiatrists, American Association of Nurse Practitioners, Australian College of Nurse Practitioners, Canadian Pharmacists Association, Optometry Australia, British Optometry Association.

National Research Register

Expert Opinion

Hand searches- key journals

2.1.4 Search

Pre-defined search terms and combinations, with database specific standardised vocabulary were employed to ensure all relevant studies were retrieved [63 71 73 74]. This was essential to ensure that no studies were missed due to different words being used to describe the same concepts [63 71 73 74]. Methods were considered based on the indexing methodology utilised by the specific database being searched, therefore ensuring that variations between databases did not lead to deficits in the study harvest [63].

For transparency, Figure 4 illustrates an example full electronic search strategy for studies investigating clinical effectiveness in Medline OvidSP, enabling the reader to repeat the process [67]. Where a pilot study was identified, the definitive study was sought, or the authors contacted to determine whether further published or unpublished research had been undertaken. The reference lists of the identified literature were searched to ensure no studies were missed [71 74]. In addition, experts in the area were consulted to detect any further studies [63 71 73 74].

Figure 4: Full electronic search strategy for Medline OvidSP (Clinical effectiveness). Originally undertaken: 25th May 2015.

1. independent* prescrib*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
2. supplementary prescrib*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
3. nurs* prescrib*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
4. pharmac* prescrib*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
5. podiatr* prescrib*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
6. chiropad* prescrib*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
7. radiograph* prescrib*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
8. optometr* prescrib*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
9. physiotherap* prescrib*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
10. physio* prescrib*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
11. autonomous prescrib*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
12. non-medical prescrib*.mp.
13. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12
14. Clinical effective*.mp.
15. Treatment outcome*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
16. Error*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
17. clinical effectiveness/
18. medication error/
19. 14 or 15 or 16 or 17 or 18
20. 13 and 19

2.2.5 Study Selection

Two investigators searched information sources (TN/EGC) and independently assessed studies for inclusion by grading each eligibility criterion. The use of two investigators hoped to reduce the possibility of missing relevant literature or excluding relevant research where challenging judgements were necessary for selection or rejection of a study [68]. In the event

of a selection disagreement a third reviewer (AR, methodological expert) was available to mediate any conflict [68 73]. Both reviewers independently evaluated studies by title and abstract for potential eligibility. Following discussion between reviewers, if a study could not explicitly be excluded on the basis of its title and abstract, its full text was reviewed [64 66]. All potentially relevant studies proceeded forward to the review of full text. The two independent reviewers made independent judgements as to whether or not an individual study was included in the review based on the study's full text fulfilling the eligibility criteria. The numbers of studies included and excluded at the different stages were recorded [63 68 71].

2.2.6 Data Collection Process

Data extraction was performed by the primary reviewer (TN) and checked and agreed by the secondary reviewer (EGC). Data extraction utilised pre-determined data extraction sheets specific to the review objective which had been piloted, refined and agreed by the researchers prior to use, ensuring that all relevant data were extracted [68 71]. Any differences were resolved at a consensus meeting of all authors [73], and the third reviewer (AR) checked for consistency and clarity.

2.2.7 Data Items

Study design, profession of prescribers, type of NMP, participants (patient groups) and indications, interventions, study settings, timing of assessments, and outcome measures were extracted [63] to allow for assessment of homogeneity [63 71].

The research objective dictated the key outcome measures. These were predefined as validated tools measuring:

1. Clinical effectiveness: pain, functional impairment, disability, health, appropriateness of treatment, social impact [75].
2. Cost effectiveness: "the cost of achieving a benefit by different means" [75].

2.2.8 Risk of Bias

The evaluation of a study's internal validity is a key component of a systematic review [63 68]. Specific eligibility criteria are utilised by systematic reviews aiming to minimise bias whilst collating and synthesising evidence from all the relevant literature. In order to obtain reliable conclusions via a systematic review the potential limitations of the included studies must be examined [63 64 68 71]. Many RCT quality assessment tools are available, but with variation in the definition of "quality", such tools often aim to investigate researchers' conduct rather than methodological flaws, appropriateness of analysis and transparency of reporting [63]. It is often impossible to know which biases and to what extent biases have affected the outcomes of research, leading to potential over or underestimation of effect size [63].

The Cochrane Risk of Bias Tool was developed by the Cochrane Collaboration through empirical research to promote consistency in quality assessments across systematic reviews, specifically assessing the methodological risk of bias within RCTs [76 77]. The tool was selected for use as it has been shown to exhibit acceptable inter-rater reliability (ICC=0.58 (95% CI 0.20–0.81)) [76]. Each reviewer independently assessed the risk of bias

within each included study [63 77]. Results were tabulated to demonstrate the risk of bias across included trials [77].

2.2.9 Summary Measures and Synthesis of Results

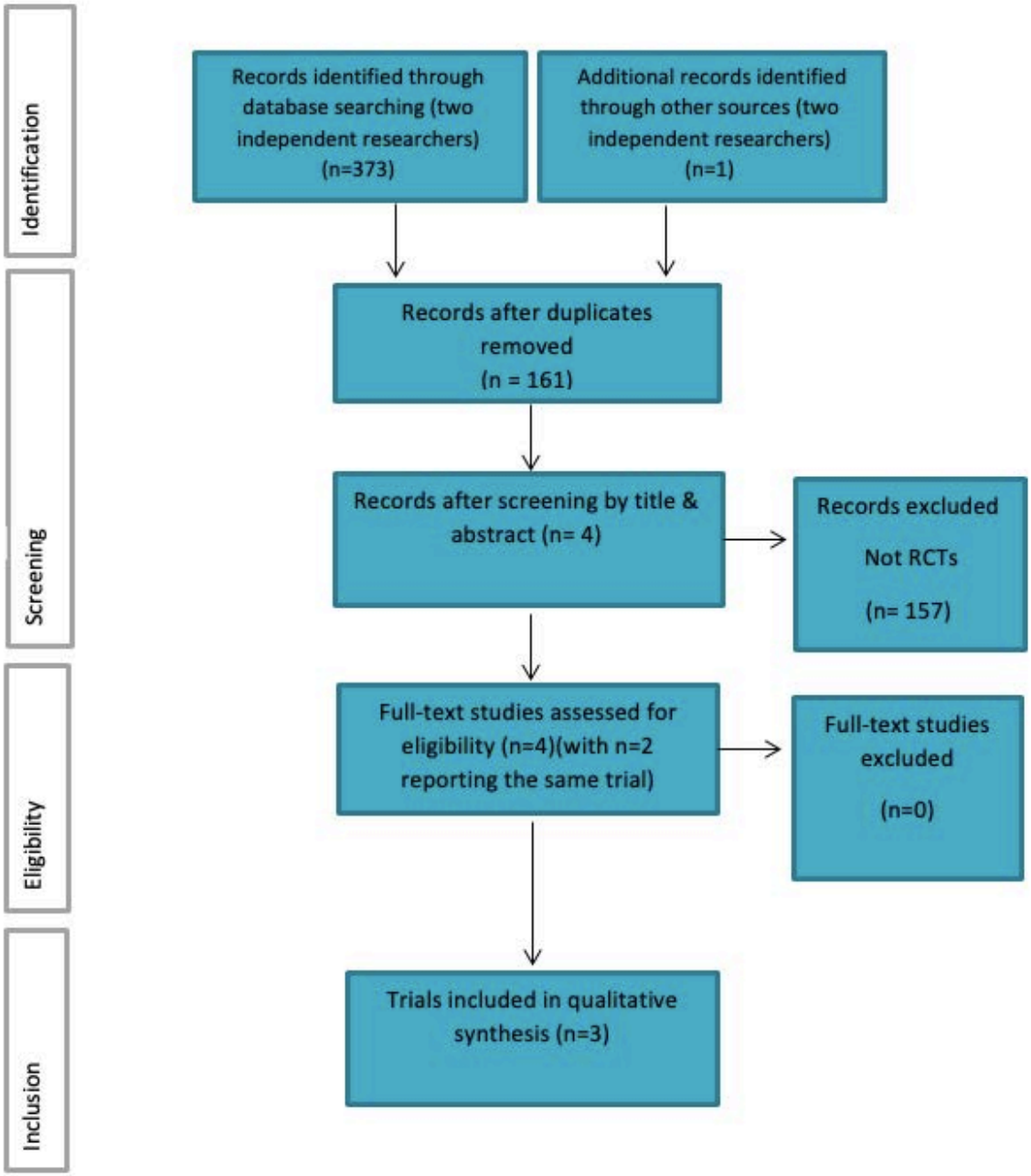
An explanation of each included trial's characteristics and outcome data were tabulated. The potential grouping of data across trials was completed by using the tabulate data. Data homogeneity was assessed to determine whether meta-analysis was possible [78-80]. Narrative synthesis was used to synthesise the data [64 73 81]. Narrative synthesis uses words and text to describe the findings of the synthesis and is recommended by the Cochrane Collaboration and the Centre for Reviews and Dissemination where statistical meta-analysis is not possible [64 73 81]. Within and between studies analyses were undertaken in the context of risk of bias [64 67].

2.2 RESULTS

2.2.1 Study Selection

The search strategy identified 373 potentially relevant studies. Following screening for duplicates, 61 citations remained. No relevant unpublished studies were found, and no further studies were identified from the Internet searches, reviews of the national research register or via experts in the field. All studies retrieved were written in English, therefore no studies were excluded due to language. Reviewing by title and abstract excluded 158 studies that were not RCTs. The full texts of the remaining 3 trials [82-84] were examined in detail and evaluated as meeting the eligibility criteria. A further article [85] retrieved when examining the reference lists of retrieved studies was included as it presented additional data to an included RCT. Data from the 2 articles were considered as 1 pilot trial (The PIPPC pilot trial) [82 85]. Therefore, 3 trials (2 definitive trials and 1 pilot trial) were included. All included trials investigated clinical effectiveness (n=3) [83-85]; 1 trial investigated cost effectiveness [82]. Figure 5 presents the number of studies at each stage of the selection process. One hundred percent inter-reviewer agreement was achieved following open discussion at each stage. Third reviewer mediation was not required.

Figure 5: Study selection, PRISMA flow diagram (adapted from Moher et al, 2009)



2.2.2 Study Characteristics

Study characteristics and descriptive data for the 3 included trials are summarised in Table 1. All 3 trials involved pharmacy as the NMP profession evaluated in the experimental arms of trials. The setting for 1 trial was the UK [82 85], and for 2 was Australia [83 84]. All included trials compared pharmacist prescribing within a service or specific patient population to usual care.

A total of n=932 participants with an age range of 18-89 years, were randomised across the 3 trials. Details regarding the participants' specific diagnoses were not disclosed. Participants were either: admitted to a tertiary hospital for surgery, involving an overnight stay [83 84], or received regular prescriptions for medication for chronic pain within a primary care setting [82 85].

Two trials were completed at single site surgical departments of tertiary hospitals in Australia (Brisbane, Queensland and Newcastle, New South Wales)[83 84], with a third trial undertaken in primary care across 6 general practices in the UK (England and Scotland). The type and scope of NMP utilised by the pharmacists varied. One trial guided by protocols, used supplementary prescribing to prescribe the patients' regular medication [84]. One trial used independent prescribing only, where the scope of prescribing was to either continue or withhold regular medications and to prescribe VTE prophylaxis in accordance with local and Australian guidelines [83], and a single trial, owing to regulations in place at the time of study, utilised supplementary prescribing to prescribe controlled drugs and independent prescribing for all other required medications [82 85].

The prescribing pharmacists in 2 trials were registered independent pharmacist prescribers having completed an Independent Pharmacist Prescribing Course accredited by the

General Pharmaceutical Council, UK [82 83 85]. An amendment to the Queensland Health (Drugs and Poisons) Regulation 1996 enabled the qualified pharmacists to prescribe in Queensland, Australia [83]. There was no disclosure of the mechanisms (qualification/credentialing/accreditation) that were required for the pharmacists to undertake legal supplementary prescribing in the trial completed in New South Wales, Australia [84].

2.2.3 Outcomes: Clinical effectiveness

Primary outcome measures assessing clinical effectiveness varied. Bruhn et al (2013) used the SF12v2 and the Health Utilities Index (HUI). However, because licencing costs were required to score the data, the HUI was not subsequently analysed. Hale et al (2013) and Marotti et al (2011) did not specify a validated patient reported outcome measure, however they analysed the safety of NMP practice, assessing the frequency of omission and prescribing errors when compared against a patient's medical history, and the number of medication doses inappropriately missed during an inpatient stay respectively.

No comparable secondary outcome measures were used across the 3 trials. Bruhn et al (2013) assessed pain using the 'Chronic Pain Grade' measure and anxiety and depression with the 'HADS' (Hospital Anxiety and Depression Scale). The other trials focused on the uses of the medicines prescribed, with 1 trial examining the appropriateness of VTE prophylaxis prescribing [83] and the other examining the number of medications chartered at an incorrect dose or frequency, and the number of missed doses of specific medications post operatively [84].

Table 1. Study Characteristics of included trials

Trial	Design	Participants & Indication	Intervention & Setting	Outcome Measures	Between Group Results	Additional Information
The PIPPC Trial (Neilson et al, 2015, Bruhn, 2013)[82 85]	Pilot RCT: Three Groups: Pharmacist medication review plus face-to-face prescribing. Pharmacist medication review with GP prescribing. Treatment as usual Recruitment March-June 2010	Patients >18 years, living independently, receiving regular prescribed medication for pain. Patients must have received ≥2 acute prescriptions within the preceding 120 days for an analgesic and/or NSAID. GPs excluded patients with severe mental illness, recent bereavement, alcohol/drug addiction and cancer pain Baseline: n=68 mean (SD) age 66.1 (12.1), 54.4% female n=62, age 65.7 (14.2), 46% female n=63, age 64.9 (11.6), 37% female	A: Face-to-face pharmacist prescribing, with pre-consultation paper-based medication review; patients completed a pain diary. All non-controlled drugs issued via IP. Controlled drugs issued by SP (regulations at the time). B: Pharmacists undertook paper-based medication reviews focussed on pain related prescription medications, implementation by GPs. C: Treatment as usual GP care X6 pharmacist prescribers utilised *Setting:* GP practices, primary care pharmacies. UK (Scotland & England)	*Primary Clinical outcome:* SF12v2 Health Utilities Index (data not analysed due to licencing laws) *Secondary Clinical:* CPG HADS *Primary Economic:* Costs associated with: Intervention (source- PSSRU 2009/2010) pain related hospitalisation (source- IDS Scotland March 2010) primary care visits for chronic pain (source- PSSRU 2009/2010) primary care telephone contacts for chronic pain (source- PSSRU 2009/2010) OTC pain related medication: Source- BNF 61, March 2011 *Secondary- Effect of pharmacist-led intervention:* QALYs- based on SF-6D	*Clinical outcomes:* SF12v2: no statistically significant difference between groups. CPG: Statistically significant improvement for group A compared to groups B&C for intensity (p=0.02) but not disability (p=0.55). HADS: Statistically significant improvement in HADS scores for group A compared to group B&C (A: p=0.022; D: p=0.045) *Cost effectiveness outcomes:* *Resource use and costs:* Positive incremental mean cost differences reported for groups A&B compared to C, indicating group A&B interventions are more expensive than group C. *QALYs:* After adjusting for baseline SF-6D scores, baseline costs/controlling for baseline patient characteristics, QALYs for groups A&B were largely unchanged relative to group C.	NMP Qualification: Independent Pharmacist Prescribing Course accredited by the General Pharmaceutical Council, UK. NMP- Pharmacists Independent Prescribing, supplementary prescribing. Exploratory trial to estimate the sample size for full trial- no formal power calculation. Optimal trial size estimated at 780 per group for full study. Funding: Medical Research Council (grant ID: 85356).

Trial	Design	Participants & Indication	Intervention & Setting	Outcome Measures	Between Group Results	Additional Information
Hale et al, 2013[83]	RCT: Two Groups: Pharmacist generated medication chart/plan for peri-operative medication/ prescribed VTE prophylaxis. TAU. Post consent, patients randomised using computer-generated randomisation in blocks of 10. Independently prepared sealed envelopes containing 1 or 0 then determine allocation. Conducted between June-Sept 2009.	All patients > 18 years, who attended the PAC. Patients were excluded if unable to communicate due to language barrier or undergoing day surgery. Baseline: n=190, mean (mean range) age 57.6 (18-89), 58% male n=194, mean (mean range) age 55.8 (18-86), 59% male	*Intervention:* Group A: Patients seen by a nurse, prescribing pharmacist, RMO and anaesthetist. (Pharmacist prior to RMO). Pharmacist undertook duties as per usual care, plus prescribing. The scope of prescribing: continuing/ withholding regular medications & prescribing VTE prophylaxis according to local & national guidelines. Group B: all 4 professionals consulted in no particular order. Prescribing was the responsibility of the RMO. X1 Pharmacy Prescriber utilised. *Setting:* X1 Tertiary Hospital Elective Surgery Preadmissions clinic (PAC) at Princess Alexandria Hospital, Brisbane, Australia.	*Primary clinical outcome:* Frequency of omission & prescribing errors when compared against patient's medical history. The clinical significance was also analysed. *Secondary clinical outcome:* Appropriateness of VTE prophylaxis prescribing.	*Clinical outcomes:* Significantly less unintended omissions of medications by group A compared to group B. Significantly fewer prescribing errors involving selection of drug, dose or frequency by group A compared to group B. VTE prophylaxis on admission to the ward approx. 93% group A & 90% group B, revealing no significant difference. No difference in appropriateness of VTE prophylaxis on admission between the two groups.	NMP Qualification: Independent Pharmacist Prescribing Course accredited by the General Pharmaceutical Council, UK. NMP- Pharmacists Independent Prescribing. An amendment was facilitated to the Queensland Health (Drugs and Poisons) Regulation 1996 to enable the qualified pharmacists to prescribe in Queensland, Australia. Power calculations based on pilot data used to calculate sample size. Funding: explicitly states no funding received.

Trial	Design	Participants & Indication	Intervention & Setting	Outcome Measures	Between Group Results	Additional Information
Marotti et al, 2011[84]	RTC: Three Groups: Pharmacist medication history plus supplementary prescribing. Pharmacist medication history taking, prescribing through usual process. TAU. Blinded computer-generated randomisation. Conducted between Nov 2008- March 2009	All adults (no definition) elective surgery patients excluding orthopaedics. Patients excluded if: no regular medications, unable to provide consent, medications charted at a pre-op clinic appointment, day case. Baseline: n=118, median (IQR) age 64 (47-75), 51% male n=119, median (IQR) age 62 (52-71), 55% male n=118, median (IQR) age 65 (54-75), 49% male	*Intervention:* Groups A&B- pharmacists interviewed patients at the time of admission on day of surgery & documented regular medication list. Group A- the pharmacist prescribed the regular medications on the medication chart via supplementary prescribing. Group C- patients had no interaction with the pharmacist prior to surgery. Medications were charted immediately post-surgery by the medical officer in the normal time frame. *Setting:* X1 Tertiary Hospital. All surgical units, John Hunter Hospital, Newcastle, NSW, Australia.	*Primary clinical outcome:* The number of medication doses missed inappropriately during the inpatient stay. *Secondary clinical outcome:* Number of medications charted at incorrect dose or frequency. Number of missed medication doses post operatively of significant medications e.g. beta blockers, 3-hydroxy-3-methyl-glutaryl-CoA reductase inhibitors, antiplatelets, anticoagulants.	*Clinical Outcomes:* Significantly reduce number of missed doses per patient during hospital stay for group A ($p=0.02$) but not group B compared to group C. Significantly less medications charted at an incorrect dose for Groups A ($p<0.001$) &B ($p=0.004$) compared to group C, with group A having less errors than group B. Significantly less numbers of medications charted at an incorrect frequency by groups A&B compared to group C ($p<0.001$).	Non-medical prescribing qualification/ credential/ accreditation not disclosed. NMP- Pharmacists supplementary prescribing. No power calculations used to calculate sample size. Funding: Not reported

IP- Independent Prescribing, SP- Supplementary Prescribing, CPG- Chronic pain grade (CPG), HADS- Hospital Anxiety & Depression Score, PSSRU- Personal Social Services Research Unit, QALYs- Quality-adjusted life years, TAU- Treatment as usual, Venous thromboembolism- VTE, PAC- Pre-admission clinic, ROM- Resident Medical Office

2.2.4 Outcomes: Cost effectiveness

The PIPPC trial evaluated the costs associated with: intervention, pain related hospitalisation, primary care visits for chronic pain, primary care chronic pain related telephone contacts, and prescribed and non-prescribed OTC pain related medicines [82]. Quality-adjusted life years (QALYs) were calculated [82]. The QALYs in the PIPPC trial were generated from the associated costs and analysis of clinical outcomes from the SF-6D (patient reported outcome measure). As this trial was a pilot, the expected value of sample information was calculated to assess whether a definitive trial would be worthwhile.

2.2.5 Risk of Bias and quality assessment

One hundred percent inter-reviewer agreement was achieved regarding risk of bias assessment, with no mediation required from the third reviewer. Table 3 provides a summary of the overall risk of bias assessed using the Cochrane Risk of Bias Tool for each included trial. Of the 3 included trials, 1 was high risk of bias [83], 1 unclear [84], and 1 low risk of bias [82 85]. Marotti et al (2011) was assessed as unclear risk of bias, as the reviewers were unable to view the registered trial protocol, therefore bias owing to selective outcome reporting remained unclear. Hale et al (2013) was assessed as high risk of bias with the domain 'blinding of participants' rated at high risk owing to the control group being aware of the intervention being measured. All other domains were rated low risk. It was agreed that the weight of this domain to overall risk of bias within the RCT was substantial, as the resident medical officers involved in the trials were aware of the pharmacist prescribing as part of a formal study. Losses to follow up were reported in all included trials [83 84]. Across all trials, losses were less than 20% and therefore considered acceptable [86]. Although 1 trial

was rated as high risk of bias, the majority of the included studies were rated as low or unclear risk of bias [77]. Therefore, the overall risk of bias across trials was evaluated as unclear [77]

GRADE Assessment

Table 2. GRADE Assessment Summary

Clinical effectiveness: NMP V TAU		Sample population size **(n)= 932**
Trials Contrubuting: Bruhn et al, 2013 [85]; Hale et al, 2013 [83]; Marotti et al, 2011 [84]		
Type of evidence	+4	RCTs
Quality	–1	Problem with 1 element, blinding not utilised in any trial
Consistency	0	Most studies show similar results
Directness	–1	Problem with 1 element, difficulty generalising across all specialities, professions, locations, health-sectors, internationally
Effect size	+1	<0.5 for all studies
Total	3	Moderate Quality

Cost-effectiveness: NMP V TAU		Sample population size **(n)= 193**
Trials Contrubuting: Neilson et al, 2015 [82]		
Type of evidence	+4	RCTs
Quality	–1	Problem with 1 element, Other methodological concerns: incomplete inclusion and used of SF12 data
Consistency	0	Only x1 trial included
Directness	–1	Problem with 1 element, difficulty generalising across all specialities, professions, locations, health-sectors, internationally
Effect size	+1	<0.5 for all studies
Total	3	Moderate Quality

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GRADE (the Grading of Recommendations, Assessment, Development and Evaluation system) assessment (Table 2) demonstrated moderate quality evidence for both the clinical and cost effectiveness of NMP.

Table 3. Summary assessment of the overall risk of bias for each study

Study	Domain of risk of bias							Summary within study	Comments on high-risk components
	1	2	3	4	5a	5b	6		
PIPPC Trial [82 85]	L	L	L	L	L	L	L	**Low** (7)	
Hale et al, 2013[83]	L	L	H	L	L	L	L	Low (6) **High** (1)	One high risk domain: 3 "RMO's in clinic during the study were aware of the intervention pharmacist's role, which may have led to an increased number and quality of medication charts prescribed in the control arm." [83]
Marotti et al, 2011[84]	L	L	L	L	U	U	L	Low (5) **Unclear** (2)	
Overall risk of bias across studies								**Unclear risk of bias**	

Key:

Domain of risk of bias: 1, sequence generation; 2, allocation concealment; 3, blinding of participants; 4, incomplete outcome data; 5a, short-term selective outcome reporting; 5b, long-term selective outcome reporting 6, other sources of bias.

Levels of risk of bias: L, low risk of bias; U, unclear risk of bias; H, high risk of bias

Summary within study: Low, low risk of bias for all key risk criteria; Unclear, unclear risk of bias for all key risk criteria; High, high risk of bias for all key risk criteria.

RMO- Resident Medical Officer

2.2.6 Summary Measures and Synthesis of Results

2.2.6.1 Clinical Effectiveness Outcomes

In all included trials p values were used to report statistical significance. Effect sizes and 95% confidence intervals (CIs) were not reported in the included trials.

SF-12v2: for functional health and wellbeing from the patient's perspective, the PIPPC trial[82 85] at low risk of bias found no significant difference (p=0.75) between groups.

Chronic Pain Grade (CPG): for overall chronic pain severity (pain intensity and pain-related disability), the trial by Bruhn et al (2013) at low risk of bias found significant improvement on the pain intensity subscale (p=0.02) for the pharmacist experimental prescribing groups when compared to treatment as usual. This improvement was not found for the disability subscale (p=0.55).

Hospital Anxiety and Depression Scale (HADS): for depression, anxiety and emotional distress, the trial by Bruhn et al (2013) at low risk of bias found that both the experimental groups involving prescribing pharmacists were seen to improve significantly more compared to the treatment as usual group (Group A: Group C p=0.022, Group B: Group C p=0.045).

The frequency of omission and prescribing errors: when compared against a patient's medical history, the trial by Hale et al (2013) which was at high risk of bias found significantly less unintended omissions of medications when prescribed by the pharmacist (p<0.001). There were significantly fewer prescribing errors concerning selection of drug, dose or frequency in the NMP group (p<0.001), and significantly less medication orders

from the NMP group with at least 1 constituent of the prescription missing, incorrect or imprecise compared to that of the control group (p<0.001).

Prescription of VTE prophylaxis: the trial by Hale et al (2013) at high risk of bias found no significant difference between the NMP group and the control group (p=0.29) for the appropriateness of prescription of VTE prophylaxis.

The number of medication doses missed inappropriately during an inpatient stay: the trial by Marotti et al (2011) that had an unclear risk of bias, found a significant difference (p=0.002) between the pharmacist supplementary prescribing group compared to the pharmacist drug history taking group and the control group for the number of medication doses inappropriately missed during an inpatient stay. The number of drugs charted at the wrong dose and/ or frequency was significantly reduced in the pharmacy history taking group and the pharmacist-prescribing group (p<0.001), compared to that of the control group. The pharmacist-prescribing group were also seen to have fewer dose errors compared to the pharmacy drug history taking group (p=0.004).

2.2.6.2 Cost Effectiveness Outcomes

Associated Costs: the PIPPC trial [82] which had a low risk of bias, found that both pharmacist prescriber-led intervention groups were less costly than TAU based on raw unadjusted mean total costs. Adjustment for variances in baseline costs and controlling for baseline participant characteristics resulted in a positive incremental mean cost difference for both the experimental groups compared to the TAU group. Following adjustments, both pharmacist prescribing and review groups were significantly (regression coefficient p=0.00) more expensive than usual care secondary to baseline costs.

Quality-Adjusted Life Years (QALYs): the PIPPC trial [82] at low risk of bias found for unadjusted data, that both experimental groups generated increased QALYs compared to TAU. Following adjustment for baseline costs, pharmacist-led groups were largely unchanged relative to the TAU ('pharmacist prescribing' group, 0.0069 QALYs, <-0.0091 to 0.0229>, 'pharmacist medication review' group, 0.0097QALYs, <-0.0054 to 0.0248>), although the adjusted difference in cost was reduced in the prescribing group (£21, from -£124 to £167) and increased in the review group (£75, from -£72 to £221) relative to the TAU group.

2.2.6.3 Meta-analysis

Meta-analysis was not justified owing to insufficient homogeneity of the outcome measures used across the trials. Although the interventions used across the trials were similar, the low number of trials included compounded the heterogeneity of the outcome measures.

2.2.7 Additional Analyses

No additional analyse were completed.

2.3 DISCUSSION

2.3.1 Summary of Evidence

Owing to the low number of included trials and overall unclear risk of bias, recommendations about NMP in the context of its potential clinical and cost-effectiveness are limited. Adequate patient safety and clinical outcomes are key elements in clinical effectiveness required for the valid and ethical use of any clinical intervention. Evidence with an overall unclear risk of bias across the trials investigating the safe practice of NMP on tertiary care surgical wards, indicates that NMP may lead to a significant reduction in omissions and prescribing errors, with the medications prescribed by medical and non-medical prescribers being equally appropriate [83 84]. Further, the PIPPC pilot trial low risk of bias evidence [85], suggests that NMP is practical, acceptable and leads to improvement in pain outcomes in primary care. However, it is unclear from the PIPPC trial data whether the participants' improved pain outcomes were due to the changes in medication prescribed by the pharmacists and/or participants' education regarding optimal timing for administration of the medications. The limited number and heterogeneity of the included trials did not allow for meta-analysis. This evidence, when combined with the findings from the previous Cochrane review [87], might indicate that non-medical prescribers can independently optimise medication management for chronic pain as effectively as medical prescribers, and therefore have the potential to effectively support over-stretched medical practitioners working in pain management in primary care.

Embedding a new clinical tool or process into practice often requires explicit economic benefit before it is adopted by a health community [1 60]. For this reason, it was surprising that only one pilot RCT evaluating the cost-effectiveness of NMP exists [82], even though

NMP is now widely practised internationally by a range of health professions. It is important that the results of this trial are interpreted in the context of it being a pilot trial, which had the aim to estimate optimal sample size for a definitive trial, not to determine effectiveness. The trial's results [82], evaluated as having low risk of bias, suggest at first glance that pharmacist prescribing may be more costly than traditional treatment once baseline costs are accounted for (e.g. education costs required for pharmacist prescribers to become qualified, endorsed and registered as non-medical prescribers). However, these baseline costs relate directly to the development of new services that use NMP, where non-medical prescribers do not currently exist and full support for new non-medical prescribers is required. This may be short sighted, reflecting only initial set-up costs, rather than future long-term patient care. As the development, implementation and utilisation of NMP varies across professions internationally, future economic assessment should ensure that both initial and ongoing costs are analysed, establishing economic benchmarks for future comparisons. The SF-6D outcome measure was used to calculate a QALY effect [82], with results indicating that the use of non-medical prescribers generated increased QALYs. However, incomplete data (one third of questionnaires incomplete), possibly owing to participant understanding and the complexity of the measure [82] may have had significant influence on the outcomes and should be considered further prior to the design of an adequately powered definitive trial.

Comparison of the results from this systematic review with the wider literature is difficult, as no RCTs in addition to those included in the present review have been undertaken, and there are no previous systematic reviews. Previous economic evaluations have used predictive economic-modelling based on pathology-specific clinical pathways to predict potential cost-effectiveness, rather than investigating the efficacy of NMP across clinical

services using clinical trials with low risk of bias [1 15 25 53]. These economic models all support the use of NMP within the limitation of their specific methods, supplementing the findings of this review with warnings of potentially high implementation costs.

The majority of the literature has concentrated on reporting the experiences of stakeholders and has not used validated outcome measures to investigate cause and effect relationships related to the uses of NMP [82]. A large evaluation of nurse and pharmacist prescribing assessed 100 consultations involving prescribing activity across 10 sites using the Medication Appropriateness Index (MAI) [15]. The evaluation concluded that a high level of clinically appropriate prescribing decisions are being made, however did not assess for efficacy. A similar evaluation of physiotherapist and podiatrist prescribing [25] in the UK, synthesised data from prescription audit, audit of the patient records and surveys of clinicians and patients to assess the quality, safety and clinical appropriateness of NMP. Results from this evaluation were deemed inconclusive due to the audit methods employed, with the small sample size limiting the external validity of the findings [25].

The potential benefits of NMP in terms of clinical and cost-effectiveness are illustrated by the included trials, however the deficit of low risk of bias RCTs across professions, specialities and settings, highlights the need for adequately powered low risk of bias RCTs to inform both clinical and cost-effectiveness across important outcome measures. In order to enhance the quality and comparability of future RCTs, the development of a minimum dataset of important outcome measures for the assessment of NMP would be beneficial, providing healthcare managers, clinical care quality and safety agencies as well as the general public with the required evidence needed to evaluate the overall value of NMP.

The original database searches were completed in May 2015. Searches were re-run prior to publication with no additional trials meeting inclusion criteria [88]. In December 2019 searches and study selection procedures were repeated. Again, no further trials met inclusion criteria, indicating that the systematic review remains contemporary.

2.3.2 Strengths and Limitations

This is the first systematic review to synthesise the existing evidence using rigorous methods to provide clarity of the level and quality of existing evidence. Evaluation of the evidence using GRADE (the Grading of Recommendations, Assessment, Development and Evaluation system) assessment revealed moderate quality evidence for both the clinical and cost effectiveness of NMP **Error! Reference source not found.**[89]. However, the limited number of trials available for inclusion and overall unclear risk of bias of the included trials limits the external validity of the review across all NMP professions, specialities and locations. Each trial used different outcome measures limiting scope for meta-analysis, due to limited homogeneity. Only NMP by pharmacists was investigated limiting generalisability across all professions. Limitations in the diversity of the included nations, specialities, methods of NMP (independent versus supplementary) and the nature of the use of NMP were evident between the included studies, resulting in high heterogeneity, limiting their comparability and ability to make generalisations.

The minimum qualification required to be endorsed as a non-medical prescriber differs internationally, with competency requirements potentially variable within countries that have state, territory or provincial jurisdictions. Two of the 3 included trials declared that the prescribers had attended an independent prescribing course accredited by the General

Pharmaceutical Council, UK, meeting UK standards [82 83 85]. The third trial did not disclose the minimum standards required to prescribe within the limits of the research context in NSW, Australia [84]. The knowledge and experience of the clinicians undertaking the treatments analysed could therefore have been inconsistent, introducing bias and limiting external validity.

Limitations of the methods utilised in the systematic review are acknowledged. The lead researcher (TN) was utilised as a reviewer; therefore, reviewer bias may be argued leading to the inclusion of studies likely to prove anticipated outcomes [90]. Attempts were made to minimise this risk by engaging parallel reviewers, who independently reviewed for both inclusion and for risk of bias. If disagreement occurred between the parallel reviewers, an independent third reviewer was available for consultation [73].

2.4 CONCLUSION

This systematic review has identified limited evidence with moderate quality and unclear risk of bias evaluating the clinical effectiveness of NMP across all professions and clinical settings. Three trials have shown significant results indicating that NMP is safe and can provide effective clinical outcomes for patients. The benefit to the health economy remains unclear, with the cost-effectiveness of NMP assessed by a single pilot RCT that, although at low risk of bias, by its nature was not powered to evaluate cost-effectiveness. Adequately powered low risk of bias RCTs, evaluating safety, quality, appropriateness of care and economic benefit across a range of clinical professions, specialities and settings are urgently required. Evidence from future RCTs can then be used to inform politicians, policy makers, clinicians and healthcare managers when considering the utilisation of NMP

in the planning and provision of future quality and effective healthcare services[1 39]. The development of a minimum dataset of outcome measures is required to ensure homogeneity/ comparability of data when analysing and assessing NMP within and across individual clinical fields, professions, and across international healthcare boundaries.

2.5 FUNDING

This systematic review was supported by an Academically Accredited Course funding grant awarded by the Chartered Society of Physiotherapy, UK. The Chartered Society of Physiotherapy accepts no responsibility for content and has played no role in study design, methodology, data collection, data analysis/interpretation or report writing.

2.6 DISSEMINATION OF RESULTS

The results of the research have been published in the international peer review journal PLOS One (Appendix 2) [88].

Noblet T, Marriott J, Graham-Clarke E, Rushton A. Clinical and cost-effectiveness of non-medical prescribing: A systematic review of randomised controlled trials. PLOS ONE 2018;13(3): e0193286. doi: 10.1371/journal.pone.0193286

Expert reviewers' comments and the authors' response to reviewers are found in Appendix 3. Findings have also presented at peer reviewed national and international conferences:

Noblet T, Marriott J, Graham-Clarke E, Rushton A. Clinical and cost-effectiveness of non-medical prescribing: A systematic review of randomised controlled trials. Poster, Physiotherapy UK 2018, Oct 2018; Birmingham, UK- Award/Prize for best poster

Noblet T, Marriott J, Graham-Clarke E, et al. Clinical and cost-effectiveness of non-medical prescribing: A systematic review of randomised controlled trials. World Confederation of Physical Therapy Congress 2019, May 2019; Geneva, Switzerland

2.7 CHAPTER SUMMARY

This chapter presented a rigorous systematic review evaluating the clinical and cost-effectiveness of NMP. It was envisaged that findings may aid the effective implementation and utilisation of physiotherapist independent prescribing. Despite growing interest in NMP, the systematic review demonstrated that owing to a deficit in RCTs with low risk of bias, the clinical and cost-effectiveness of NMP remains unclear. The review highlights that adequately powered low risk of bias RCTs, evaluating safety, quality, appropriateness of care and economic benefit across a range of clinical professions, specialities and settings are urgently required.

Implementation of new innovation in healthcare is dependent upon clear clinical and economic benefits. It is clear that the current clinical and cost-effectiveness literature is limited in its ability to provide this evidence. As best practice for the implementation and utilisation of NMP is not evident from the literature evaluating effectiveness, the barriers to and facilitators of the implementation and utilisation of NMP require evaluation to enable the development of an implementation framework to promote quality and safety.

The following chapter seeks to establish an evidence base regarding the barriers to and facilitators of iNMP. It is hoped that the findings may be used to facilitate the safe and successful implementation and utilisation of physiotherapist independent prescribing to the benefit of health service consumers, and that data can be used to inform a future low risk of bias RCT.

CHAPTER 3: BARRIERS AND FACILITATORS OF THE USE OF INDEPENDENT NON-MEDICAL PRESCRIBING IN CLINICAL PRACTICE: A MIXED METHODS SYSTEMATIC REVIEW

Chapter overview:

This chapter reports the findings from a mixed methods systematic review designed to evaluate the barriers and facilitators of the use of iNMP in clinical practice, addressing thesis objective 2. Data from n=12,117 participants across 43 qualitative and 7 quantitative studies were analysed, synthesised and is presented. An iNMP implementation framework is developed and its potential uses discussed.

The majority of this chapter is taken verbatim from the following publication in which I am principal author:

Noblet T, Marriott J, Graham-Clarke E, Rushton A. Barriers to and facilitators of independent non-medical prescribing in clinical practice: a mixed methods systematic review. Journal of Physiotherapy 2017;63(4):221-34. doi: https://doi.org/10.1016/j.jphys.2017.09.001

To ensure the reader has a clear understanding as to why methodological decisions were made, the methods section of the published protocol article has been extended for additional clarity and transparency. Due to limitations in word count for publication, the published discussion of findings was reduced. This chapter provides a fully detailed discussion of the study's findings and further discusses the strengths and weaknesses of the study.

Details of authors' contributions to the published paper (as acknowledged in the article):

TN is a PhD candidate at the University of Birmingham (UK). AR is a reader in musculoskeletal rehabilitation sciences and lead supervisor. JM is a professor of clinical pharmacy and co-supervisor. Both supervisors ensured the rigour of methods and analyses. EGC is a consultant pharmacist and non-medical prescribing lead within the NHS. EGC acted as second reviewer for this systematic review. TN wrote the first draft of this article and led on subsequent drafts with feedback from supervisors and experts.

3.0 BACKGROUND

Independent physiotherapist prescribing was introduced in the UK in 2012, with the first physiotherapists qualifying as independent prescribers in 2014 [91]. Physiotherapists in Australia have now expressed an interest in NMP and commenced national processes to evaluate potential clinical need, quality and safety issues [39]. The implementation and legal utilisation of NMP will require healthcare policy modification and legislative reform. Organisational objectives, professional issues and societal influence must be reflected in national and local policy if change is to occur [47]. However, robust research is required to guide the implementation of evidence based NMP practice and the necessary changes in policy.

Pharmacist prescribing has demonstrated clinical effectiveness for the management of chronic pain in primary care and tertiary surgical units, with statistically significant improvements in pain intensity ($p=0.02$), anxiety and depression ($p=0.022$) [85], and reduced prescribing errors ($p<0.001$)[84] compared to traditional practices [83-85]. The clinical

effectiveness of prescribing in physiotherapy-specific settings has not yet been examined because the implementation of physiotherapist independent prescribing is recent. The systematic review detailed in Chapter 2 concludes that the benefit of NMP to the health economy remains unclear, with the cost-effectiveness of NMP assessed by a single pilot RCT to date [88]. With no quality evidence available to advocate for the clinical or economic benefit of utilising physiotherapist independent prescribing in health services, the physiotherapy profession must ensure it learns from the experiences of other professions and their application of strategies to implement and utilise NMP in a quality manner [92]. Successful implementation of new clinical innovations (such as iNMP) is dependent on exploiting facilitators and planning for potential barriers where economic data does not yet exist [47 48]. The analysis and synthesis of the evidence from the other NMP professions is paramount to understand the factors acting to enable or block iNMP [92 93]. Establishing an evidence base regarding the barriers to and facilitators of iNMP is required for successful acceptance and quality implementation and utilisation of physiotherapist independent prescribing.

The intent of this 3-phase sequential mixed methods systematic review was to examine NMP internationally, identifying factors that affect the implementation and/or utilisation of iNMP to inform future strategy for physiotherapy. Phase 1 explores the available qualitative literature, synthesising themes from the experiences of associated stakeholders relating to the factors that facilitate the implementation of iNMP, or factors that create barriers to its utilisation. As these variables are not yet known, qualitative data were collected across all health professions, disciplines and specialities [94]. Themes developed in the qualitative phase were then used to extract data examining the barriers and facilitators from quantitative studies in phase 2. The rationale for the quantitative phase was to add

value to the qualitative synthesis; examining the extent to which the identified themes were seen to influence the uptake of iNMP into clinical practice [94]. Phase 3 then combined the data from both phases 1 and 2, aiming to assess whether the qualitative themes identified confirmed or refuted the quantitative data [94 95]. It was hoped that the data synthesised, and framework developed would encourage the safe and successful implementation of physiotherapy prescribing, where indicated, internationally.

Research Questions

Do barriers to and facilitators of the use/implementation of iNMP exist? If so:

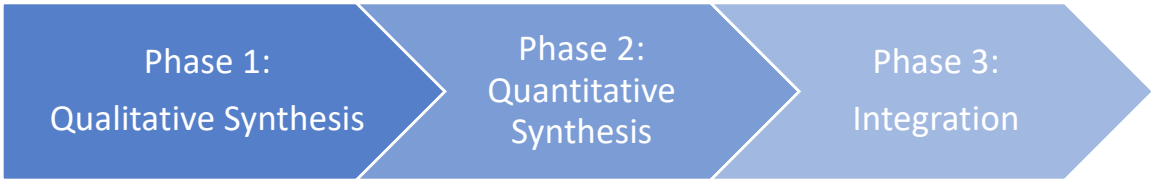
- What are the barriers to the use/implementation of iNMP?
- What are the factors that facilitate the use/implementation of iNMP?

Objectives

1. To assess what is known about the barriers to and facilitators of iNMP.
2. To examine the extent to which the identified barriers to and facilitators of iNMP influence the up take into the clinical practice of non-medical health professionals.
3. To assess whether the qualitative evidence identifying the barriers to and facilitators of iNMP complement or refute the quantitative evidence examining its implementation into practice.

3.1 METHODS

Following the completion of scoping searches, it was clear that both qualitative and quantitative literature exists evaluating the barriers and facilitators of iNMP. A sequential exploratory approach as defined by Creswell (2008) was utilised as the mixed methods design, in order to harmonise the qualitative and quantitative literature and enhance analysis of the available data. It was theorised that this method enabled a richer synthesis, generating data relevant to clinicians, managers and policy makers; therefore, facilitating change within healthcare policy and practice [95-97]. The purpose of this strategy was "to use the quantitative data and results to assist in the interpretation of the qualitative findings" [94]p211, therefore enabling integration of the qualitative and quantitative data via rigorous examination of the qualitative themes [94 95 97 98].



The sequential exploratory method begins with the qualitative phase (phase 1), in this case aiming to assess what is known about the barriers to and facilitators of iNMP [94 95]. In the qualitative phase the reviewers analysed all studies retained as per the systematic review protocol, generating qualitative themes which informed the quantitative phase (phase 2).

In phase 2, quantitative data related to the emergent qualitative themes from phase 1, were extracted and synthesised from quantitative studies obtained via the original searches [94]. The aim of phase 2 was to examine the extent to which the qualitative themes

were seen to influence the use of iNMP in clinical practice according to the quantitative literature [94-98].

The results from phases 1 and 2 were then integrated in phase 3, aiming to explore whether the qualitative and quantitative findings confirmed or refuted each other, or were simply complementary [94-98].

To ensure quality and transparency, the mixed methods systematic review was conducted according to a pre-defined protocol that followed the Cochrane handbook [63 65 66], and was reported in accordance with the PRISMA statement [66]. The PRISMA statement was developed to provide a 'gold standard' for the reporting of a wide array of systematic review types, and was modified where indicated to account for the complexities required by the systematic review's mixed methodology [68]. For clarity a copy of the PRISMA checklist for this mixed method systematic review is found in Appendix 4 [66 67].

3.1.1 Protocol Registration

The systematic review protocol was registered with PROSPERO (registration number: CRD42015017212) to ensure transparency and avoid duplication [64 68]. No changes were made to the original protocol registered. Following completion of the study the record was closed as per register policy.

3.1.2 Eligibility Criteria

PICOS was used to inform eligibility criteria [99]. When questioning efficacy PICOS is frequently used to frame the research question. Although other frameworks have been

proposed and developed for use in mixed methods research, such as SPIDER (Sample, Phenomenon of Interest, Design, Evaluation, Research type) [100]; research evaluating the reliability of such tools indicate that current database-indexing limits their use, yielding proportionally fewer relevant articles compared to PICOS when used to inform search strategies [100]. All studies satisfying the eligibility criteria outlined in Figure 6 were included in the systematic review.

Figure 6: Chapter 3 Eligibility criteria

<table>
<tr><td colspan="2">Population</td></tr>
<tr><td colspan="2">Independent non-medical prescribers from any professional group with legal authorisation to prescribe medicines independently [70], or stakeholders engaged with non-medical prescribers/ NMP services.</td></tr>
<tr><td colspan="2">Intervention</td></tr>
<tr><td colspan="2">NMP provided by a professional group with legal authorisation to prescribe medicines independently [70].</td></tr>
<tr><td colspan="2">Comparator(s)/ control</td></tr>
<tr><td colspan="2">Not applicable</td></tr>
<tr><td colspan="2">Outcomes- Inclusion of papers with either or both qualitative and quantitative outcomes as specified:</td></tr>
<tr><td>Qualitative outcomes
Data describing: consumers', carers', healthcare professionals' perceptions and experiences of the barriers to, the facilitators of independent NMP [63].</td><td>Quantitative Outcome Measures- Quantitative survey questions assessing the barriers to, the facilitators of independent NMP.
E.g. economic comparisons, patient satisfaction/ expectation, staff satisfaction/expectation, educational satisfaction/expectation, location comparisons, health sector/speciality comparisons [63].</td></tr>
<tr><td colspan="2">Study Design- Inclusion of papers with either or both qualitative and quantitative outcomes as specified:</td></tr>
<tr><td>Qualitative:
Any design- empirical qualitative studies including a description of the sampling strategy, data collection procedures and the type of data-analysis considered. Each paper should include the methodology/ research techniques chosen[101].</td><td>Quantitative:
Any design, to ensure no quantitative data is missed [63].</td></tr>
<tr><td colspan="2">Exclusion Criteria</td></tr>
<tr><td>Qualitative Studies:
Descriptive papers/ editorials/ opinion papers due to internal bias [101].
Not written in English were excluded rather than restricted; providing information on potential bias [67].
Not reporting research design/ methodologies [101].</td><td>Quantitative Studies:
Studies not written in English were excluded once identified to provide information on potential bias [67].</td></tr>
</table>

3.1.3 Information Sources

Information sources were searched in accordance with targeted subject-specific strategies independently tailored for each of the databases identified in Figure 7. The specific databases searched were selected following discussion with subject matter experts, methodologists and advice from specialist librarians at the University of Birmingham (UK). The information resources accessed were thought to ensure that a fully holistic literature

search was achieved [63 64 71]. The search period was January 1994- June 2015. This reflected the time period since the introduction of the first iNMP internationally across all prescribing professions [58 72].

Figure 7: Chapter 3 Information Sources

Databases searched:
CINAHL, EMBASE, MEDLINE, AMED, NICE, Medicines Complete, HMIC, ASSIA, Web of Science, Health and Safety Science Abstracts
Selected internet sites:
PUBMED, Turning Research into Practice, Google Scholar, the Royal College of Nursing, Royal Pharmaceutical Society, King's Fund, National Institute of Clinical Excellence, Department of Health, National Prescribing Centre, Chartered Society of Physiotherapy, Society of Chiropodists and Podiatrists, American Association of Nurse Practitioners, Australian College of Nurse Practitioners, Canadian Pharmacists Association, Optometry Australia, British Optometry Association
National Research Register
Hand searching key journals
System for Information on Grey Literature, Unpublished research
Expert Opinion
The reference lists of all retrieved papers

3.1.4 Search

A pre-determined search strategy was utilised for the sources searched, with database specific standardised vocabulary being employed to ensure all relevant studies were retrieved. This was essential to ensure that no literature was missed due to different words being used to describe the same concepts [63 71 73 74]. Methods were considered based on the indexing methodology utilised by the specific database being searched, therefore ensuring that variations between databases did not lead to holes in the literature harvest [63]. A full

electronic search strategy for the Medline OvidSP search can be found in Appendix 5, enabling any reader to repeat the process [67].

Where an article reporting a pilot study was identified, the reviewers searched for an associated article reporting the definitive study. Authors were contacted if the definitive study was not traced to confirm existence and/or any other related published/unpublished literature. The reference lists of the identified literature were searched to ensure no studies were missed [71 74]. In addition, experts in the area were consulted in an effort to detect any further studies [63 71 73 74].

3.1.5 Study Selection

In an attempt to ensure that no relevant literature was overlooked, two reviewers (TN/EGC) independently searched information sources and assessed the identified literature for inclusion, aiming to reduce the possibility of excluding relevant research where challenging judgements were necessary [63 68]. A third reviewer (AR) mediated in cases of disagreement [68 73].

Reviewers independently evaluated articles by title and abstract for potential inclusion/exclusion. Following discussion, if a study could not be explicitly excluded on the basis of its title and abstract, its full text was reviewed [64 67]. All potentially relevant articles proceeded forward to the review of full texts. The numbers of articles included and excluded at the different phases were recorded [63 68 71].

3.1.6 Data Collection Process

3.1.6.1 Phase 1: Qualitative Data

Data assessing stakeholders' experiences of the barriers to and facilitators of iNMP were extracted independently by one reviewer (TN) using NVivo 11 software (QSR International, Melbourne, Australia) [71]. Data extraction was reviewed by a second reviewer (EGC), ensuring all relevant data were extracted. Differences in opinion were resolved at a consensus meeting [73]. A third reviewer (AR) was available to settle any disputes.

3.1.6.2 Phase 2: Quantitative Data

Data pertaining to themes identified in phase 1 were extracted from the quantitative studies independently by the two reviewers (TN, EGC) using pre-determined data extraction sheets specific to the study objective [71]. Differences were resolved at a consensus meeting. The third reviewer (AR) checked for consistency, clarity and aided resolution throughout the process.

3.1.7 Data Items

Included studies' characteristics including study design, country, NMP profession studied, healthcare setting, healthcare speciality and participants (clinicians, patients, public etc.), were tabulated and analysed.

3.1.7.1 Phase 1: Qualitative Data

Quotations from study participants and text found in the results/findings sections in each study were entered verbatim into NVivo 11 software (QSR International, Melbourne, Australia) for thematic analysis.

3.1.7.2 Phase 2: Quantitative Data

Data from quantitative survey questions assessing the themes identified in stage 1 were extracted from all the included quantitative studies for analysis.

3.1.7.3 Phase 3: Integration

Data items collected in phases 1 & 2 were utilised.

3.1.8 Quality Assessment

3.1.8.1 Quality Assessment of Individual Studies:

Quality assessment aims to evaluate the adequacy and specificity of studies' methodology and reporting [102 103]. Whilst acknowledging that factors such as journal space and editing may limit reported detail [101-103]; it is important that quality assessment differentiates between stylistic traits and the study's methodological quality [103]. A plethora of validated tools are available to assess quantitative methods such as: the Cochrane risk of bias tool, QUOROM, MOOSE, STROBE [102 104]. However, the efficacy of quality assessment for qualitative research continues to be questioned. It is argued that quality assessments focused on theoretical approaches to evaluation do not represent the diversity of

qualitative philosophies and methodologies. Therefore, reviews incorporating qualitative literature must employ an assessment tool that ensures the appraisal of the technical adequacy of the qualitative design [101 104].

The literature recommends an iterative approach to quality assessment of qualitative research as rigid checklist tools are unable to reflect key principles of qualitative work [103 104]. Systematic reviews evaluating the use of quality assessment tools have unanimously concluded that no 'gold standard' currently exists [103 105 106]. Early mixed method reviews utilised different quality assessment tools for quantitative and qualitative studies included, as validated tools aimed to assess single methodological designs. Consequently, the key quality domains were assessed and weighted in different ways, with numerical summary scores exhibiting bias dependent on the design being assessed. As a result, the use of multiple quality assessment tools in one review is not recommended when evaluating the overall quality of a body of evidence obtained through mixed methods [102-104]. Mixed-method researchers are now developing specific quality assessment tools [104] that are flexible in nature, so as to facilitate the appraisal of the different methodological approaches [107].

The comprehensiveness of reporting and transparency of included studies in this systematic review was evaluated using the Quality Assessment Tool for Studies with Diverse Designs (QATSDD)[104], producing a quality rating score for each study. The QATSDD critical appraisal tool is a 16-item tool specifically developed for use in mixed method systematic reviews [104]. The quality assessment domains are developed from evaluation of literature assessing established quality assessment tools for both qualitative and quantitative research methodologies. This included: QUOROM, CONSORT guidelines,

MOOSE, STROBE, CASP, and The Quality in Qualitative Evaluation Framework [104]. Each item is scored between 0-3, with the sum of the items generating an overall quality score. Good validity, inter-rater reliability and test-retest reliability (k = 71.5%) have been established for the use of QATSSD across a diversity of study designs, demonstrating the tool's value for consistent quality assessment in mixed methods research [102] [104]. Two researchers (TN/EGC) independently assessed each study, with disagreements discussed and resolved in a consensus meeting [73]. The third reviewer (AR) was available to resolve conflict if required.

3.1.8.2 Quality Assessment Across Studies:

The quality rating as assessed using the QATSDD Tool was tabulated for each included study to demonstrate the overall quality of the literature across studies [63].

3.1.9 Data analysis and synthesis of results

A three-step process of analysis synthesised the qualitative and quantitative data.

3.1.9.1 Phase 1: Qualitative

For qualitative literature the Cochrane collaboration advocate that following the quality assessment all studies assessed remain included, no matter the quality assessment conclusions. This ensured the inclusion of all valuable insights within the systematic review [101].

To ensure a quality and trustworthy qualitative data analysis, a thematic analytical approach was used to synthesise the qualitative evidence [108], enabling the identification of

significant themes within an iterative and organised, analytical framework [107]. It is acknowledged that the iterative nature makes thematic analysis hard to define. Analysis may be a combination of descriptive and interpretive [108], with analysis structured either towards themes of a high explanatory value, or those with a higher frequency being acknowledged as the prominent influential factors [107 108]. This flexibility allows integration of quantitative and qualitative evidence, facilitating a holistic systematic review including all of the relevant literature [94]. Line by line coding of data relating to barriers and facilitators of iNMP was undertaken by one reviewer (TN). Data were grouped into descriptive themes, then developed into analytical themes and subthemes [108]. Two reviewers reviewed preliminary themes/subthemes, re-reading all included studies to ensure the identification of all relevant data were complete [108]. The themes/subthemes were then scrutinised by a panel of experts to agree findings. Characteristics and outcomes of the included studies were tabulated.

3.1.9.2 Phase 2: Quantitative

Data from quantitative survey questions assessing the themes identified in phase 1 were extracted from the quantitative studies. Studies' characteristics and outcome data were tabulated. Within and between study analyses was combined with an overall assessment of the quality of the phase 2 data [64 67]. A textual narrative analysis of the quantitative evidence was undertaken independently to the qualitative data analysed in phase 1 [74]. A textual narrative synthesis using descriptive words and text to summarise the data across the studies was adopted, as this technique is beneficial when synthesising different types of research data that may present within surveys [109]. It provided a way to describe

differences in the included studies, whilst making transparent accounts about the appropriateness of methods and research contexts and identifying deficits in the literature [108 109]. The narrative synthesis addressed both statistically significant and non-significant outcomes for each of the included studies separately. Additional commentary evaluated importance and contexts of the individual results in relation to the aim of the phase [71 74 109].

3.1.9.3 Phase 3: Integration

Phase 1 and 2 data were compared through an integration process, to determine agreement or disagreement to identified themes/subthemes [94 95]. Data were tabulated into an integration matrix, enabling an overall influence (criteria found in Figure 8) of the subtheme in each qualitative theme to be determined [95 108 110].

Figure 8: Influence Factor Criteria

Barrier shown with statistical significance	B
Barrier reported with no statistical significance testing undertaken	b
Facilitator shown with statistical significance	F
Facilitator reported with no statistical significance testing undertaken	f
No impact, no statistical significance on testing	NI
Not assessed	NA

Evaluation of the level of agreement for the qualitative themes/subtheme factors was synthesised across the quantitative studies using the criteria cited in Figure 9 [110]. Whether phase 1 and 2 data corroborated and confirmed findings was observed and reported. To

demonstrate the key factors that affect the implementation and utilisation of iNMP, the integrated data were used to develop an implementation framework[108].

Figure 9: Agreement Synthesis Criteria

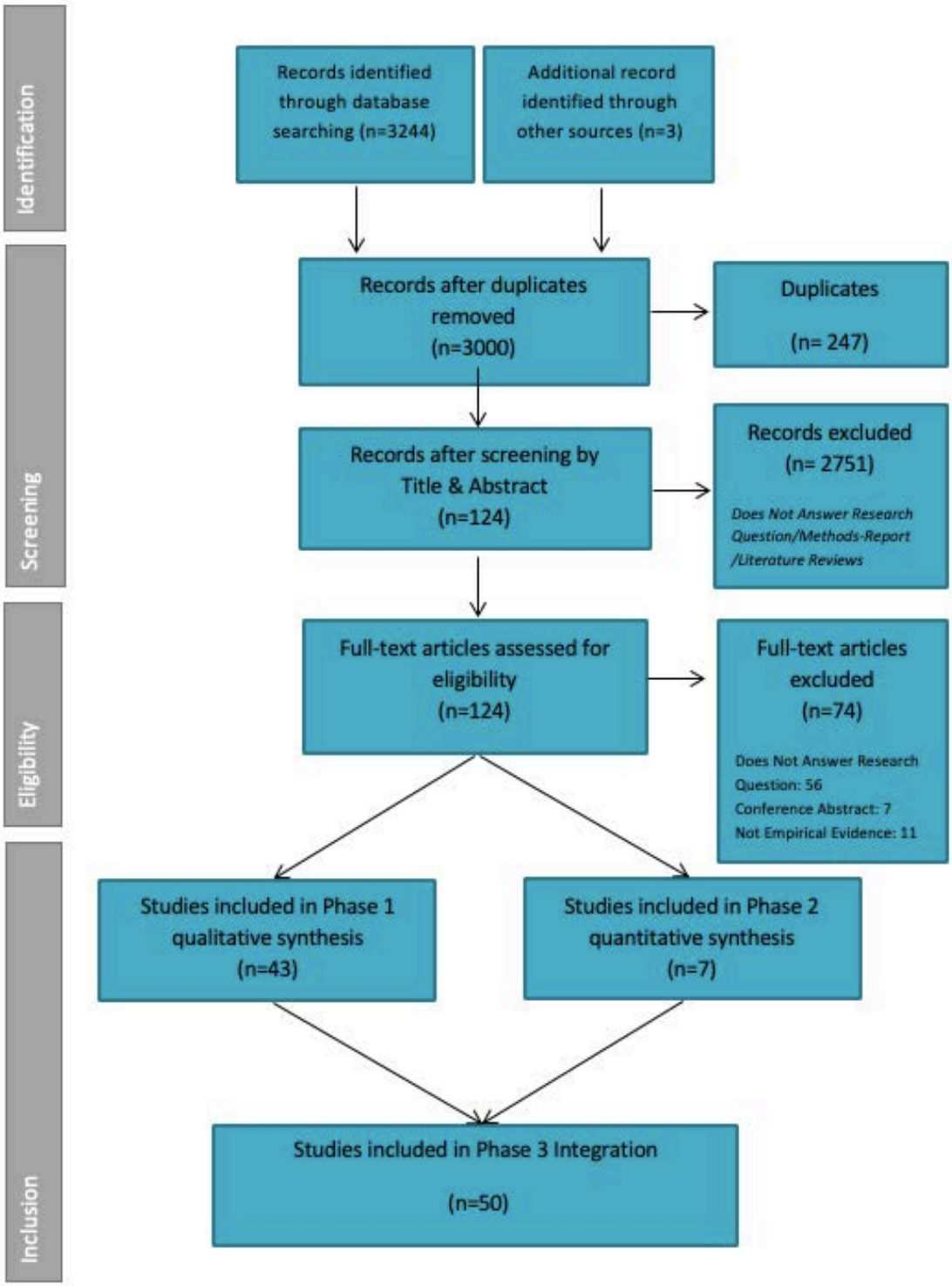
Barrier to independent NMP	B results only
Potential barrier to independent NMP	Mix of B, b & NI results
Facilitator of independent NMP	F results only
Potential facilitator of independent NMP	Mix of F, f & NI results
Exclusive evidence of no impact	NI results only
Contradictory evidence	Mix of B/b, F/f, NI results
Not Assessed	NA results only.
Key: Barrier (B), Facilitator (F), Potential Barrier (b), Potential Facilitator (f), No Impact (NI), Not Assessed (NA)	

3.2 RESULTS

3.2.1 Study Characteristics

A total of 3247 (3244 from database searches, 3 from reference lists) potentially relevant studies were identified. No unpublished studies were identified, and no further studies were identified from the internet searches, reviews of the national research register or via experts in the field. All studies retrieved were written in English, therefore no studies were excluded due to language. Following removal of duplicates (n=247), 3000 citations remained. Screening by title and abstract excluded 2751 studies, with full texts of the remaining 124 studies examined in detail. This resulted in 43 studies meeting eligibility criteria for phase 1, and 7 studies for phase 2; totalling 50 included studies. One hundred percent inter-reviewer agreement was achieved following open discussion. Third reviewer mediation was not required. Figure 10 presents the number of studies at each stage of the systematic review selection process.

Figure 10: Chapter 3 Study selection, PRISMA flow diagram (adapted from Moher et al, 2009)



3.2.2 PHASE 1: Qualitative

3.2.2.1 Study Characteristics

Characteristics of the studies included in phase 1 are summarised in the first 3 columns of Table 5. More detailed characteristics are available in Appendix 6. Studies were undertaken in 3 countries; 39 (91%) in the UK, 2 (4.5%) in Canada and 2 (4.5%) in the USA.

3.2.2.1 Study methods

Of the 43 included studies, n=24 (56%) utilised interviews, n=11 (26%) surveys, and n=1 (2%) focus groups as the primary research method. The remaining n=7 (16%) studies used a mixed methods approach including surveys, interviews, focus groups, non-participant observation.

3.2.2.2 Participants

Across the 43 studies 7344 participants were recruited. In 2 instances, data from 1 sample were reported across 2 studies. Where sample populations were duplicated across multiple studies reporting different data, participants were counted once [111-114]. Table 4 demonstrates the number of individual stakeholders engaged with each data collection method and summarises the stakeholder groups engaged with each data collection method. A few participants (0.4%) had no defined role, being described as general stakeholders.

Table 4. The number of stakeholders engaged with each data collection method

Stakeholder	Surveys (n)	Interviews (n)	Focus Groups (n)	Observation (n)	Total, n (%)
Nurses	4053	222	42	2	4319 (59)
Service users	2055	420	0	52	2527 (34)
Pharmacists	152	93	0	0	245 (3)
Medical Doctors	0	91	21	2	114 (2)
NMP Leads	44	28	0	0	72 (1)
General	0	30	0	0	30 (0.4)
Administrative Staff	0	20	0	0	20 (0.3)
Managers	0	17	0	0	17 (0.2)
Total (n)	6304	921	63	56	7344 (100)

3.2.2.3 Intervention

Most of the included studies investigated nurse iNMP (n=33, 77%), with pharmacists the only other professional group specifically investigated (n=6, 14%). Two studies investigated both nurse and pharmacist iNMP together (5%), with a further 2 studies investigating iNMP from all potential professional groups (5%).

3.2.2.4 Setting

Study settings included both community healthcare (39.5%), and hospital settings (14%), with most studies conducted across both healthcare settings (46.5%). Forty-two percent of included studies encompassed all healthcare specialities (n=18). The remaining studies studied: mental health (16%), paediatrics (7%), dermatology (5%), general practice (5%),

oncology and palliative care (5%), diabetes (5%), pain management (5%), HIV (2%), district nursing (2%), addiction (2%), dementia (2%) and cardiology (2%).

3.2.2.5 Quality assessment

Quality scores of Phase 1 studies are summarised in Table 5 and ranged 5-35 (mean=20.95). Detailed quality criteria information is provided in Appendix 7. One hundred percent inter-reviewer agreement was achieved, with no mediation required from the third reviewer. One hundred percent of the included studies reported a procedure for data collection and clear research setting; 98% of studies recruited a sample of a reasonable size, with 93% of studies reporting detailed recruitment data. Less than 40% of studies reported a rationale for the choice of data collection tool, with only 60% of studies providing any justification for the analytical methods selected.

Table 5. Phase 1, Included Studies, Characteristics & Quality

Ref No	Study	Setting and speciality	Non-medical prescribers' participation *Total n, (n) from each profession*	*QATSDD Score*
1	Avery et al, 2007[115]	Community Care, Hospital Care Range of Specialities	**Total n=110** Surveys n=85: Nurses n=80, Midwives n=3, Pharmacists n=2, Interviewed n=25: Nurses n=16, Doctors n=5, Pharmacist n=1, Managers n=3,	18
2	Bennett & Jones, 2008[116]	Community Care, HIV	**Total n=8** Surveys: Nurses n=8 Focus Groups: Nurses n=8	19
3	Bradley & Nolan, 2007[117]	Community Care, Hospital Care Range of Specialities	**Total n=45** Nurses n=45, Face-to-face interview n=31, Telephone interview n=14	19
4	Bradley et al, 2008[118]	Community Care, Hospital Care Mental Health	**Total n=15** Nurses n=15	9
5	Carey et al, 2009[119]	Hospital Care Paediatrics	**Total n= 21** Nurses n=7, Doctors n=11, Managers n=3	20
6	Carey et al, 2010[52]	Community Care Dermatology	**Total n=40** Nurses (prescribers) n=11, Doctors n=12, Admin Staff n=11, Nurses (Non-prescribers) n=6	19
7	Courtenay & Carey, 2009[120]	Hospital Care Paediatrics	**Total n=14** Nurse prescribers n=7, Doctors (consultant level) n=4, Managers n=3	30
8	Courtenay et al, 2011[121]	Community Care, Hospital Care Range of Specialities	**Total n=28** NMP leads n=28	25
9	Cousins & Donnell, 2012[122]	Community Care General Practice	**Total n=6** Nurses n=6	24

10	Downer & Shepherd, 2010[123]	Community Care District nursing	**Total n=8** District nurses n=8	20
11	Earle et al, 2011[124]	Community Care Mental Health	**Total n=8** Nurse prescribers n=2, Service users n=6	26
12	Glod & Manchester, 2000[125]	Community Care, Hospital Care Mental Health	**Total n=1352** Advance practice nurses n=1352	27
13	Guirguis et al, 2014[126]	Community Care Range of Specialities	**Total n=38** Pharmacist prescribers n=13, Non-prescribing pharmacists n=25	32
14	Hales, 2002[127]	Community Care, Hospital Care Mental Health	**Total n=32** Advanced Practice Nurses **n=32**	9
15	Hall et al, 2003[128]	Community Care Range of Specialities	**Total n=21** Community Nurses **n=21**	9
16	Hall et al, 2006[129]	Community Care Range of Specialities	**Total n= 67** Interviewed n=23: District nurses n=11, Health visitors n=10, Practice nurses n=2 Surveys: NMP Leads n=44	27
17	Hill et al, 2014[130]	Community Care Addiction Services	**Total n=97** Service users n=86, Pharmacist prescribers n=5, Doctors n=6	14
18	Hobson et al, 2010[131]	Community Care, Hospital Care Range of Specialities	**Total n=18** Service users n=18	31

19	Jones et al, 2011[132]	Hospital Care Range of Specialities	**Total: n=196** Interviewed n=18: prescribers (profession not stated) n=3, mentors/colleagues n=7, Managers n=8 Structured non-participant observation of nurse prescribers n=2, Doctors n=2, consultations n=52 Surveys: Service users n=122	35
20	Kelly et al, 2010[133]	Community Care General Practice	**Total n=151** Community Practice nurses n=151	17
21	Lewis-Evans & Jester, 2004[134]	Community Care Range of Specialities	**Total n=7** Nurses n=7	28
22	Luker et al, 1997[135]	Community Care Range of Specialities	**Total n=256** Service users n=256; pre-prescribing n=157, post prescribing n=148 (33.3% interviewed post- were also interviewed pre-prescribing).	5
23	Maclure et al, 2013[51]	Community Care, Hospital Care Range of Specialities	**Total n=1855** Service users n=1855	18
24	Makowsky et al, 2013[136]	Community Care Range of Specialities	**Total n=38** Pharmacists n=38	32
25	McCann et al, 2011[137]	Community Care, Hospital Care Range of Specialities	**Total n=105** Pharmacists n=105	20
26	McCann et al, 2012[138]	Community Care, Hospital Care Range of Specialities	**Total n= 35** Pharmacists n=11, Doctors n=11, Other Stakeholders n=13	25
27	Mulholland, 2014[139]	Hospital Care Paediatrics	**Total n=45** Pharmacists n=45	11

28	Nolan et al, 2004[140]	Community Care, Hospital Care Mental Health	**Total n=51** Nurses n=51	17
29	Page et al, 2008[141]	Hospital Care Dementia	**Total n=20** Service users n=13, Staff (non-prescribers) n=7	19
30	Ross & Kettles, 2012[142]	Community Care, Hospital Care Mental Health	**Total n=45** Nurses n=33, Focus group, Nurses n=12	34
31	Ryan-Woolley et al 2008[112]	Community Care, Hospital Care Oncology & Palliative Care	**Total n=2252** Nurses n=2252	15
32	Ryan-Woolley et al 2007[111]	Community Care, Hospital Care Oncology & Palliative Care	**Total n=2252** Nurses n=2252	19
33	Scrafton et al, 2012[143]	Hospital Care Range of Specialities	**Total n=6** Nurses n=6	29
34	Shannon & Spence, 2011[144]	Community Care, Hospital Care Cardiology	**Total n=21** Focus Groups: Doctors n=21 Interviews: Doctors n=21,	24
35	Stenner et al, 2009[145]	Community Care, Hospital Care Dermatology	**Total n=18** Doctors n=12, Nurses (non-prescribers) n=6	22
36	Stenner et al, 2010[146]	Community Care, Hospital Care Diabetes	**Total n=31** Nurse prescribers n=10, Doctors n=9, Admin staff n=9, Nurses (non-prescribers) n=3	21
37	Stenner & Courtenay, 2008a[113]	Community Care, Hospital Care Pain Management	**Total n=26** Nurse prescribers n=26	22

38	Stenner & Courtenay, 2008b[114]	Community Care, Hospital Care Pain Management	**Total n=26** Nurse prescribers n=26	28
39	Stenner et al 2011[50]	Community Care Diabetes	**Total n=41** Service Users n=41	23
40	Travers, 2005[147]	Community Care Range of Specialities	**Total n=7** Focus Groups: Nurses n=7 Interviews: Nurses n=7,	10
41	While & Biggs, 2004[148]	Community Care Range of Specialities	**Total n=91** Community Nurses n=91	20
42	Wix, 2007[149]	Community Care, Hospital Care Mental Health	**Total n=78** Service users n=78	10
43	Young, 2009[150]	Community Care Range of Specialities	**Total n=5** Community Nurses n=5	19

3.2.2.5 Outcomes and Synthesis of Results

All included studies reported barriers to, or facilitators of iNMP or both, noting that factors in general can be both a barrier and facilitator depending on context. Four major themes (TH1-4) were identified:

1. Systems factors (TH1); legislation & regulation, management & organisation, policies & practices, and delivery and growth.
2. Education and support factors (TH2); qualifications, ongoing learning and professional backing.
3. Personal and professional factors (TH3); knowledge, views, perceptions and actions.
4. Financial factors (TH4); costs and funding mechanisms.

The overall themes and their subthemes are described below. Table 6 lists the studies that reported or discussed each theme, providing illustrative quotations from participants or from study authors for each subtheme. It is acknowledged that the themes interact with each other, due to close relationships and crossover. The schema detailed in Figure 11 was developed throughout the iterative thematic analysis, by mapping the development of the themes/subthemes via the coding process. It illustrates the conceptual, continuous inter-relationships between the themes/subthemes.

Figure 11: A schema to show the inter-relationships between the themes/subthemes relating to the barriers to and facilitators of independent non-medical prescribing

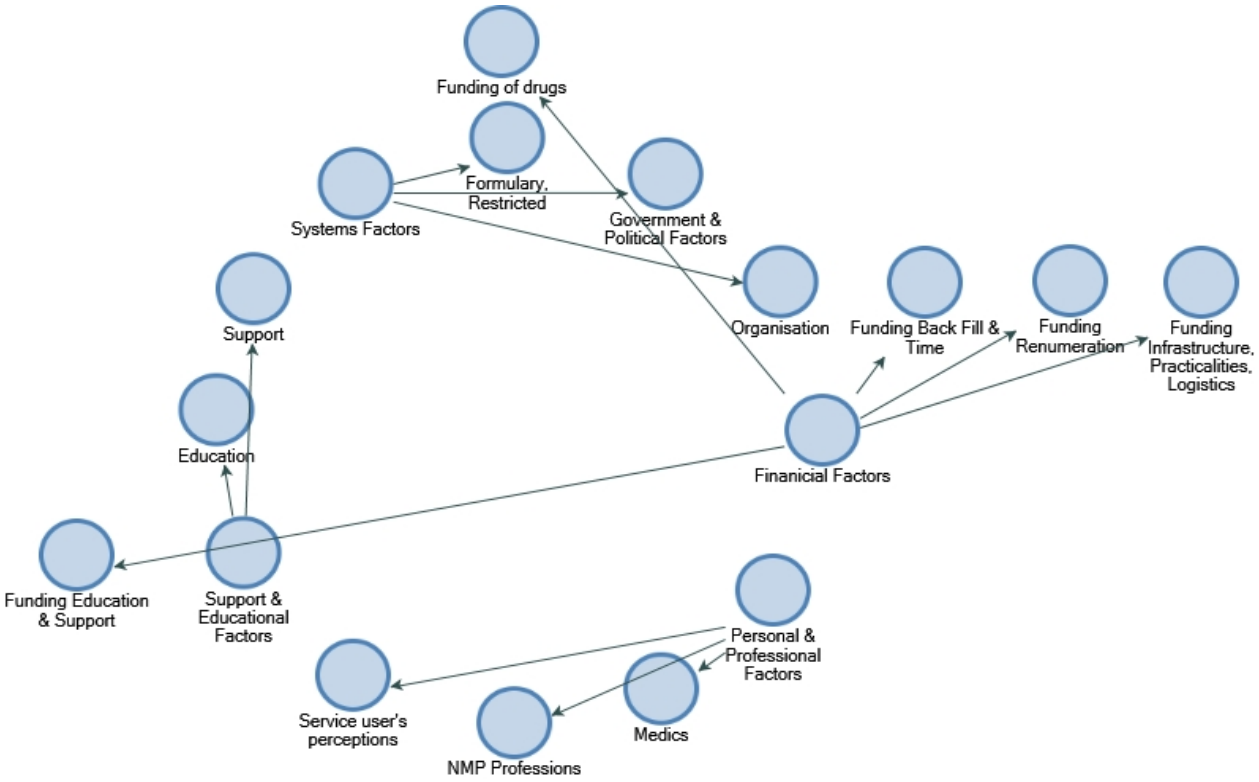


Table 6. Studies that Reported or Discussed Each Theme & Illustrative Quotations from the Studies' Participants/Authors

	Example Quotations from Included Studies	n (%)	Key Elements	Reference Number for Each Included Study Reporting the Subtheme
Theme, TH1.0: System Factors		**32 (74)**		
Subtheme TH1.1: Government & Political Factors	"The introduction of this initiative was accompanied by a lot of pressure from the Department of Health on the Trusts to push through as many nurses as quickly as possible." [115]p3 "The Government had given these free places for training and there was this sort of scrabble for all of us to be put into doing it whether or not we needed it." [143]p2046 "…a lack of leadership at both a national and strategic health authority level" [121]p8 "Participants believed that patient benefit rather than doctor shortage should be the motivation behind nurses prescribing." [143]p2049	**4 (9)** 1 (2) 1 (2) 1 (2) 2 (5)	 Drivers Funding Sources Cohesive Thinking & Strategy Motives	1, 8, 30, 33 1 33 8 30, 33
Subtheme TH1.2: Organisational Factors	"Ensuring that clinical governance systems were in place and up-to-date was felt to be a critical part…" [121]p5 "It is particularly important that pharmacists develop a culture of safety, do not prescribe outside their areas of competency and are supported in their prescribing role, rigorous and robust governance procedures should be in place where pharmacist prescribers operate…" [137]p830 "Established policies and procedures for: a) identifying the need for NMP development within the Trust, b) rigorous selection procedure c) clinical governance procedures for NMP." [121]p8	**31 (72)** 15 (35) 16 (37) 1 (2) 3 (7) 4 (9) 5 (12) 5 (12) 6 (14) 7 (16) 26 (60)	 **Clinical Governance Policy & Audit** **Practicalities & Logistics** *Consultation room availability* *Prescription pads* *Qualification to prescribing time* *Finances* *Administration* *Medical records* *IT & communications* **Policy Development & Implementation**	1, 2, 3, 4, 5, 6, 7, 8, 11, 12, 13, 14, 16, 18, 19, 20, 23, 24, 25, 26, 28, 30, 31, 32, 33, 35, 36, 37, 38, 40, 41 1, 4, 5, 6, 7, 8, 16, 23, 25, 26, 30, 32, 33, 38, 40 2, 8, 12, 13, 16, 18, 23, 25, 26, 30, 31, 32, 33, 36, 37, 41 18 16, 30, 36 8, 30, 31, 32 2, 8, 16, 25, 37 12, 13, 16, 25, 30 16, 18, 23, 25, 37, 41 8, 18, 25, 26, 30, 33, 36

	"…an institutional strategy is required if nonmedical prescribing is to be successful in these settings." [115]p3 "…there is a need for the organisation to develop a clearly defined strategy and protocols for the implementation of non-medical prescribing, and this strategy must include substantive input from doctors." [115]p4 "Logistical barriers to implementation identified such as information technology issues (lack of access to patient notes in primary care)." [137]p830 "A colleague completed a course 12 months ago and still no policy is in place to enable her to prescribe. This discourages others from making the effort and attending the course." [112]p175	7 (16) 5 (12) 12 (28) 19 (44) 16 (37) 10 (23) 4 (9)	*Human Recourses* *Location& Organisational Jurisdiction* *Selection Criteria for the NMP Course* *Strategic & Transparent Approach* *Collaboration, Consultation, Definition & Scope of Practice* *Service & Organisational Need* *Innovation & Future Proofing*	1, 2, 3, 4, 5, 6, 7, 8, 11, 14, 16, 18, 19, 20, 23, 24, 25, 26, 28, 30, 31, 32, 33, 35, 38, 40 2, 4, 5, 6, 7, 8, 30 1, 4, 8, 16, 18 1, 4, 5, 7, 8, 11, 14, 28, 30, 33, 35, 40, 1, 3, 4, 5, 6, 7, 8, 14, 19, 23, 24, 25, 26, 30, 31, 32, 33, 38, 40 1, 3, 5, 7, 8, 14, 19, 23, 24, 25, 26, 30, 31, 33, 38, 40 1, 4, 5, 6, 7, 8, 30, 31, 32, 38, 4, 6, 8, 30
Subtheme TH1.3: Formulary	"I wanted to do the nurse prescribing course for two years – until the BNF was opened fully, it was not worth my while." [133]p23 "local formulary restrictions and formal agreements (such as an 'intent to prescribe'), were helpful in defining the limits of practice and assisting nurses to resist pressure from patients or professionals to prescribe outside of their area of competence…." [114]p281 "The participants were very positive about prescribing and the improvements it had brought to their roles in providing holistic care. However, they all stated that the limitations of the formulary severely restricted its usefulness.", "'It really does frustrate me, especially when I know exactly what I'm looking at and I know exactly what I need to prescribe, but I have to ask the patient to come back later because I can't prescribe off the [formulary]…" [147]p165	**10 (23)** 3 (7) 1 (2) 10 (23)	Open Formulary- Facilitators of NMP Limited Formulary- Facilitators of NMP Limited Formulary- Barriers to NMP	1, 2, 8, 20, 21, 28, 33, 38, 40, 41 1, 20, 21 38 1, 2, 8, 20, 21, 28, 33, 38, 40, 41

Theme, TH2.0: Education and Support Factors		**27 (63)**		
Subtheme TH2.1 Education	"…. access to CPD and formal feedback are areas that need to be developed by education providers and more formally embraced by managers within each organisation." [52]p505 "…haphazard approach and lack of a formal national infrastructure to guide CPD activity was viewed negatively and appeared to be the cause of some frustration…" [143]p2047 "….created a feeling of dissatisfaction with my work, as I feel underpaid for the responsibility I have now undertaken in practice. This does not encourage me to undertake an onerous course for little financial recompense." [133]p24 "Undertaking any course can be stressful and can generate anxiety. There is anecdotal evidence that the prescribing course, including a mathematics test that requires a 100% mark to pass, has generated a lot of anxiety among participants." [133]p23 "GP employers are often unwilling to support courses when they are expected to absorb the cost of locum practice nurse cover." [133]p23 "As nurses are unable to undertake the prescribing course without the support of a medical supervisor, they are dependent on a doctor agreeing to supervise." [142]p930 "…. the majority of prescribers…… thought that the prescribing course did not adequately prepare them to prescribe." [142]p927	**18 (42)** 11 (26) 11 (26) 1 (2) 1 (2) 2 (5) 3 (7) 7 (16)	 **Continuous Professional Development** **NMP Course** *Incentive to attend* *Prerequisites* *Funding* *Medical Supervisor* *Content*	5, 6, 8, 10, 11, 14, 20, 21, 27, 28, 30, 32, 33, 36, 37, 38, 40, 41 6, 8, 10, 11, 14, 20, 21, 30, 33, 38, 40 5, 10, 20, 27, 28, 30, 32, 33, 37, 40, 41 20 8 20, 27 28, 30, 32 8, 10, 30, 32, 33, 40, 41
Subtheme TH2.2 Support	"Participants accessed support from clinicians and peers, non-medical prescribing groups, specialist networks…" [52]p504	**23 (53)** 9 (21) 6 (14)	 NMP Professions MDT	1, 5, 6, 7, 8, 10, 11, 14, 16, 18, 20, 21, 23, 24, 26, 27, 30, 31, 32, 33, 37, 38, 39 5, 6, 10, 11, 14, 16, 24, 30, 38 5, 6, 21, 26, 32, 38

	"Team processes and communication between the different disciplines within the team impacted on the success of a pharmacist prescriber." [138]p130 "A number of respondents perceived a lack of medical support as their main reason for not wishing to undertake nurse prescribing training. 'There is a lack of understanding by medical staff. I know nurses who have undertaken the course and are unable to use their skills. It seems pointless to do nurse prescribing training unless it can be used effectively." [112]p175 "Lack of support included lack of supervision, lack of support in the prescribing role, and lack of support from all professionals involved. The lack of support from management in permitting the implementation of nurse prescribing when the prescriber has qualified." [142]p927 "The significant contribution that NMP leads play in embedding NMP within organisations should be acknowledged by clearer national guidance for the role, its responsibilities and workload." [121]p9	5 (12) 5 (12) 3 (7) 3 (7) 2 (5) 1 (2)	Medical Profession Health Service Managers Service Users Government NMP leads Time	5, 24, 30, 31, 32 10, 24, 27, 30, 31 18, 23, 39 1, 8, 33 7, 8 5
Theme, TH3.0: Personal and Professional Factors; thoughts and perceptions regarding the acceptability and value of NMP		**34 (79)**		
Subtheme TH3.1 Members of the Medical Profession	"I think it's useful because a lot of the junior doctors obviously rotate through every three to six months and actually if anything someone who's a permanent team member is probably more familiar with the drugs and protocols and the dose ranges." [120]p2672 "When I have a patient that I know can be followed up by a Nurse Practitioner I am thrilled because I have got no room in my follow up clinics…. what I have actually done is become dependent. I mean if the Nurse Practitioner in this department was withdrawn, I would not be able to look after the patients under my care." [52]p502	**26 (60)** 16 (37) 18 (42)	 Positives Negatives	1, 3, 4, 5, 6, 7, 10, 12, 14, 16, 17, 19, 20, 21, 22, 24, 28, 30, 31, 33, 34, 35, 40, 41, 42, 43 1, 4, 6, 7, 10, 14, 17, 19, 21, 22, 24, 35, 40, 41, 42, 43 1, 3, 4, 5, 7, 12, 14, 16, 20, 24, 28, 30, 31, 33, 34, 40, 41, 42

	"junior doctors … they said that I was taking over their role...they were saying, 'Oh yeah and you're taking over our role and they won't need us…" [117]p125 "I am the doctor; I am supposed to be in charge…." [120]p2673 "…. nurses described a lack of support from GP colleagues and in some cases, this extended to GPs specifically instructing nurses not to prescribe for their patients." [129]p407			
Subtheme TH3.2 Members of the NMP Professions	"I get more job satisfaction now because I can instigate treatment or first pills. If the patient is coming for the pill, I can prescribe it and see them again. It has given me more autonomy" [122]p225 "I'm not sure that the qualification would improve my level of patient care. [Doctors] sign scripts as required" [133]p83 "There is absolutely no financial incentive for taking on the huge responsibility of prescribing…" [142]p927 "In the area that I work I have pockets of deprivation. I know if I am going into those areas, I tend not to take my prescription pad with me. I keep it locked up in the office and if they need prescriptions I either ask somebody to come to clinic to collect it or I ask them to get it from the GP just because I'd feel vulnerable carrying a pad about with me at that time." [129]p407	**15 (35)** 11 (26) 4 (9) 3 (7) 3 (7)	 Job Satisfaction, Recruitment & Retention No need to prescribe Remuneration Staff safety	9, 10, 11, 13, 14, 16, 17, 20, 21, 24, 25, 28, 30, 31, 43 9, 10, 11, 14, 17, 20, 21, 24, 25, 28, 43 13, 20, 28, 31 9, 14, 30 16, 20, 28
Subtheme TH3.3 Service Users	"…. I would be very happy for pharmacist to prescribe medicines which I take on a regular basis, for example, my inhalers or tablets for reflux…." [51]p706 "Service users felt that the nurse prescriber knew what she was talking about and had a good understanding of their circumstances and their illness…." [141]p146	**4 (9)** 4 (9) 2 (5)	 Positives Negatives	18, 23, 29, 39 18, 23, 29, 39 18, 23,

	"As far as I'm concerned, I am extremely worried about anyone other than a doctor prescribing any medicines…." [51]p705 "…. also, I think there is no privacy in a pharmacy is there? I don't think there is anyway ... You kind of chat over the counter for all and sundry to hear." [131]p116			
Theme, TH4.0: Financial Factors		**11 (26)**		
Subtheme TH4.1 Education & Support	"Nurse prescribing education was offered by line managers to the nurses……..the reason behind this, some suggested, was that there was no direct cost incurred by the employer at that time. The availability of centrally funded prescribing education therefore appears to have been a significant factor in the uptake of training." [143]p2046 "The Trust will not allow me to undertake nurse prescribing training. There is no management support — no time or funding" [112]p174	**4 (9)**		25, 27, 31, 33
Subtheme TH4.2 Infrastructure, Practicalities & logistics	"….barriers such as cost and access to patient records are preventing benefits from occurring for outpatients in chronic pain" [113]p33 "…..financial pressures, both organisational and personal (e.g. cost of indemnity insurance) as barriers to expanding the services offered by prescribing pharmacists" [137]p830	**3 (7)**		25, 31, 37
Subtheme TH4.3 Remuneration	"Recognition in terms of status and pay for the increased responsibility of prescribing aroused the most emotion and sense of unfairness and was found to be a major barrier in the study. Many believed the prescribing role would not be taken seriously until it was remunerated." [142] p930	**3 (7)**		9, 14, 30

Subtheme TH4.4 Time & Backfill	"I believe it is impossible to carry a large caseload with no one covering it to go on this course (nurse prescribing training)..." [112] p174	**3 (7)**		16, 25, 31
Subtheme TH4.5 Drugs	"Reducing prescribing costs in secondary care meant that only onsite treatment and emergency medication are financed and all other prescribing has to go through primary care via the General Practitioner" [143]p2048 "Another frustration was their inability to prescribe for patients attending their clinic if the patient's GP was located in another Trust" [129]p407	**4 (9)**		1, 15, 16, 33

TH1.0: Systems Factors

Participants in 32 (74%) of the included studies, with a quality rating range of 9-35, highlighted a range of system factors that may act as either barriers or facilitators to implementing NMP, including government and political factors, organisational factors and practices and delivery.

TH1.1: Government and Political Factors

In 4 (9%) studies with a quality rating range of 18-34, participants reported that factors such as political motive, availability of government funding for education, adequate and appropriate political drive and strategic/cohesive planning at all levels of government could either facilitate the use of NMP or act as barriers [115 121 142 143].

Specifically, participants recognised that issues such as implementation pressure on health services from the DOH, reflecting key political messages regarding the benefits of iNMP for both service users and the local health economy as well as access to implementation funding were paramount in overcoming the recognised barriers to implementation from external sources [115 143]. Further, the absence of political leadership and a politically driven promotion of non-medical prescribers as cheap alternatives to doctors, rather than clinicians with an adjunct skill able to enhance patient access to appropriate care, were reported as potential barriers to the availability of non-medical prescribers [121 142].

TH1.2: Organisational Factors

In 31 (72%) studies with a quality rating range of 9-35, participants highlighted certain organisational factors that play a significant part in facilitating successful implementation of NMP. It was recognised when these factors were not considered appropriately, they could act as reciprocal barriers to such implementation. Organisational factors can be categorised as follows: clinical governance; practicalities and logistics; policy development and implementation.

Clinical Governance

Participants from 15 (35%) studies with a quality rating range of 9-34, recognised the importance of having robust local clinical governance policies, pathways and procedures in place prior to training staff to be non-medical prescribers as a prerequisite to successful implementation [51 52 111 114 115 118-121 129 137 138 142 143 147].

To that end, participants considered that local governance policy must be standardised to ensure quality of care and patient safety and that lines of authority and responsibility should be clearly defined [115 142]. Scope, parameters, boundaries and guidelines should be clearly documented in both policy and job descriptions and should be readily accessible to all appropriate stakeholders [142]. Induction to a new place of work must be standardised for all prescribers, to ensure awareness of local prescribing policies and procedures [120]. Individuals must prescribe within their individual competency, with transparent governance policy alleviating concerns due to pressure to prescribe outside of scope from senior colleagues and managers [137 138 143 147]. Participants clearly stated that adequate

support mechanisms with time and funding for adequate CPD activities should be openly documented in any governance policy developed [52 113].

Further, participants deemed it essential that institutions ensure access to patients' medical records where required and introduce clear policies regarding clinical documentation, incident reporting and communication [51 129 138]. Participants recommended that databases should be developed locally to record non-medical prescribers' work settings and whether a prescriber is active. Audit of prescribing practice and compliance with continuous professional development (CPD) requirements should also be recorded for transparency and accountability [121]. In fact, audit of prescribing practice was highlighted as critical to ensure evidence-based clinical practice, as well as to showcase potential savings due to non-medical prescribers reducing or stopping medicines appropriately [118].

Governance of practitioners prescribing in private practice and prescribers who are non-active or rarely prescribe were emphasised as difficult issues in the successful implementation of NMP [121]. Participants stressed that to prevent these issues becoming barriers, such factors should be resolved locally prior to training staff and implementing NMP into a health service [121]. Improvements in local clinical governance compliance with the introduction of NMP was also cited by participants, demonstrated by a reduction in instances in which medical prescribers sign prescriptions for patients assessed by another health professional [52].

Practicalities and Logistics

Participants in 16 (37%) studies, with a quality rating range of 15-34 highlighted practical and logistical issues as potential facilitators or barriers to the successful implementation of NMP. Participants noted that financial processes enabling the correct infrastructure, administration and logistics related to NMP, must be in place prior to implementation [116] [121]. Appropriate IT and communications infrastructures, with access to medical records as required for safe practice were also considered essential in facilitating successful implementation [121] [129] [131] [137] [138] [142] [143].

A lack of access to prescription pads or electronic prescribing for non-medical prescribers was recognised as a fundamental barrier to prescribing following qualification as a non-medical prescriber [129] [142] [146]. Further, excessive delays in access to prescription pads were noted as a fundamental issue that prevents clinicians from utilising their prescribing skills in the long-term [121] [142]. Both local and national administrative processes required for prescriber authorisation and to undertake the process of prescribing a medicine, were seen to be barriers across all countries studied [125] [129] [137] [151]. Participants reported that the processes are often too long and arduous, resulting in many potential prescribers feeling that the outcome is not worth the stress and effort of the process [125] [151]. To that end, the administrative processes linked to authorisation were reported as taking so long in some cases that prescribers had lost their confidence to prescribe by the time they were given the authority and facilities to do so [151].

The availability of appropriate clinical facilities was also considered to be an important factor in the successful implementation of NMP [131]. Service users reported that they prefer to discuss health matters in a private setting. It was recognised that in facilities where a

consultation room is not available (such as some community pharmacies) assessment of patients' needs may be compromised, thus presenting a barrier to the safe, successful use of NMP in such environments [131].

Policy Development and Implementation

Participants in 16 (37%) studies, with a quality rating range of 9-35 reported the importance of a strategic and transparent approach to the development and implementation of national and local NMP policy, as a key barrier or facilitator of iNMP.

On the one hand, facilitation was recognised when a strategic, collaborative and consultative approach was undertaken to develop and implement NMP into a service [115 121 132]. This method was reported to reduce the risk of professional territorialism, ensuring that patient-centred care is the focus rather than a specific profession's interests [117]. Participants considered that anxieties were alleviated by open discussion, educating stakeholders about NMP roles openly defining scope of practice, lines of authority and responsibility as well as clearly documenting strategy and protocols [115 117 120].

On the other hand, a lack of vision regarding the benefits of commissioning innovative areas of practice was reported as a barrier to NMP [121]. It was recognised that for NMP to become embedded in practice, the development and implementation of NMP should address issues such as workforce planning, selection criteria of non-medical prescribers, CPD requirements and developing a clinical support framework, [117-119 142]. Participants reported that the implementation of NMP should enhance service and organisation requirements, directly reflecting the health needs of the local community [118 119].

The future proofing of NMP services was also highlighted as a historical area of weakness that acted as a barrier to the expansion of NMP across health services. One study [118] found that if NMP is to develop in a health service, 4-5 non-medical prescribers should be trained to ensure support, and adequate succession planning. Participants recognised that well-defined selection criteria aimed at selecting the best candidates to undertake NMP training helped facilitate safe and effective NMP into practice [119 120]. Conversely, others warned that overly restrictive criteria may serve as a barrier to the expansion of NMP into new areas of practice without a defined speciality [121].

Another prominent concern among participants regarding the successful implementation of NMP was the barrier of a fragmented health service caused by the division of funding for service provision and prescription drugs, plus geographical restrictions due to law, regulation or organisational jurisdiction [118 121 129]. Participants noted that these factors were often integral to the success of NMP implementation across a locality as a whole [118 119]. To counteract that, innovative service design as well as utilising an individual profession's skills, talents, mastery and key pillars of practice to optimise patient outcomes were recommended. Simply utilising NMP professionals to replace medical staff in conventional clinical environments, where budgets, or medical staff availability dictate were deemed short sighted and identified as long-term barriers [52 121].

TH1.3: Formulary

Participants in 10 (23%) studies with a quality rating range of 10-29, reported that the type of formulary available both nationally and locally has a profound effect regarding the uptake and successful implementation of iNMP [114-116 121 133 134 140 143 147 148]. The majority of

participants identified the use of a 'limited formulary' as a potential barrier to the successful implementation of NMP. Due to the dynamic nature of drug availability, and constantly evolving evidence-based practice, frustrations were frequently felt because of limitations to practice secondary to formulary restrictions [114 140 147 148]. Participants reported regularly encountering situations in which they could not prescribe the appropriate medication, because it was not within the out-dated formulary governing their practice [140 147]. Further, some independent non-medical prescribers in the UK reported that they had waited until the British National Formulary (BNF) had been opened prior to completing the NMP qualification. They considered that prior to the BNF opening, their practice would have been too restricted to be worthwhile [133].

However, one study [114] acknowledged that a 'limited formulary' might in fact act as a facilitator of NMP. It was argued that by defining the limits of practice, new independent prescribers would be able to resist the pressure from patients, managers and clinical colleagues to prescribe out of scope, avoiding conflict which might evolve into a NMP barrier [114]. In addition, open formularies were reported to actively facilitate successful NMP implementation. The release of restrictions imposed by 'limited formularies', were reported to allow competent clinicians to prescribe within their professional code of conduct, reducing patient waiting times and further easing the workloads of medical prescribers; who previously would have to prescribe if the required drug was absent from the NMP restricted formulary [115 133 134].

TH2.0: Education and Support

Participants in 27 (63%) of the included studies, with a quality rating range of 9-34, reported that the education processes linked to the application of NMP, and the level and type of support offered to non-medical prescribers by stakeholders can act as either barriers to or facilitators of successfully implementing iNMP.

TH2.1: Education

Participants in 18 (42%) studies, with a quality rating range of 9-34, highlighted that access to education was a key factor in either facilitating NMP practice or acting as barrier to practice. Participants discussed education in two distinct categories: the NMP course and CPD.

NMP Course

The NMP course was discussed by participants in 11 (26%) studies, with a quality rating range of 9-34. Participants reported that attendance on the NMP course was often influenced by their employers' willingness to provide financial support for tuition fees and relief from employment duties to allow clinicians to complete the required academic and clinical components [133].

Further, limited incentives to undertake the NMP course, alongside pre-existing busy clinical caseloads, with no financial gain following completion of the course, left many clinicians unwilling to undertake an NMP course [133]. Some participants also felt that the course prerequisites act as a barrier to becoming a non-medical prescriber, due to the cost

and time related to completing the numeracy, pharmacology and assessment/diagnostics training [121]. Nevertheless, other participants recognised the prerequisites as imperative to maintaining quality standards and ensuring academic ability, therefore facilitating quality NMP and its success [121].

Many participants felt that although the NMP course fulfilled nationally agreed standards, the generic nature did not adequately prepare them to prescribe, with pharmacology content frequently described as lacking [123 142 143 147]. In spite of this, the generic, non-speciality specific nature of NMP courses was also reported to facilitate NMP by providing access to all associated professions; where small professional cohorts would usually limit universities developing and running courses [142 143].

Participants also highlighted that accessing a medical supervisor in order to complete the course often acted as a barrier to successful implementation of NMP. Medical professionals' willingness to undertake this role was acknowledged to be variable, with many non-medical prescribers reporting that they did not think their medical mentorship was adequate [111 140 142].

Continuous Professional Development (CPD)

Participants in 11 (26%) studies with a quality rating range of 9-34 discussed CPD requirements as barriers to or facilitators of successful implementation of iNMP. Participants reported that a formal national infrastructure to guide CPD would be beneficial, as support from managers, availability of speciality courses, funding and time were highlighted as barriers to accessing the required and appropriate CPD activities and courses [52 121 133 143]. This lack of access and time was conceived to limit non-medical

prescribers' ability to stay on top of the related evidence base, and was reported to have a direct influence on the amount NMP was utilised in practice [52 121 127 143]. Participants reported that the introduction of 'buddy systems' alongside regular in-house multidisciplinary CPD within health services, were good, economic ways of maintaining evidence-based use of medicines [124 147].

TH2.2: Support

Participants in 23 (53%) studies with a quality rating range of 9-34 reported that appropriate support from a suitable range of stakeholders was integral in introducing NMP into practice. A lack of support from any stakeholder group was considered a barrier [52 119-121]. The type and level of support required to implement, maintain and develop NMP in practice was reported to depend on the participant's reasons for having contact with NMP and their role within the health service [112 121 134 142]. Engagement and support from all parties, especially medical staff and health managers were reported as essential for the planning and successful implementation of NMP [123 136 142].

In particular, support from medical professionals as clinical supervisors whilst clinicians train and as mentors following qualification, was strongly emphasised by participants as being important. Positive medical support was also observed as a facilitator to NMP, however the availability of time to undertake mentored activities was recognised as a potential barrier [119 142]. Support from healthcare managers and government were reported as key to ensure provision of policy, funding and to facilitate organisational pressure to enable implementation of NMP. These groups were recognised as essential in overcoming barriers presented by other stakeholders [112 115 123 136 143].

Support from within the NMP professions and greater MDT was most frequently mentioned across the included studies. Participants reported this support as fundamental to: advocate for colleagues to be trained to prescribe, act as buddies to reduce feelings of isolation, and develop services once clinicians are established [119 124 127 142]. The adoption of NMP lead roles was reported as crucial for co-ordination and promoting the benefits of NMP, ensuring that organisations provide safe environments for non-medical prescribers to prescribe, and liaising with higher education providers [120 121].

Service users' poor knowledge and understanding of the level of education and experience required by non-medical prescribers in order to practice were acknowledged as potential barriers to the successful implementation of NMP [50 131]. Participants accepted that support from service users was vital [50 131], with service user consultation recognised as fundamental when contemplating health service redesign [50 51 131].

TH3.0: Personal and Professional Factors

Participants in 34 (79%) studies, with a quality rating range of 5-35, reported that the thoughts and perceptions relating to the acceptability and value of NMP from the following 3 groups of key stakeholders had a significant impact on the uptake and subsequent utilisation of NMP: members of the medical profession, members of the NMP professions and service users.

TH3.1: Members of the Medical Profession

Participants in 26 (60%) studies with a quality rating range of 5-35 reported that the thoughts and perceptions of those in the medical profession led to significant actions to either facilitate or block implementation of NMP. Specifically, positive thoughts and perceptions of medical professionals were reported in 16 (37%) studies, whereas 18 (42%) studies reported negative thoughts and perceptions.

Negative thoughts and perceptions were widely held to result from a lack of understanding of NMP roles and responsibilities, causing fear of deskilling or loss of power and/or control by medical staff [112 115 120]. Medical practitioners reported confusion about autonomy, responsibility and insurance which in turn led to a lack of support for NMP [115]. Practitioners working in private practice acknowledged the threat of non-medical prescribers competing for business with medical colleagues [127], and junior doctors felt that non-medical prescribers threatened their roles [117]. Further, some GPs wanted to maintain ownership of patients in health systems in which general practices take responsibility for direct funding of medicines [115 143]. Some participants also reported that the handwritten prescriptions utilised by local non-medical prescribers were often not compatible with electronic prescribing systems, compromising communication and in turn patient safety.

Conversely, medical professionals with positive feelings towards NMP acknowledged the benefits of NMP to service users, healthcare staff and the health economy [52 118]. Participants reported an enhancement in service provision, efficiency and also improved patient care [52]. Doctors acknowledged that non-medical prescribers who had a strong and established relationship with the medical team had the experience and knowledge to prescribe successfully [120 145 147]. NMP was also reported to be extremely helpful in reducing

and avoiding waiting lists, especially in specialities where long-term drug monitoring is prevalent [52 115 118]. Participants reported that when doctors were unable to see patients in a timely manner, non-medical prescribers' ability to initiate, titrate and modify treatments had a positive effect on patients' access to medicines [52 115 118-120]. It was also acknowledged that non-medical prescribers, unlike junior doctors are permanent team members, and therefore become more familiar with drugs, protocols and dose ranges [120]. Recognition of these benefits was reported to drive medical professionals to advocate for the inclusion of NMP into local healthcare systems [52 115 118-120].

TH3.2: Members of the NMP Professions

Participants in 15 (35%) studies with a quality rating range of 5-35 cited that members of the NMP professions themselves could act as both barriers and facilitators to NMP. The main facilitator observed by participants was that of job satisfaction [122 123 133]. Some participants reported that the inclusion of NMP into their roles give them more autonomy, improving the level of patient care they are able to offer [122 123 133].

In opposition to this, other participants reported that the increased risk and responsibilities associated with NMP increased their work-related stress and anxiety, restricting time spent on traditional areas of their practice [112 133]. Many participants supportive of NMP also recognised that NMP would not enhance their individual roles within interdisciplinary teams, as medical prescribers are readily available to prescribe [112 133 140 152].

The phase of an individual's career was also highlighted to affect the uptake of NMP into practice. As a high level of experience is deemed beneficial prior to undertaking NMP

training, it was acknowledged that many clinicians with the necessary experience might prioritise non-clinical job roles, pursue other areas of study or are nearing retirement, not wishing to undertake an NMP course [127 133].

Participants acknowledged the lack of additional remuneration offered to non-medical prescribers as a practical barrier to successful implementation of NMP [122 127 142]. Specifically, the enhanced responsibility and associated safety risks, with no reward (financial or otherwise), was reported to deter many from extending their scope of practice to include the prescription of medicines [129 133 140].

TH3.3: Service Users

Participants in 4 (9%) studies with a quality rating range of 11-29 recognised that the thoughts and perceptions of service users were integral in the successful development and implementation of NMP services. Four (9%) studies reported positive thoughts and perceptions which were seen to be key [50 51 131 141]. The majority of participants were happy with NMP services, citing closer relationships with NMP clinicians than doctors due to the time limitations within medical clinics as benefits of NMP. NMP services were recognised as often being more convenient, providing faster access to the treatment they require than traditional medical care [50 141]. Conversely, participants in 2 (5%) studies reported that they felt prescribing responsibilities belong to medical professionals and were unsure about the qualifications possessed by non-medical prescribers [51 131]. A final subgroup reported that they were happy for non-medical prescribers to monitor long-term medicines use, however assessment of a new medical condition was felt to be the job of the medical practitioner [51].

To avoid poor uptake of NMP services participants recommended that service users were consulted at all the levels and in all phases of service planning, with the education of service users considered essential if these key stakeholders are to be avoided as a barrier to the successful implementation of NMP [50 51 131 141].

TH4.0: Financial Factors

Participants in 11 (26%) studies with a quality rating range of 9-34, reported financial factors to be key facilitators or barriers to NMP. Financial factors underpinned all other themes/subthemes, with adequate funding facilitating NMP into practice, and inadequate funding creating and reinforcing significant barriers to the successful implementation of NMP [115 122 139 143].

Participants considered that funding for time and education should include financial support for initial completion of the NMP course as well as CPD [112 137 139 143]. Appropriate financial resources are required to backfill roles previously undertaken by non-medical prescribers whilst training and following implementation of NMP into their roles [112 129 137 143]. Participants advised that when planning, implementing and developing any NMP services, organisations must ensure they have sufficient financial resources for the necessary infrastructure, logistics, remuneration of staff and other practical implications of NMP such as administrative support and insurance [113 127 137 142].

Participants also highlighted the funding of drugs themselves as a possible impediment to the successful implementation of NMP. Issues related to equity and equality of patient care, especially where patient care crosses borders, organisational boundaries and/or

funding pools, were considered immoral, frustrating, and a barrier to good practice and the successful implementation of NMP [115 129 143].

3.2.3 PHASE 2: Quantitative

3.2.3.1 Study Characteristics

Seven studies were included in phase 2 of the systematic review [49 152-157]; their characteristics summarised in the first 3 columns of Table 7. More detailed characteristics are available in Appendix 8.

Table 7. Phase 2, Included Studies, Characteristics & Quality

Study	Design, setting and speciality	Non-medical prescribers' participation *Total N, (n) from each profession*	Quality *QATSDD Score*
Courtenay & Carey, 2008 [153]	Survey: Postal questionnaire 2006 Range of Specialities	**Total N=1992** Nurses n=1992	21
Courtenay et al, 2012 [49]	Survey: Online questionnaire 2010-2011 Range of Specialities	**Total N=883** Nurses n=793, Managers n=33, Pharmacists n=36, Allied health & Optometrists n=9, not disclosed n=12	22
Farrell et al, 2011 [154]	Survey: Online or postal questionnaire Collection year not recorded Oncology	**Total N=103** Nurses n=103	17
Gumber et al, 2012 [157]	Survey: Postal questionnaire 2010 Range of Specialities	Total **N=20** Nurses n=18, Pharmacists n=2	14
Hutchison et al, 2012 [152]	Survey: Online questionnaire 2010 Range of Specialities	**Total N=342** Pharmacists n=342	19
Kaplan & Brown, 2004 [155]	Survey: Postal questionnaire 2001 Range of Specialities	**Total N=1241** Nurses n=1241	20
Larsen, 2004 [156]	Survey: Postal questionnaire 20 Emergency/ Urgent care	**Total N=192** Managers n=192	14

3.2.3.2 Study Methods

All 7 included studies utilised survey methodology [152-157]. Distribution of questionnaires was varied with n=4 (57%) studies using postal questionnaires [153 155-157], n=2 (29%) using online questionnaires [49 152] and n=1 (14%) providing participants with a choice of both methods [154]. The studies were undertaken in 3 countries from 2001-2011, with 5 (71%) in the UK, 1 (14%) in Canada and 1 (14%) in USA.

3.2.3.3 Participants

A total of 4773 participants were recruited across the 7 studies [152-157]. The key stakeholders recruited were nurses (86.8%), pharmacists (8%), health service managers (4.7%) and allied health/optometrists (0.2%). A small percentage of participants (0.3%) did not disclose their job roles or profession.

3.2.3.4 Interventions

Most of the included studies investigated nurse iNMP (n=4, 57%) [153-156]. Pharmacists were the only other profession individually investigated (n=1, 14%) [152]. One study investigated both nurse and pharmacist iNMP (14%) [157], with 1 further study investigating iNMP as a whole; including all potential professionals (14%) [49]. Six (86%) studies included participants working across both community and hospital settings [153-157], with 1 (16%) focusing on hospital care [152]. Five (71%) studies encompassed all healthcare specialities [49 152 153 155 157], the remaining studies focused on individual specialities including oncology (14%)[154] and emergency/urgent care (14%) [156].

3.2.3.5 Outcomes

All 7 studies contained at least 1 quantitative survey question relating to barriers or facilitators of NMP [49 152-157]. Data supported 3 of the 4 (75%) themes synthesised in phase 1. Four (57%) studies contained data relating to 'Systems Factors' [49 153-155], 5 (71%) studies 'Education & Support' [49 153 155-157] and 5 (71%) studies 'Personal & Professional Factors' [152-155 157]. No studies contained data directly relating to 'Financial Factors'.

3.2.3.6 Quality assessment

Quality scores of the studies included in Phase 2 are summarised in Table 7 and ranged 14-22 (mean=18), with detail of individual quality criteria in Appendix 9. One hundred percent inter-reviewer agreement was achieved regarding quality assessment, with no mediation required from the third reviewer. One hundred percent of the included studies reported a procedure for data collection and clear research setting, with a representative sample of a reasonable size and detailed recruitment data. Less than 45% of studies reported a rationale for the choice of data collection tool, with only 14% of studies providing any justification for the analytical methods selected.

3.2.3.7 Results of Individual Studies and Synthesis of Results

Table 8 summarises the results of individual studies. Each study used different survey questions, measured on a variety of scales. Therefore, meta-analysis was not possible due to the heterogenous nature of the data collected within the included studies.

System Factors

Four studies investigated systems factors [49 153-155]. Results highlighted local policy and lack of access to computer generated prescriptions as key barriers [153 155]. One study [154] assessed barriers due to time, capacity and resources, finding whole health-organisations, rather than individual directorates, were responsible for limiting use of iNMP due to these factors [154]. One study [49] reported 85.5% of employers had up-to-date policies in place, facilitating quality and safe use of NMP. Key elements of these policies were: (1) agreed and documented scope of practice; (2) regular clinical services audit; and (3) standardised procedures for communicating updates regarding safety warning and drug alerts [153].

Education and Support Factors

Two studies investigated education and support factors[49 155]. Results revealed NMP course content, support following qualification, and adequate access to CPD were key factors[49]. Barriers were examined across 3 studies[153 155 157]. Results identified a lack of support from medical professionals and peers, and deficiency of adequate supervision when training to prescribe[153 155 157]. One study investigated factors influencing healthcare managers' decisions to send clinicians on the NMP course[156]. Facilitating factors identified were: (1) increasing autonomy; (2) improvements in patient care; (3) improvements in clinicians' pharmacology knowledge; and (4) improved accountability. Barriers were: (1) time; (2) factors related to the backfill of course candidates; (3) medical supervisor requirements; and (4) a limited formulary being too restrictive to be beneficial[156].

Personal and Professional Factors

Three studies [153] [155] [157] investigated personal and professional factors. Objections and concerns by medical professionals and pharmacists regarding competency, liability and competition were found to be important external factors[155]. Internal factors such as a professional's caseload and fear of litigation were also demonstrated [157]. One study [154] found time, capacity and resources were barriers, reported in some cases as induced by nursing and medical directorates with further reasoning not reported [154]. One study [152] investigated the level of influence of factors affecting an individual's decision to seek or not seek NMP authorisation. Those that had chosen to seek authorisation reported a high relevance to practice and increased efficiency/ job satisfaction as key motivators. Clinicians who decided not to seek authorisation reported concerns regarding increased liability and poor relevance to their practice as key factors not to prescribe [152].

Table 8. Outcomes from Individual Studies Linked to Key Themes

Theme: System Factors - Mean QATSDD Rating 20 (range 17-22)			
Study	Findings Related to Theme	Significance Tested?	QATSDD Rating
Courtenay & Carey, 2008[153]	Barriers to independent NMP: (reported by n (%) participants) Local policy 619 (66%), National policy 87 (9.3%) Unable to utilise computer generated prescriptions 575 (61.3%) Access to medical records 26 (2.8%)	No	21
Kaplan & Brown, 2004[155]	Barriers to independent NMP: (reported by n (%) participants) Restricted formularies 183 (24%)	No	20
Farrell et al 2011[154]	Time & capacity and resources were reported to be barriers induced by: (reported by n (%) participants) The health organisation (n=41, 40.6%) Nursing directorate (n=14, 13.9%) Medical directorate (n=22, 21.8%)	No	17
Courtenay et al, 2012[49]	88.5% of employers had up to date NMP policies in place. Policies dictated: (reported by n (%) participants) Regular audit and review of clinical services n=561 (74.3%) Regular feedback data re. Prescribing practice n=328 (43.7%) Access own prescribing practice data n=281 (37.3%) Agreed scope of practice with employers n=642 (85.1%) Supplied with safety warnings, drug alerts etc. n=678 (89.5%) Non-medical prescribers involved in the development of local formularies and guideline n=357 (47.7%)	No	22

Theme: Education & Support Factors- Mean QATSDD Rating 18 (range 14-22)			
Study	Findings Related to Theme	Significance Tested?	QATSDD Rating
Courtenay et al, 2012[49]	Facilitators of independent NMP: (reported by n (%) participants) Adequate support following qualification as an independent non-medical prescriber 304 (47%) Adequate access to CPD to support their prescribing roles 561 (74.3%)	No	22
Courtenay & Carey, 2008[153]	Barriers to independent NMP: (reported by n (%) participants) Lack of peer support 126 (13.4%)	No	21
Kaplan & Brown, 2004[155]	Barriers to independent NMP: (reported by n (%) participants) Medical professional availability to support 33 (4%)	No	20
Gumber et al, 2012[157]	Barriers to independent NMP: (Influence reported on Likert scale) Adequate supervision; Strongly agree n=4 (20%), Agree n=10 (50%), Undecided n=4 (20%), Disagree n=2 (10%) Facilitators of independent NMP: Prescribing course content; Strongly agree n=4 (20%), Agree n=12 (60%), Undecided n=2 (10%), Disagree n=2 (10%) Support and guidance from medical professional; Strongly agree n=11 (55%), Agree n=9 (45%)	No	14
Larsen, 2004[156]	Facilitative factors influencing managers' decision to send clinicians on the NMP course: (% participants agreed with factor); Autonomy (44%), Patient care (37%), Improve clinicians' pharmacology (38%), Improve knowledge of accountability (34%), Requested by staff (18%), Recruitment & retention (11%), Organisational drivers (14%) Barriers influencing managers' decision not to send clinicians on the NMP course: (% participants agreed with factor); Time (11%), Backfill (17%), Formulary too limited to be beneficial (29%), Finding medical supervisor (11%), Poor medical support (2%), Funding of drugs (0.5%), Poor intra-professional support (1.6%)	No	14

Theme: Personal and Professional Factors- Mean QATSDD Rating 18 (range 14-21)			
Study	Findings Related to Theme	Significance Tested?	QATSDD Rating
Courtenay & Carey, 2008[153]	Barriers to independent NMP: (reported by n (%) participants) Objections by Medical professionals/Pharmacists 153 (16.3%)	No	21
Kaplan & Brown, 2004[155]	Barriers to independent NMP: (reported by n (%) participants) Medical professionals' concerns regarding liability 183 (24%) Competition between medical and non-medical prescribers 33 (4%)	No	20
Gumber et al 2012[157]	Barriers to independent NMP: (Influence reported on Likert scale) Conflicts with medical staff; Agree n=9 (45%), Undecided n=1 (5%), Disagree n=4 (20%), Strongly disagree n=6 (30%) Significant increases in caseload; Strongly agree n=2 (10%), Agree n=11 (55%), Undecided n=5 (25%), Disagree n=1 (5%), Strongly disagree n=1 (5%) Fear of litigation; Agree n=7 (35%), Undecided n=7 (35%), Disagree n=5 (25%), Strongly disagree n=1 (5%)	No	14
Farrell et al, 2011[154]	Time & capacity and resources were found to be barriers induced by: (reported by n (%) participants) Nursing directorate 14 (13.9%) Medical directorate 22 (21.8%)	No	17
Hutchison et al, 2012[152]	Level of influence on individual's decision to seek NMP authorisation: (scale; *not at all, slightly, somewhat, moderately, strongly)* *Influential factors- rating by clinicians whom had applied for authorisation to prescribe:* Relevance to practice- Strongly (70.3%), Moderately (21.6%), Somewhat (5.4%), Slightly (2.7%), Not at all (0%) Increased efficiency- Strongly (62.2%), Moderately (21.6%), Somewhat (2.7%), Slightly (10.8%), Not at all (2.7%) Importance to the profession- Strongly (55.6%), Moderately (22.2%), Somewhat (11.1%), Slightly (2.8%), Not at all (8.3%) Time- Strongly (8.3%), Moderately (19.4%), Somewhat (5.6%), Slightly (11.1%), Not at all (55.6%) Job satisfaction- Strongly (37.1%), Moderately (28.6%), Somewhat (11.4%), Slightly (8.6%), Not at all (14.3%)	No	19

	Concerns, increased liability- Strongly (17.1%), Moderately (17.1%), Somewhat (17.1%), Slightly (34.3%), Not at all (14.3%) *Influential factors- rating of factors by clinicians whom decided NOT to apply for authorisation to prescribe:* Relevance to practice- Strongly (36.7%), Moderately (25.5%), Somewhat (16.7%), Slightly (6%), Not at all (15.1%) Increased efficiency- Strongly (16.3%), Moderately (15.9%), Somewhat (17.1%), Slightly (14.3%), Not at all (36.3%) Importance to the profession- Strongly (13.8%), Moderately (13%), Somewhat (21.1%), Slightly (10.9%), Not at all (41.3%) Time- Strongly (17.8%), Moderately (17.8%), Somewhat (16.6%), Slightly (8.9%), Not at all (38.9%) Job satisfaction- Strongly (6.5%), Moderately (15.1%), Somewhat (15.5%), Slightly (17.6%), Not at all (45.3%) Concerns, increased liability- Strongly (23.4%), Moderately (22.5%), Somewhat (22.5%), Slightly (16.4%), Not at all (15.2%)		

3.2.4 PHASE 3: Integration

3.2.4.1 Study Characteristics

Data from 12,117 participants (combined from phases 1 & 2) were integrated. Table 9 shows the total number of participants from each stakeholder group involved in iNMP included in the integration. Seventy-three percent of all included studies reported funding sources within the published article.

Table 9. Total Number of Participants Included in the Systematic Review

Stakeholder Group	Total, n (%)
Nurses	8466 (70%)
Service users	2527 (21%)
Pharmacists	625 (5%)
Managers	242 (2%)
Medical Doctors	114 (0.9%)
NMP Leads	72 (0.6%)
Others	42 (0.3%)
Administrative Staff	20 (<0.1%)
Allied Health Professionals	9 (<0.1%)
Total (n)	12,117 (100)

3.2.4.2 Integration of Phase 1 and 2 Results

Data from phases 1 and 2 were brought together in the integration matrix (Figure 12) and used to construct the resultant 'NMP Implementation Framework' (Figure 13).

The rows of the matrix represent the subthemes developed from synthesis of the qualitative studies in phase 1, and the columns contain citations of the quantitative studies included in phase 2. Intersecting cells contain the level of agreement or "influence factor"

between each quantitative study's data and the qualitative subtheme. The "influence factor" was calculated in accordance with the criteria in Figure 9.

Data extracted from the quantitative studies corroborated the existence and importance of the subthemes identified in 3 themes developed in Phase 1. Integration was undertaken for 6 (75%) subthemes within these themes. No data from phase 2 disagreed with the thematic synthesis. Integration was not possible for financial factors, government and political factors and service users' subthemes, as no data relating to these theme/ subthemes was retrieved in phase 2.

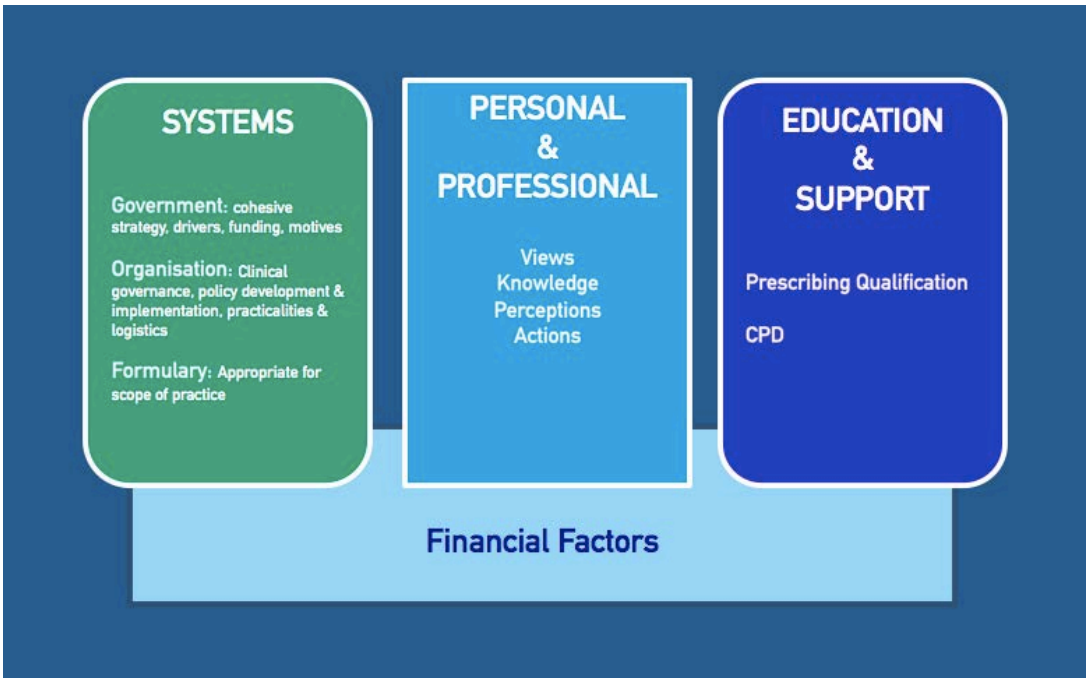
Figure 12: Qualitative and Quantitative data Integration Matrix

Theme/Subtheme (Phase 1)	Study Reference Number (Phase 2)							**Overall Impact Across Studies**
	44	45	46	47	48	49	50	
TH1.0 Systems Factors								
Government and Political Factors	NA	NA	NA	NA	NA	NA	NA	**Not Assessed**
Organisational Factors	b	b, f	b	NA	NA	NA	NA	**Potential Barrier & Facilitator**
Restricted Formulary	NA	NA	NA	NA	NA	b	NA	**Potential Barrier**
TH2.0 Education and Support								
Education	NA	f	NA	b, f	NA	NA	b, f	**Potential Barrier & Facilitator**
Support	b	f	NA	b, f	NA	b	b, f	**Potential Barrier & Facilitator**
TH3.0 Personal and Professional Factors								
Members of the Medical Profession	b	NA	b	b	NA	b	NA	**Potential Barrier**
Members of the NMP Professions	b	NA	b	b	b, f	NA	NA	**Potential Barrier & Facilitator**
Service Users	NA	NA	NA	NA	NA	NA	NA	**Not Assessed**
TH4.0 Financial Factors Not Assessed by Included Quantitative Studies								
Key: barrier shown with statistical significance (B), barrier reported with no statistical significance testing undertaken (b), facilitator shown with statistical significance (F), facilitator reported with no statistical significance testing undertaken (f), no impact, no statistical significance on testing (NI), not assessed (NA)								

3.2.4.3 Quality assessment across phases 1 and 2

Quality scores of the studies included in Phases 1 and 2 had a range 5-35 (mean= 20.56). Owing to the broad contribution of the included studies across the synthesised themes, the quality of the evidence used to generate each individual theme was diverse.

Figure 13: NMP Implementation Framework: factors to consider when implementing iNMP



3.3 DISCUSSION

3.3.1 Summary of Evidence

This rigorous systematic review assessed what is known about the barriers to and facilitators of iNMP, evaluating the extent to which specific factors impact successful implementation and utilisation; synthesising data from n=50 studies of diverse quality (QATSDD range, 5-35). Identified barriers and facilitators reflected 4 themes: system factors; education and support factors; personal and professional factors; and financial factors. Whether a factor acted as a barrier or a facilitator was context dependent. The quantitative survey data corroborated the themes developed from the qualitative literature, providing valuable insight into the perceived barriers and facilitators to iNMP across the key stakeholder groups.

3.3.2 System Considerations

The findings from this systematic review demonstrated that the successful implementation of iNMP requires a co-ordinated, transparent and inclusive approach at all levels [115 121 132]. From national governments to local clinical departments or businesses, the development of laws, regulations, guidelines, policies and procedures must be created with consistency and through consultation with all key stakeholders. It is also essential that the process be flexible enough to meet a local community's needs [115 121 143]. A thorough and transparent development and implementation process is fundamental in limiting implementation barriers such as personal and professional self-interest, professional territorialism, fear of change, unhealthy competition and poor quality or unsafe clinical practice [117 127]. To alleviate the risk from these potential barriers, a strategic, collaborative and consultative

process is recommended [115 121 143]. Comprehensive education of all stakeholders, from those implementing NMP services to those applying and benefiting from them, is integral to strategy development and should include training on the potential benefits and risks informing decision-making, alongside open discussions and debates to alleviate concerns [115 117 120].

The review's findings indicate that historically, successful implementation and acceptance of iNMP has benefitted on a national level from government instigated targets and political pressures, along with incentives such as innovation and implementation funding for education and necessary infrastructure [115 143]. Locally, implementation appears to be driven by highly motivated individuals inspired to improve the delivery of healthcare within existing services [122 123 133]. These observations confirm results from a study completed in the UK that evaluated nurse and pharmacist independent prescribing [15]. This large national evaluation recognised that a lack of local planning and strategic vision has been a key barrier within the UK in the past. The study concluded that the aspirations of individual practitioners to provide quality care led them to pursue NMP qualifications and thus these individuals have been instrumental in successful implementation of iNMP [15]. More recent audit data from the UK has identified a gradual change in implementation drivers [1]. Centrally driven political agendas although still potentially significant, are now being strengthened locally through recognition of potential economic savings to the local health economy [1]. Unfortunately, a contemporary evaluation of physiotherapist and podiatrist independent prescribing has established that poor strategic planning leading to time and budgetary obstructions remains a dominant barrier to implementation in the UK [25].

With potential economic savings driving the successful implementation of NMP within health organisations, the necessity for robust local clinical governance policy to protect both those using NMP services and non-medical prescribers themselves is paramount, and was highlighted throughout both the qualitative and quantitative literature included within this systematic review [49 115 121 153]. Clinical governance policies must be included in the induction procedures for new staff and accessible to all associated stakeholders, to ensure transparency and accountability [120]. Where possible, policy should be locally defined within an agreed national framework, as different clinical settings will require different procedures and safeguards depending on locality, availability of immediate clinical support and professional speciality [142]. This systematic review identified the requirement for clearly defining scope, parameters, boundaries, accountability and lines of responsibility in order to avoid risks associated with potential confusion and ambiguity [142]. For example, clear and accessible standards and guidelines documenting requirements for clinical and process documentation, emergency policies, incident reporting and communication are essential to embed a culture of quality and safety [137 138 142 143]. Further, governance relating to audit of practice and CPD requirements should be clearly established and adhered to. It is recommended that registers of prescribing clinicians and practice locations be kept both nationally and locally, aiding in the governance of accountability and consumer interests [121]. The importance of clinical governance to minimise the risk of clinical incidents and errors is recognised in both public and private healthcare settings, across primary, secondary and tertiary care. Further recommendations emphasise the importance of resolving issues related to governance in order to facilitate successful implementation of NMP.

This review establishes that iNMP should be integrated as an additional clinical skill, complementing traditional expertise and scope of practice, to enhance patient care [121 142]. It is postulated that for iNMP to be implemented successfully, the misconception that non-medical prescribers should simply be utilised as inexpensive replacements for medical staff in conventional clinic environments must be clarified [121 142]. The simple unloading of prescribing appears to conform better to a supplementary prescribing model rather than effective use of iNMP. Clinicians must prescribe within their own competency, within their professional codes of conduct and in accordance with both national and local policy [137 138 142 143 147]. Any pressure from clinical colleagues and healthcare managers to prescribe out of scope must be identified and managed appropriately. NMP should be integrated as an additional clinical skill, complementing traditional expertise and scope of practice, to enhance patient care [121 142]. Adoption of innovative service designs, with patients' best interests at the heart of all decision-making may therefore be key to successfully optimising NMP practice. Clinicians applying NMP may work across jurisdictional and organisational boundaries, with their patients often requiring care both in the community and hospital settings. Where this is the case, health organisations should work together to ensure, where possible, that bureaucracy does not limit clinicians' abilities to provide the care required by the service users [118 121 129].

This review's findings demonstrate that practical and logistical factors might be key to successful implementation and ongoing use of NMP. The provision of the appropriate infrastructure (including facilities, IT and communications), administrative support and logistics were highlighted as key by the included studies, and are acknowledged in the wider literature to dramatically affect the integration of any new healthcare service [158]. Ideally, non-medical prescribers should be able to access medical records, as well as

diagnostics and investigation results required for assessment, diagnosis and monitoring [121] [129] [131] [153] [154]. This review also highlights that timely registration, authorisation to prescribe and access to electronic prescribing or traditional prescription pads appears key in reducing qualification to prescribing time, optimising the likelihood that a non-medical prescriber will feel confident enough to use their prescribing skills [129] [142] [146]. Organisations should therefore give due consideration to these practical factors when designing NMP systems. To ensure the longevity and future expansion of NMP, health organisations should aim to future-proof services through workforce and succession planning, alongside clinical outcome and cost-effectiveness audits to ensure ongoing quality, effectiveness and funding.

Debate over the barriers created by limiting or restricting formulary for use by non-medical prescribers was described in both the qualitative and quantitative literature of this systematic review. Owing to innovations in medical science, clinicians, health organisations and authorities have recognised that legally restricted formularies may quickly become outdated [114] [140] [147] [148]. Restrictions within scope of practice are thought to deter potential non-medical prescribers from training, and lead to professional frustration and low levels of engagement for those qualified [133]. Although it is argued that limiting the availability of a full national formulary to non-medical clinicians may reduce the risks of unsafe practice, many believe that iNMP should be guided by an individual's competency and scope of practice [115] [133] [155]. Formularies written in law have the potential to confine the use of up-to-date evidence-based practice and further limit the expansion of iNMP. It is therefore suggested that risk may be managed via local formulary defined in organisational policy. This method has the benefit of flexibility without restrictions in law, whilst protecting the local prescribers and service users [115] [133].

3.3.3 Educational Considerations

Pre-agreed academic and professional requirements, NMP qualification and ongoing CPD requirements were identified in this systematic review as impacting the successful implementation and ongoing use of NMP [49 52 121 143]. Selection criteria alongside academic and professional prerequisites are currently utilised by health organisations and higher education institutions to ensure academic ability, safeguard quality and select suitable candidates onto an NMP course [121]. It must be acknowledged that meeting these criteria may involve candidates completing additional education; acting as a significant barrier to many clinicians wishing to extend their scope to include NMP. Few financial incentives exist to encourage clinicians to undertake NMP training [133]. Therefore, on-going funding associated with time, course fees, backfill of staff and ongoing CPD activity must be included in organisational budgets to enable successful implementation. The relatively small number of eligible candidates wishing to undertake NMP qualifications has led to the development of multidisciplinary programmes in order for universities to feasibly run the courses [142 143]. Although these courses fulfil nationally agreed standards, the evidence suggests that a lack of profession-specific content may lead to candidates feeling underprepared [123 142 143]. Further, lack of access to qualified independent prescribers as mentors may impede qualification, with inconsistencies in mentorship quality affecting a clinician's confidence to prescribe in the long-term [111 142 155]. These factors therefore require further investigation to ensure high quality education and resource optimisation.

As with all areas of clinical practice, CPD is essential to ensure ongoing evidence-based practice and quality of care. Access to appropriate and relevant CPD as well as the time to complete CPD activities appear to be variable and organisation specific [49 133 143 155]. This

review highlights a clear inconsistency in the quality and quantity of CPD activities available. To address this inconsistency, it has been suggested that national frameworks be developed that govern/direct CPD activity and to encourage support from managers for clinicians to access time and funding [52 121 133 143]. It is recommended that registers of prescribing clinicians and practice locations be kept both nationally and locally, aiding in the governance of accountability and consumer interests [121]. To overcome a deficit in the availability of speciality specific CPD courses, in-house and external 'buddy systems' and multidisciplinary in-service and special interest group training programmes are recommended [124 147].

3.3.4 Thoughts and Perceptions of Stakeholders

This systematic review illustrates that the positive or negative thoughts and perceptions about the acceptability and value of NMP of individual stakeholders and their wider professions, clearly influences the level of support offered directly to non-medical prescribers, their educational activities and to NMP services as a whole. These key themes appear intimately linked, with alignment between the qualitative and quantitative data indicating that these areas are key to the successful implementation of iNMP. Previous research investigating the influence of team effectiveness and organisational context on implementation of clinical innovation confirms that success not only depends on the interests and skills of individuals, but also the respect, motivation, integration and co-ordinated interaction of a team as a whole [159]. Therefore, engagement and support from all stakeholder groups including government, local health authorities, managers,

professionals and service users is essential for service design, implementation and further development of NMP services.

A large proportion of the studies reviewed acknowledged that successful adoption of iNMP requires medical professionals' engagement not only in consultative, planning and governance roles, but also as supervisors for clinicians undertaking a NMP course and as mentors following qualification [123 136 142 155]. Fears such as the risk of deskilling, loss of power and job roles, competition to earnings in private practice and confusion regarding autonomy, responsibility, liability and insurance, may influence the level of support attained from those in medical roles [112 115 120]. Contrary to this, many medical professionals regard NMP as an enhancement in service provision and efficiency, with the potential to improve patient care. When implemented well, medical professionals have reported the absence or reduction in waiting lists and improvements in timely patient monitoring and reviews, welcoming the sharing of the clinical burden associated with modern day health care [52 118]. This systematic review's findings demonstrate an almost even split between medical professionals' positive and negative 'thoughts and perceptions' about NMP; with 16 studies reporting positive findings and 18 studies reporting negative findings. However, the reported thoughts and perceptions may have limited transferability to the wider medical community, as only 114 medical professionals from a narrow range of specialities were included in the review.

Supportive medical staff frequently identified highly skilled and experienced clinicians as ideal candidates to train as non-medical prescribers. These clinicians are often colleagues who have worked alongside the medical staff in multidisciplinary teams for many years and have earned the respect of their medical colleagues [120 145]. Interestingly, this highly

regarded population, whilst understanding the benefits of NMP, frequently comment that they have no need to prescribe due to their close working relationship and proximity with medical professionals in clinics [112 133 152]. Some senior clinicians, who are supportive of younger colleagues completing NMP qualifications, believe that pursuing the qualification themselves would be a poor investment in time and money as they near retirement, or carry smaller clinical caseloads, with the majority of their time utilised for managerial pursuits, teaching or research [133].

The importance of support from within and across the NMP professions to the successful implementation of NMP was inherent across a large number of the included studies. Improved job satisfaction due to increased autonomy and the ability to provide improved patient care appear to be key drivers for clinicians undertaking NMP roles [122 123 133]. Conversely, increased job stress and anxiety, associated safety risks and restricted time to complete traditional roles, with no increase in remuneration for the increased responsibility, are commonly associated as barriers to undertaking NMP qualifications [112 133]. These negative aspects could be alleviated by better engagement of and more support from key stakeholders. Consistent with the findings of previous research [160], this review emphasises the benefits of adopting NMP lead roles within health organisations to aid in overcoming systems, personal and professional barriers [120 121]. Although there appears to be a lack of clear definition surrounding the NMP lead role, research in the UK has confirmed that the main functions of the role include: strategic influence, operational management and clinical governance [160]. NMP leads may therefore be key to managing implementation, coordination and promotion at strategic and policy levels. By supporting the successful implementation of NMP through advocating for colleagues, disseminating important prescribing related information and supporting non-medical prescribers, NMP

leads can also assist with reducing feelings of isolation, where the number of prescribers are limited.

3.3.5 Service Users

The qualitative synthesis of this review demonstrated that service users' knowledge, opinions, perceptions, needs and preferences appear key to the successful implementation of NMP and the development of new services [50 131 141]. Although this subtheme was not investigated by the included quantitative studies, the findings are consistent with the greater health and public service literature [161 162]. The co-production of services is reported to broaden the viewpoint of development committees and enable the transfer of power from the professionals to service users. This exchange of power is thought to stimulate the local community through various communication strategies, enhancing community support to embrace innovation and accept change [161 162]. If service users are to be avoided as a barrier to success, consultation with this important stakeholder group at all levels and in all phases of iNMP service planning and development, by government and health organisations may be beneficial.

3.3.6 Financial Considerations

The remaining theme identified in the review refers to the financial factors associated with iNMP. Although this theme was not directly assessed within the included quantitative studies, financial factors were observed to underpin the influence of the barriers and facilitators of iNMP identified within the other three themes. Interestingly, participants

within the qualitative literature frequently reported time and money simultaneously [122 139 143]. Time required for activities associated with 'systems' development and maintenance or 'education and support', are acknowledged to have financial implications. These essential activities such as policy development, provision of study leave and peer support were consequently investigated within the quantitative literature [153 156 157].

The importance of financial support was evident in a large proportion of the included studies. To promote iNMP implementation and practice, health organisations should undertake thorough economic evaluation as part of planning and development phases, to secure the appropriate financial budgets required for success. It is likely that financial barriers will vary dependent on geographical location, profession and clinical speciality [113 137 142]. It is recommended that complexities related to funding streams crossing organisational boundaries or fragmented health systems should be resolved prior to offering iNMP services to ensure no detrimental effects to patient care or clinician job satisfaction [115 129 143]. Whilst the potential economic savings act to engage many individuals or professions with the benefits of utilising iNMP, some financial factors act to resist iNMP through fear of competition and loss of earnings, difficulties in modernising funding streams and increased clinical responsibility with potentially no increase in remuneration. If iNMP is to further grow and develop, these barriers must be acknowledged, planned for and resolved across all aspects of the health economy.

The original database searches were completed in May 2015. Searches were re-run prior to publication with no additional studies meeting inclusion criteria [88]. Searches and study selection procedures were repeated In December 2019. The mixed methods systematic review remains up to date with no further studies satisfying inclusion criteria.

3.3.7 Strengths and Limitations

The present review used rigorous systematic methods; utilising comprehensive searches of both published and unpublished literature using predetermined criteria to investigate the barriers to and facilitators of iNMP. Rigorous analysis of the quality of the evidence collected employed a validated framework specifically developed for mixed methods designs with a synthesis strengthened by the engagement of a multidisciplinary research team, including both registered non-medical prescribers and non-prescribers. This combination ensured specialist knowledge of iNMP alongside specific disciplinary perspectives, facilitating a rigorous analytical process. The lead researcher was utilised as a reviewer thus potentially leading to the inclusion of studies likely to prove the anticipated result [78] [79]. However, parallel reviewing techniques were employed to maximise trustworthiness, with an independent third reviewer available for consultation across all methodological stages in all phases of the review [73].

No studies were excluded from the thematic synthesis based on quality assessment scores. This ensured that all participants' views were included, evaluated and integrated within the synthesis [101] [102]. The broad contributions of all of the included studies to the synthesis of the themes, dictated that the quality of evidence used to synthesise each theme was diverse. Although the quality of the included studies was seen to vary across the studies, consistency in themes was established, strengthening the review findings. The sequential exploratory approach enabled the evaluation and integration of a rich qualitative synthesis and quantitative analysis to answer the research question, demonstrating a holistic view of the current evidence base, facilitating the development of a pragmatic and analytical framework.

The breadth and comprehensiveness of the review has enabled the development of a pragmatic and analytical framework synthesised from data collected from a population of 12,117 stakeholders engaged with iNMP. Although the majority of participants were nurses, the included participants represented community and hospital settings in both rural and urban areas, providing care across a range of cultural and ethnic diversities. Notwithstanding the diversity in contexts across the included studies, common themes were evident. Consequently, the review may be combined with other literature to aid in the future successful implementation and utilisation of iNMP across these context specific healthcare settings.

Most included studies were limited to nursing, representing a narrow group of clinical specialities potentially limiting transferability of the results across all clinical and professional specialities. The included studies were conducted in only 3 western developed countries. Although no variations in themes were noted between the included countries and the countries were representative of the current states using NMP, the small number of western countries represented may limit the transferability of this review internationally.

It may be reasonable to argue that factors such as human knowledge, perceptions, thoughts and feelings may change with time and as the incidence of NMP evolves. No temporal or spatial analysis was undertaken within the review; therefore, the contemporary nature of the barriers or facilitators identified may be limited. Caution is therefore recommended when interpreting the review's results into individual contexts.

3.4 CONCLUSION

This is the first mixed methods systematic review to investigate the barriers and facilitators of iNMP. Integration of the quantitative and qualitative data demonstrates, with strong agreement, multifactorial and context specific variables existing within 4 explicit themes. The evidence supports that when factors are acknowledged and accommodated, they become facilitators, but may become barriers when they are not. Clinical physiotherapists and other clinicians should consider whether these factors have been adequately addressed before training to become non-medical prescribers. Politicians, policy professionals, healthcare managers and clinicians should use the resulting NMP implementation framework to ensure the safe and successful adoption, implementation and utilisation of physiotherapist prescribing. Where physiotherapist prescribing is currently outside the legal scope of practice, the resulting NMP implementation framework, and this review's evidence, should be core to the implementation strategy of physiotherapy professional bodies wishing to adopt NMP practice. There is a clear need for future research to evaluate the personal and professional motivations for physiotherapy prescribing internationally, implementation strategies and the efficacy in terms of clinical and cost-effectiveness of services employing iNMP. To fully understand the long term uses of NMP it is paramount that variables such as profession, speciality, geographic location, clinical indications and funding models are assessed alongside the needs of service users, communities and the impact on all stakeholders.

3.5 DISSEMINATION OF RESULTS

The results of the research have been published in the Journal of Physiotherapy, an international peer reviewed journal (Appendix 10) [163].

Noblet T, Marriott J, Graham-Clarke E, Rushton A. Barriers to and facilitators of independent non-medical prescribing in clinical practice: a mixed methods systematic review. Journal of Physiotherapy 2017;63(4):221-34. doi: https://doi.org/10.1016/j.jphys.2017.09.001

Response to expert reviews comments prior to publication are found in Appendix 11. Findings were also dissemination at peer reviewed international and national conferences:

Noblet T, Marriott J, Graham-Clarke E, Rushton A. The Barriers to and facilitators of independent non-medical prescribing in clinical practice: a mixed methods systematic review. Podium presentation The World Confederation for Physical Therapy (WCPT) Congress. July 2017; Cape Town, South Africa.

Noblet T, Marriott J, Graham-Clarke E, Rushton A. The Barriers to and facilitators of independent non-medical prescribing in clinical practice: a mixed methods systematic review. Podium presentation, Physiotherapy UK 2018, Oct 2018; Birmingham, UK

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3.7 CHAPTER SUMMARY

This chapter aimed to establish an evidence base identifying previously reported existing barriers to, or facilitators of, the implementation and or utilisation of iNMP. Owing to the deficit in literature evaluating the clinical and cost-effectiveness of NMP, health service stakeholders are unable to use the efficacious nature of NMP to advocate for the implementation and utilisation of physiotherapist independent prescribing. Given the contemporary nature of physiotherapist independent prescribing, effective implementation and utilisation strategies must therefore be learnt from other NMP professions.

43 qualitative and 7 quantitative studies from 3 countries (n=12,117 participants) were included in the mixed methods systematic review. Barriers to and facilitators of the implementation and utilisation of NMP were evident within the literature and demonstrate multifactorial and context specific variables within 4 explicit themes (subthemes): systems (government & political, organisational, formulary); education and support (NMP courses, CPD, support requirements); personal and professional (medical profession, NMP professions, service users); and financial factors. Data from the quantitative studies corroborated qualitative themes and integration of the qualitative themes and quantitative data enabled the development of an iNMP implementation framework reflecting all key themes.

It is clear that when factors are acknowledged and planned for, they become facilitators, but when they are not, they may become barriers. The resulting NMP implementation framework may therefore be useful to aid the safe and successful implementation and utilisation of NMP.

The NMP implementation framework developed clearly identifies that personal and professional factors including views and perceptions of the individuals within a profession can strongly influence the successful implementation of NMP. Acknowledging this important finding and the lack of consultation across the Australian physiotherapy profession prior to submission of a proposal for the endorsement of registered physiotherapists as autonomous prescribers to the Physiotherapy Board of Australia; the following chapter evaluates the views and perception of the Australian physiotherapy profession about the potential introduction of physiotherapist prescribing in Australia. It is hoped that the findings detailed in Chapter 4 will inform the quality, safe and effective implementation across Australian states and territories in the future.

CHAPTER 4: VIEWS AND PERCEPTIONS ABOUT THE POTENTIAL IMPLEMENTATION OF PHYSIOTHERAPIST PRESCRIBING IN AUSTRALIA: A NATIONAL SURVEY OF AUSTRALIAN PHYSIOTHERAPISTS AND PHYSIOTHERAPY STUDENTS

Chapter overview:

This chapter presents the views and perceptions of Australian physiotherapists about the potential introduction of physiotherapist prescribing into the scope of practice of the Australian physiotherapy profession, addressing thesis objective 3. Data from 1409 participants are analysed and similarities and differences between geographical regions, health sectors and Australian Health Practitioner Regulation Agency (AHPRA) registered and student physiotherapists are discussed. Predicted benefit and risks of the introduction of physiotherapist prescribing are considered alongside the development of governance and educational frameworks.

Sections of this chapter are taken verbatim from the following publications in which I am principal author.

Noblet T, Marriott J, Jones T, Dean C, Rushton A. Views and perceptions of Australian physiotherapists and physiotherapy students about the potential implementation of physiotherapist prescribing in Australia: a survey protocol. BMC Health Services Research 2018;18(1):472. doi: 10.1186/s12913-018-3300-x

Noblet T, Marriott J, Jones T, Dean C, Rushton A. Perceptions about the implementation of physiotherapist prescribing in Australia: a national survey of Australian physiotherapists. BMJ open 2019;9(5): e024991

Noblet T, Marriott J, Jones T, Dean C, Rushton A. Perceptions of Australian physiotherapy students about the potential implementation of physiotherapist prescribing in Australia: a national survey. BMJ open 2019;9(5): e026327

To ensure the reader has a clear understanding as to why methodological decisions were made, the methods section of the published protocol article has been extended for clarity and transparency. This chapter blends the results and discussions presented across the two publications. Data are synthesised across AHPRA registered physiotherapists and student physiotherapists, additional results presented, and all findings discussed. An expanded evaluation of the strengths and weaknesses of the study is detailed.

Details of authors' contributions to the published paper (as acknowledged in the article):

TN is a PhD candidate at the University of Birmingham (UK). AR is a reader in musculoskeletal rehabilitation sciences and lead supervisor. JM is a professor of clinical pharmacy and co-supervisor. Both supervisors ensured the rigour of methods and analyses. CD is a professor of physiotherapy and TJ is an associate professor of physiotherapy at Macquarie University (Australia). CD and TJ acted as expert advisors. TN wrote the first draft of this article and led on subsequent drafts with feedback from supervisors and experts.

4.0 BACKGROUND

The ever-increasing healthcare requirements of the Australian population require additional healthcare workers across all disciplines [164]. The necessity for the physiotherapy workforce to meet the demands of the growing and ageing population requires the training of new physiotherapists alongside retention of senior physiotherapists with advanced clinical expertise [164]. Increasing numbers of junior physiotherapists are being educated through traditional and contemporary entry-level physiotherapy programmes across Australia [165], resulting in physiotherapy being the third largest healthcare profession nationally [166]. Although attrition through retirement is inevitable, anecdotal evidence suggests a high-level of attrition in the early years following qualification owing to burnout, stress or ill health, family responsibilities or dissatisfaction with the profession [164 166 167]. Research demonstrates that a perceived lack of clinical and professional support, limited potential for promotion or formal career progression, alongside poor professional recognition and low remuneration contributes to 30% of clinicians being dissatisfied with their roles [166].

The mounting prevalence of complex, chronic disease alongside the ageing and growing population in Australia is increasing the burden on healthcare systems [168]. Innovation in practice is required to meet increasing demands, with many health professionals now working with an extended and advanced scope of practice [6 169]. Advanced physiotherapist roles have been introduced internationally, enabling innovative evidence-based care to optimise patient outcomes and develop the profession so that it is fit for the future [170-173]. In Australia, advanced MSK practitioners have been introduced to orthopaedic interface-services and emergency departments [22]. A recent systematic review examining the

substitution of medical doctors for physiotherapists in the management of MSK disorders has supported this expansion of roles, with physiotherapists demonstrating parity of clinical outcomes with orthopaedic surgeons, with greater patient satisfaction [172]. Following the introduction of physiotherapist independent prescribing in the UK [91], a proposal for the endorsement of registered physiotherapists as autonomous prescribers has been submitted to the Physiotherapy Board of Australia [39], aiming to further address health service inefficiencies and improve access to medicines for all Australians, across all communities regardless of their geographical location [39]; as well as improving clinicians' job satisfaction, leading to increased retention of skilled physiotherapists [39]. The Australian Physiotherapy Association (APA) in collaboration with the Australia Physiotherapy Council (APC) and Council of Physiotherapy Deans Australia and New Zealand (CPDANZ) have commenced national processes to evaluate potential clinical need, quality and safety issues [39]. The anticipated future implementation in Australia will require physiotherapists, alongside politicians, policy makers and healthcare managers, to welcome change within national and local healthcare systems [1 39 47 48].

The mixed methods systematic review of the NMP literature found in Chapter 3, evaluating the facilitators and barriers to NMP, across all professions internationally, identified 4 main themes affecting the implementation and utilisation of NMP: systems, education and support, personal and professional, and financial factors [163 174]. Analysis of the 'Personal and Professional' theme highlighted that the views and perceptions of individual clinicians' may or may not agree and/or be synergistic in nature with the overall view of the profession as a whole. This is important as potential conflict within a profession has been identified as a barrier to implementation of new clinical innovations [159]. Diverse perceptions regarding the implementation of physiotherapist prescribing and current

physiotherapeutic pharmacological knowledge and practices have been reported in national evaluations in Nigeria, South Africa and the UK [42-44 56]. Data from these evaluations have been utilised to influence national policy and the political drive towards or against the adoption of NMP within the physiotherapy profession in these countries [44 56]. Anecdotal evidence suggests that physiotherapists prescribing may retain Australian physiotherapists within the profession, as they would be able to optimally utilise their knowledge and skills, providing seamless patient care regardless of geographical location or health sector [39 175]. However, survey literature investigating the views of NMP professions in the UK and USA suggests that views about NMP by the individual professional may vary depending on the individual's job specification, access to medical support, geographical location, health sector, level of experience and the timespan of the individual's career [112 123 127 133 140].

Early identification of views and perceptions of both current practitioners and the next generation of physiotherapists in Australia is therefore required. To date no evidence exists evaluating the Australian physiotherapy professions' views and perceptions about the potential use of NMP by physiotherapists in Australia. If the profession's views are left unknown, a potential divided opinion within the physiotherapy profession may serve as a barrier to implementation of NMP in the future.

Research Question

What are the views of Australian physiotherapists and physiotherapy students regarding NMP by physiotherapists in Australia?

Objectives

1. To explore the views of Australian physiotherapists and physiotherapy students about the potential implementation and use of NMP by physiotherapists in Australia.
2. To explore how the geographical location and health sector that a clinician works in may influence the views of Australian physiotherapists about the potential implementation and application of NMP by physiotherapists in Australia.
3. To explore similarities or differences in the views of student physiotherapists and registered physiotherapists of differing years' experience, about the potential implementation and application of NMP by physiotherapists in Australia.
4. To explore the views of Australian physiotherapists and physiotherapy students about how physiotherapy prescribing might impact the care that the physiotherapy profession can provide.

4.1 METHODS

To ensure transparency and reproducibility this study protocol follows an adapted version of the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement [176], as recommended by the SUrvey Reporting GuidelinE (SURGE) guidance [177]. For clarity the modified SPIRIT checklist is found in Appendix 12. Unfortunately, no register currently exists for survey research. For this reason, the authors chose to publish the study protocol [178] to ensure quality, rigor and transparency (Appendix 13) [78 79].

4.1.1 Survey design

A cross-sectional descriptive survey design, using an online questionnaire was utilised, as this method enables the collection of a broad range of empirical data across a large geographical area in a finite time span [78 179]. An online questionnaire was adopted as this can be conducted remotely, enabling participants to complete the survey at a time and place convenient to them, without relying on availability of interviewers, therefore wide spread distribution of the questionnaire to physiotherapists located in all metropolitan, regional and remote areas, across all states and territories of Australia was possible [78 180].

4.1.2 Participants

Participant inclusion criteria are outlined in Figure 14. According to data published by the Physiotherapy Board of Australia, 30,004 physiotherapists were registered with the Australian Health Professionals Registration Authority (AHPRA) and 8943 student physiotherapists enrolled across 20 Australian universities at the time of the survey [181].

Figure 14: Chapter 4 Participant Inclusion Criteria

- Physiotherapist registered with AHPRA or a student enrolled in an accredited, entry level physiotherapy course in Australia leading to AHPRA registration as a physiotherapist.
- Able to read and understand written English.
- Able to legally consent to participate in the survey independently.

4.1.3 Data Collection

4.1.3.1 Procedure:

An advertisement containing a link to the online survey was emailed to all members of the APA on newsletters and associated clinical and professional network's electronic communications to encourage participation in the survey. A reminder advert was sent via email 4 weeks later to facilitate recruitment [78] [180]. Use of the APA membership as a platform for recruitment to this study was selected as 23,153 physiotherapists held APA membership at the time of the survey, representing the majority of physiotherapists and physiotherapy students in Australia [182].

Power calculations, using formula developed specifically for survey designs, found that a sample of n= >1045 (95%CI) was required to be representative of the total population (Figure 15) [79] [183] [184].

Figure 15: Sample size calculation

Total population= AHPRA registered physiotherapist + student physiotherapists= 38,947

$$n = \frac{p(100-p)z^2}{E^2} = 1045$$

$n = sample\ size$

$p = percentage\ occurance\ of\ state\ or\ condition\ (50\%)$

$z = percentage\ level\ of\ confidence\ (95\%)$

$E = percentage\ maximum\ error\ (3\%)$

(Taherdoost et al, 2017)[184]

The APA membership is representative of all physiotherapy specialities across all localities in Australia, representing physiotherapists throughout all years of post-registration practice as well as all student physiotherapists in Australia [182]. It was anticipated that referrals through professional networks would also occur, with participants or professionals who have gained knowledge of the survey communicating the survey's existence to other registered physiotherapists and/or physiotherapy students [78 180]. The email link was also sent to the 20 universities offering Australian physiotherapy programmes via the Council of Physiotherapy Deans Australia and New Zealand for distribution to physiotherapy students. Data collection took place between 1st March - 30th April 2017 during university term time to facilitate recruitment of the student cohort. Data were collected automatically by the online survey software, Qualtrics (Qualtrics, Provo, UT) to avoid human data inputting errors [185].

4.1.3.2 The Questionnaire:

The questionnaire was designed using evidence from the thematic synthesis of data from the mixed methods systematic review examining the barriers to and facilitator of NMP presented in Chapter 3 [163 174]. The review identified that the personal views of members of a profession utilising NMP were key to the implementation of NMP by that profession. To ensure the inclusion of the optimal questions the views, knowledge and perceptions of non-medical prescribers from a variety of international professions highlighted in the systematic review were prioritised through consultation with experts in the fields of physiotherapy, NMP and Australian state/federal law and health policy [74 78 179]. The included questions were designed to specifically answer the research objectives [74 78 179].

The online survey was built using Qualtrics Research Suite survey software (Qualtrics, Provo, UT). This software was selected as it enables online questionnaires to be completed on a range of electronic devices, including both desktop, laptop and mobile based devices, whilst storing data in real-time [186]. Context specific questioning was utilised to limit acquiescence bias [187]. To minimise the difficulty of the survey for participants and combat potential satisficing behaviour, researchers aimed to minimise duration and distractions via fluidity of design and inbuilt survey logic [188]. A short survey (5-10 minutes completion time) was designed containing one question per page to maximise recruitment and optimise participant cognitive response processes [185].

Questions/Measures:

The full questionnaire can be found in Appendix 14. In summary, the questionnaire comprised of 4 sections of questions consisting specifically of:

Section 1: Demographics

This section contained 11 closed demographic questions regarding the participants age, gender, level of experience, clinical speciality and locality (reported using the Rural, Remote and Metropolitan Areas (RRMA) classification) [189].

Section 2: Views about the physiotherapy profession

The second section contained 4 closed-answer questions regarding the participants views about NMP by physiotherapists, giving opportunity to express opinions regarding benefits and/or concerns [163].

Section 3: Views about the individual physiotherapist

The third section contained 3 closed-answer questions designed to collect data regarding the likelihood of the individual participants to train as a prescriber and their motivations/ barriers to do this should physiotherapist prescribing become a legal reality in Australia [163]. Inbuilt survey logic ensured participants were shown only those questions that were pertinent to them based on their previous answers provided.

Section 4: Wider impacts

Section 4 contained 2 open-ended questions designed to gather qualitative data regarding the participants' views and perceptions about how physiotherapist prescribing might positively or negatively impact on the care that the profession can provide to all patient groups. Open questions were utilised to allow the participants to express individualised answers to complex questions without limitation [78]. The final question also allowed participants to share any additional information that they deem applicable and relevant to the survey, aiming to capturing useful insight not considered elsewhere within the questionnaire [78 179].

4.1.3.3 Pre-testing

The questionnaire was piloted by a sample of the target population n=10 (n=7 registered physiotherapists, n=3 student physiotherapists), to test for internal consistency [179]. The pilot participants were not excluded from completing the full questionnaire. Ten participants were purposely sampled representing the physiotherapy professional population in Australia, including key specialities and student physiotherapists [78 179]. The pilot-testing followed the procedure for the main survey to enable the identification of potential problems with interpretation of the instructions and questions, and identification of any potential reasons for poor responses [78 179]. Following the pilot-testing, small changes were made to the survey logic to optimise the user experience, and Anglo-Australian terminology was clarified to minimise confusion due to linguistics.

4.1.4 Data Storage

All data were electronic and stored in password protected computer files that could be accessed only by study investigators at Macquarie University (Australia) and the University of Birmingham (UK). Participants who choose to disclose personal details were additionally protected via coding on data files. This coding was kept in a password protected computer file on the University of Birmingham and Macquarie University servers; only accessible to the research team ensuring confidentiality [78] [179]. The password-protected files will be retained for 10 years, satisfying policies at both the University of Birmingham and Macquarie University.

4.1.5 Data Analysis

Only data from completed questions from fully completed questionnaires were included in the data analysis. Statistical analyses were directed by statisticians at Macquarie University, Sydney, Australia to ensure appropriate analyses were conducted. Data from the AHPRA registered physiotherapists and student physiotherapists were analysed and presented separately and then compared to see if differences existed between the 2 groups.

4.1.5.1 Group 1: AHPRA Registered-Physiotherapists

Demographic data were tabulated, and primary descriptive analysis of the data was completed using IBM SPSS Statistics for Macintosh, Version 22.0. Comparisons of proportions from questions in sections 2 & 3, addressing objective 2, were conducted using

the PEDro confidence interval calculator (www.pedro.org.au) [190] [191]. Calculations of absolute risk reductions (ARR) with 95% confidence intervals were used to determine the likelihood that health sector or geographical location were associated with specific views [191]. Thematic analysis was used to ensure the transparent synthesis of data addressing objectives 4, collected in section 4 of the online questionnaire. This analysis enabled the identification of key themes within a structured analytical framework [108]. Answers were coded line-by-line using NVivo 11 software (QSR International, Melbourne, Australia) by one researcher (TN) and were verified by a second researcher (TJ). Independently generated themes/subthemes were then examined by a panel of experts for confirmation and agreement [108].

4.1.5.2 Group 2 Student Physiotherapists

Demographic data were tabulated [78] [79]. Data retrieved in sections 2 and 3 were summarised via primary descriptive analysis completed using IBM SPSS Statistics for Macintosh, Version 22.0 [78] [79]. Thematic analysis was utilised to synthesise the qualitative data collected from open questions in section 4, enabling the identification of themes and subthemes. One researcher (TN) independently coded the participants' answers line-by-line using NVivo 11 software (QSR International, Melbourne, Australia). Preliminary themes and subthemes were reviewed by 2 researchers (TN & TJ), then scrutinised by a panel of experts to ensure consensus [108].

4.1.5.3 Intergroup Comparison

Descriptive statistics were used to compare data from the closed questions in sections 1-3 of the survey. Following consultation with statistical experts, between group statistical significance tests were not completed as it could not be assumed that the differences between the categories on the frequency response Likert scales used were necessarily equal, therefore between group comparison was problematic, potentially leading to statistical bias and limiting the validity of the results [192-194]. Similarities and differences in the qualitative data collected from the 2 groups in section 4 of the online questionnaire were synthesised and discussed.

4.1.6 Ethical Considerations

To ensure that the survey was conducted in an ethical manner within best research practice, ethical approval was sought [78 179]. Approval was granted on 5th December 2016, by the Medical Sciences Human Research Ethics Committee (HREC), Macquarie University, Australia (Reference No**:** 5201600846), and verified by the Research Governance Officer at the University of Birmingham, UK, on the 12th December 2016 (Reference No: ERN_16-1576) (Appendix 15).

Completion of the survey via the link was entirely voluntary, with no incentives offered to participants to minimise bias [74 78]. Participant consent was gained using an online consent form following the provision of information explaining the rationale, content and research dissemination plans to ensure ethical recruitment of participants (the online information and consent form can be found in Appendix 16) [78 179]. This information and consent sections were situated at the start of the online questionnaire. A response to the online consent

question was required before participants could progress to the study questions. Any participants who selected the 'no consent' option automatically exited the questionnaire. Contact details for the research team were provided to give the participants the opportunity to have any questions they had answered [74 78]. Participants were able to stop completing the survey at any point [78 179]. All surveys were anonymous unless personal information was disclosed by the participants [179].

4.1.7 Patient and Public Involvement

The development of this study was informed by the experiences of patients and the general public acknowledged in the literature. Owing to the study's objectives, patients and the general public were not utilised in design of the study or in participant recruitment.

4.2 RESULTS

4.2.1 Group 1: AHPRA Registered-Physiotherapists

4.2.1.1 Demographics

A total of 883 participants (3% of all AHPRA registered physiotherapists) completed the questionnaire. Demographic data are presented in Table 10. Fifty-eight percent of participants had been qualified for more than 10 years, with the majority of participants (88.4%) gaining their primary professional qualification in Australia. The largest proportion of participants (n=536, 61%) identified MSK physiotherapy as their speciality area of practice. Of those working clinically, 52% of participants worked in the private health sector. There were participants from every state and territory, with the majority practising in New South Wales (n=299, 34%), Victoria (n=234, 27%), Western Australia (n=130, 15%) or Queensland (n=115, 13%). Seventy eight percent of participants worked in a major city.

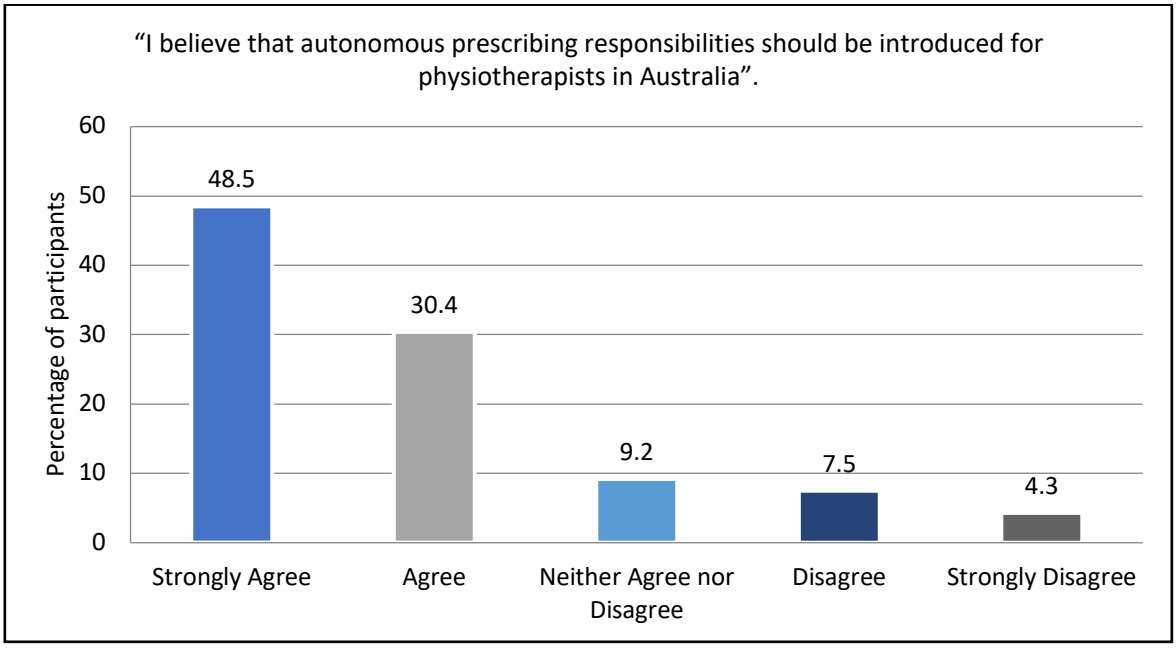
Table 10. Chapter 4 Demographic data of the AHPRA registered physiotherapists

	AHPRA Registered Physiotherapists n (%)
Total Participants	883 (100)
Gender (n=883 answered)	
Male	366 (41.4)
Female	517 (58.6)
Age (n=883 answered)	
17-29	258 (29.2)
30-39	260 (29.4)
40-49	173 (19.6)
50-59	124 (14.0)
60+	68 (7.7)
Number of years qualified as a physiotherapist (n=883 answered)	
0-4	192 (21.7)
5-9	178 (20.1)
10-14	109 (12.4)
15-19	101 (11.5)
20+	303 (34.3)
Country of Primary Qualification (n=883 answered)	
Australia	781 (88.4)
Overseas	102 (11.6)
(Belgium, Canada, Germany, Hong Kong, India, Ireland, Italy, Mexico, Netherlands, New Zealand, Philippines, Portugal, Serbia, Singapore, South Africa, Taiwan, UK, USA)	
Predominant Physiotherapy Practice Specialities: (max of 3 specialities identified per participant, n=865 answered)	
Amputees	10 (1.1)
Burns/Plastics	9 (1.0)
Cardiorespiratory	132 (14.9)
Chronic disease management	100 (11.3)
Education	58 (6.6)
Emergency Department	65 (7.4)
Gerontology/Aged care	115 (13.0)
Health promotion/ Public health	10 (1.1)
Lymphoedema	11 (1.2)
Mental Health	4 (0.5)
Musculoskeletal/ Orthopaedics	536 (60.7)
Neurology	81 (9.2)
Occupational Health	21 (2.4)
Paediatrics	37 (4.2)
Pain	105 (11.9)
Palliative Care	6 (0.7)
Rheumatology	10 (1.1)
Rural generalist	39 (4.4)
Women's health/ continence	53 (6.0)
Veterinary	2 (0.2)
Health Sector (n=872 answered)	
Public Sector	325 (37.3)
Private Sector	449 (51.5)
Educational/research institute or university	49 (5.6)
Not-for-profit organisation (NFPO)	36 (4.1)
Other	13 (1.5)
Rural, Remote and Metropolitan Areas (RRMA) classification [189] (n=783 answered)	
Major Cities of Australia	679 (77.8)
Inner Regional Australia	113 (12.9)
Regional Australia	58 (6.6)
Remote Australia	20 (2.3)
Very Remote Australia	3 (0.3)
State or Territory (n=879 answered)	
Australian Capital Territory	19 (2.2)
New South Wales	299 (34.0)
Northern Territory	7 (0.8)
Queensland	115 (13.1)
South Australia	64 (7.3)
Tasmania	11 (1.3)
Victoria	234 (26.6)
Western Australia	130 (14.8)

4.2.1.2 Participants' perceptions about the impact of physiotherapist prescribing on the physiotherapy profession

Six hundred and eighty participants (79%) reported that they strongly agreed or agreed that autonomous prescribing responsibilities should be introduced for physiotherapists in Australia, with 144 participants (12%) against the introduction (Figure 16). Potential benefits and concerns were identified.

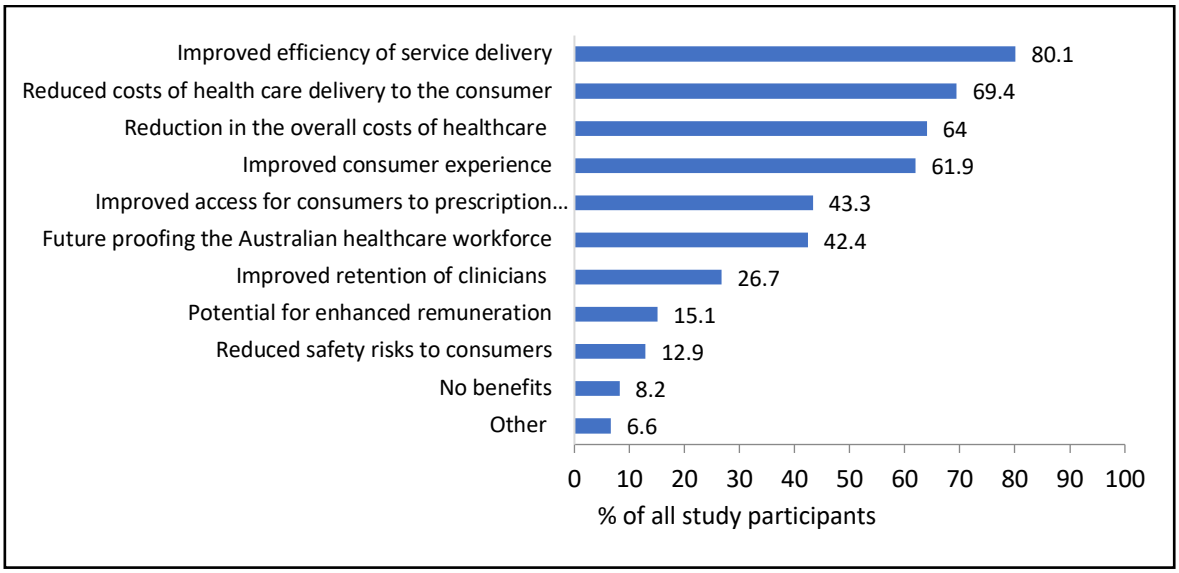
Figure 16: AHPRA registered physiotherapists' opinions on whether autonomous prescribing should be introduced for physiotherapists in Australia



The participants reported that physiotherapist prescribing could have a range of benefits in the Australian healthcare system (Figure 17). The most commonly identified benefit was an improvement in the delivery of health services (n=707, 80.1%). Reduced costs of healthcare delivery to the consumer, as well as a reduction in the overall cost of healthcare

and an improved consumer experience were also identified as potential benefits of NMP in Australia.

Figure 17: Potential benefits of physiotherapist prescribing in Australia (AHPRA registered physiotherapists)



Participants' concerns about the prescription of medicines by physiotherapists centred on quality and safety issues (Figure 18). In particular, concerns about whether physiotherapists have the knowledge required to train as a prescriber (34.8%), and a potential increased safety risk to consumers (34.1%) were raised. One third of participants (33.1%) were concerned that the expected remuneration for this service would not reflect the increased professional risk.

Figure 18: Participants' concerns about the prescription of medicines by physiotherapists (AHPRA registered physiotherapists)

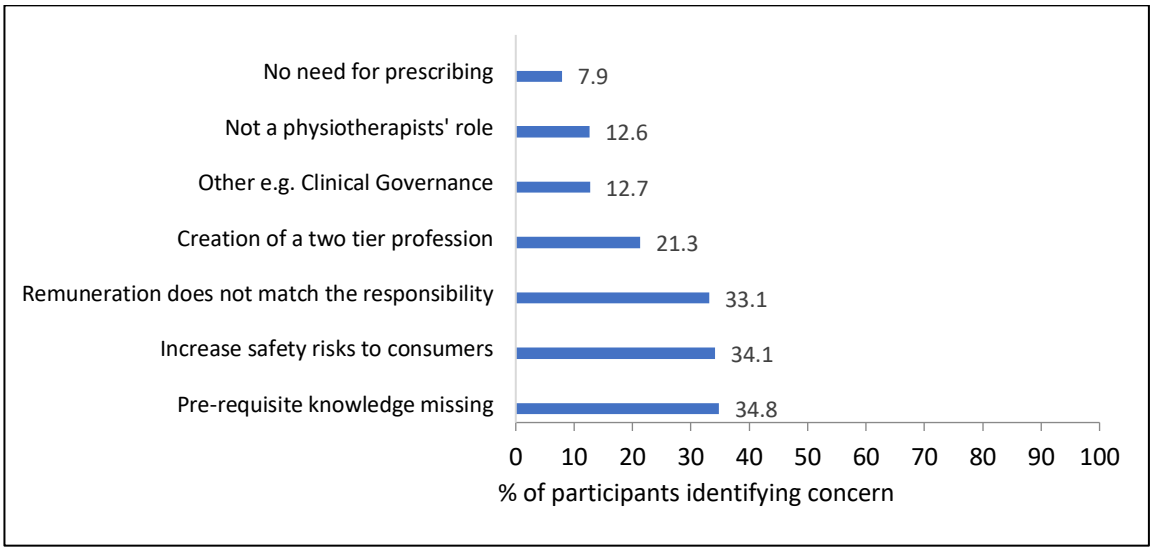
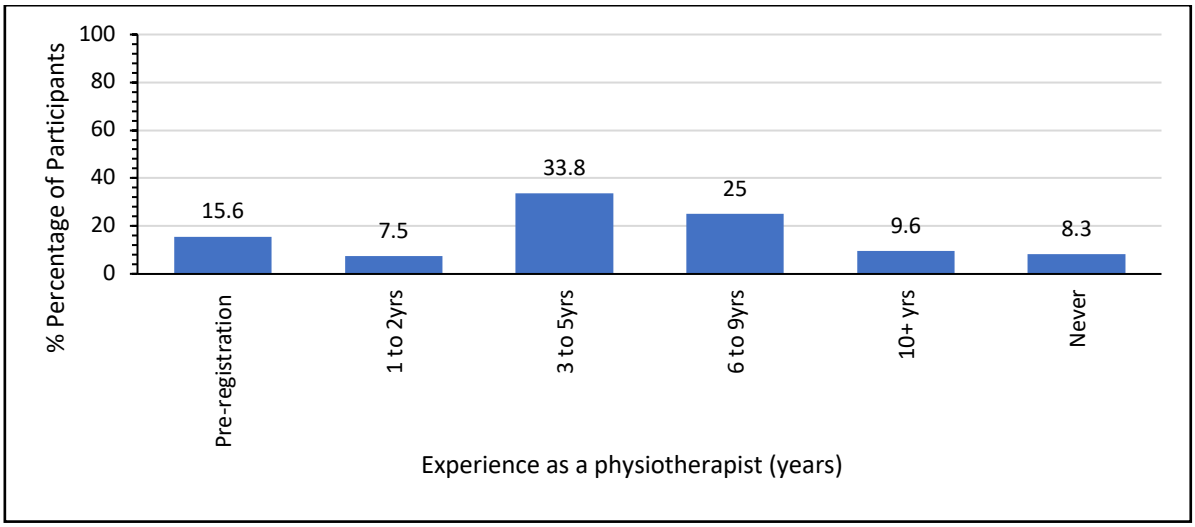


Figure 19 illustrates participants' opinions about the number of years of experience a physiotherapist should have prior to being permitted to train as a prescriber. The majority of participants felt that physiotherapists should have 3 years or more of experience (68.4%), with 34.6% believing this should be at least 6 years.

Figure 19: The number of years' experience a physiotherapist should have prior to being able to train as a physiotherapist prescriber (AHPRA registered physiotherapists)



4.2.1.3 Participants' perceptions about the impact of physiotherapist prescribing to them as an individual

Six hundred and eight participants (71.2%) would be extremely likely (n=397, 47%) or somewhat likely (n=211, 25%) to train as a prescriber if this were permitted, whilst 174 participants (20.3%) would not (Figure 20).

Figure 20: How likely are AHPRA registered physiotherapists to want to train to become a Prescriber

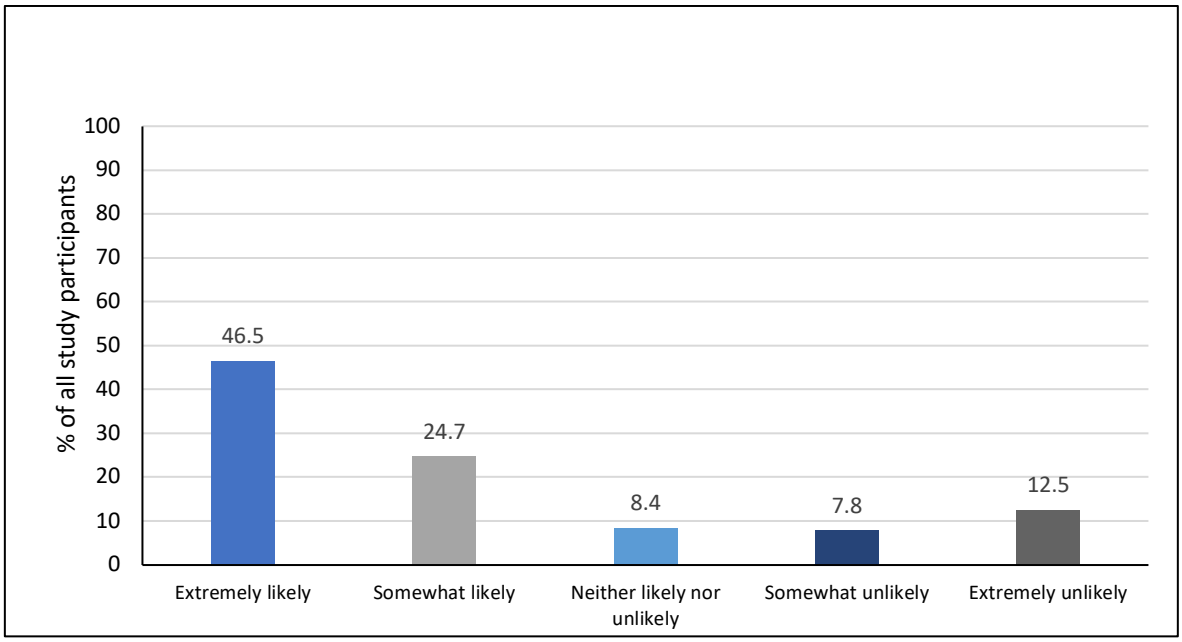
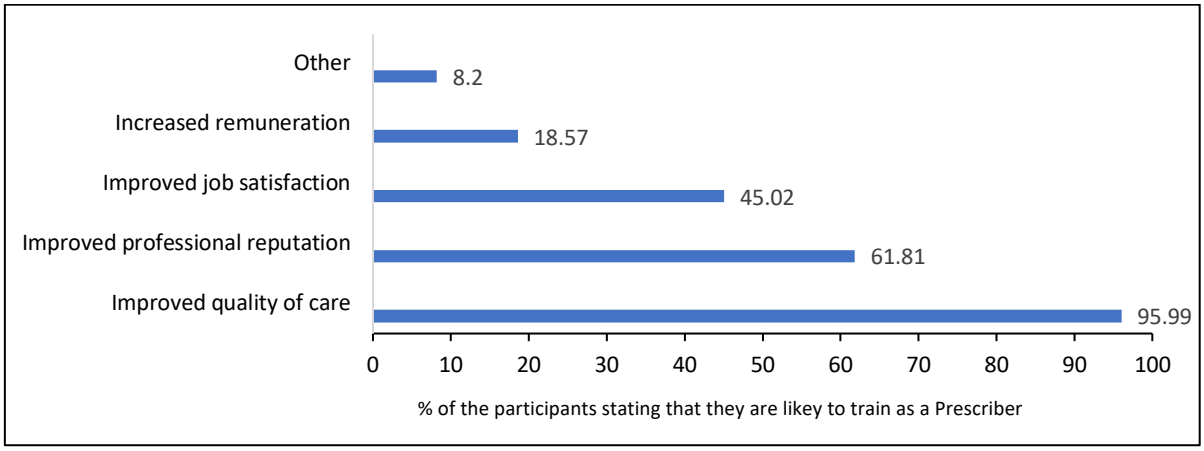


Figure 21 and Figure 22 outline the key motivators and deterrents among participants to train as a prescriber. Key motivators cited included the ability to provide improved quality of care (n=646, 96.0%) and the improved professional reputation associated with NMP (n=416, 61.8%). Some participants included increased job satisfaction (n=303, 45.0%) and remuneration (n=125, 18.6%) as motivating factors. Additionally, some participants (n=72, 10.7%) reported being motivated by potential clinical and cost-efficiencies for both for the

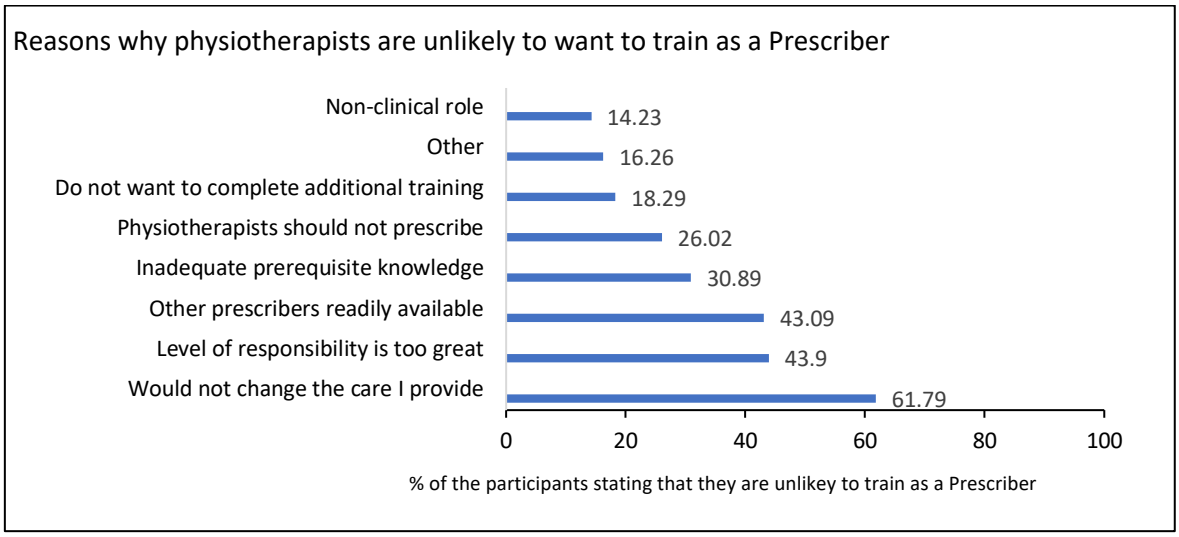
consumer and healthcare provider through enhanced clinical pathways, improved access to medicines and optimisation of clinical knowledge.

Figure 21: Key Motivators for training to be a Prescriber (AHPRA registered physiotherapists)



The most common deterrent for training to be a prescriber was the belief that this will not change the care that the individual physiotherapist would provide to their patients (n=152, 61.8%). Concerns around an increased level of clinical responsibility were also highlighted as potential deterrents (n=108, 43.9%). Some participants felt that they did not have sufficient background knowledge to undertake the prescribing course (n=76, 30.9%). Additionally, participants reported that the cost of training or distance to travel to universities would be too great, or that they were nearing retirement and did not want the additional stress of training to become a prescriber. Further, it is noted that a small number of participants reported that they would not train as prescribers as they are employed in non-clinical roles (n=35, 14.2%).

Figure 22:Key deterrents to becoming a prescriber (AHPRA registered physiotherapists)



4.2.1.4 Influence of Health Sector and Geographical Location

The percentage of participants from different health sectors and geographical locations, who agreed or strongly agreed with autonomous prescribing responsibilities being introduced for Australian physiotherapists, and those who stated that they were extremely likely or somewhat likely to want to train as a prescriber are summarised in Table 11.

Participants working in the private sector were significantly more likely to agree that autonomous prescribing responsibilities should be introduced for physiotherapists in Australia than those who work in education, not-for-profit organisations and the military (ARR 9.8%, 95%CI [0.8, 20.2]). No significant difference (ARR 1.7%; 95%CI [-4.0, 7.6]) was seen between participants who worked in the private or public healthcare sectors. Participants working in the private sector were significantly more likely to train as prescribers than those working in the public sector (ARR 9.9%; 95%CI [3.5, 16.4]) or other areas, such as within educational or research institutions (ARR 23.3%; 95%CI [12.8, 33.8]). A significantly higher proportion of participants in city regions expressed a wish to train as

a prescriber compared to those in remote regions (ARR 19.8%; 95%CI [0.8, 39.2]). Those practising in cities (ARR 24.0%, 95%CI [5.8, 43.9]) and regional areas (ARR 19.5%, 95%CI [0.4, 40.1]) were significantly more likely to agree with the introduction of physiotherapist prescribing than those from remote regions. However, there was no significant difference (ARR 4.4%, 95%CI [-2.2, 12.0]) between participants who practise in major cities compared to regional areas.

Table 11. Percentage of participants from different health sectors and geographical locations, who agreed with the introduction of physiotherapist prescribing and are likely to train

	Location RRMA % [95% Confidence Interval]			Subgroup Comparisons ARR % [95% Confidence Interval]		
Survey item	City	Regional	Remote	City: Regional	City: remote	Regional: remote
Agreed or strongly agreed with autonomous prescribing	80.1 [77.3, 83.3]	76.1 [69.0, 81.9]	56.5 [36.8, 74.4]	4.4 [-2.2, 12.0]	24.0 [5.8, 43.9] *	19.5 [0.4, 40.1] *
Likely to train as a prescriber	71.9 [68.4, 75.2]	70.9 [63.4, 77.3]	52.2 [33.0-70.8]	1.0 [-6.3, 9.1]	19.8 [0.8, 39.2] *	18.7 [-1.3, 39]
	Health Sector % [95% Confidence Interval]			Subgroup Comparisons ARR % [95% Confidence Interval]		
Survey item	Private	Public	Other	Private: Public	Private: Other	Public: Other
Agreed or strongly agreed with autonomous prescribing	80.7 [76.8, 84.1)	79.0 [74.2, 83.1]	70.8 [61.1, 79.0]	1.7 [-4.0, 7.6]	9.8 [0.8, 20.2] *	8.2 [-1.3, 18.8]
Likely to train as a prescriber	77.4 [73.3, 81.1]	67.5 [62.2, 72.5]	54.2 [44.2, 63.8]	9.9 [3.5, 16.4] *	23.3 [12.8, 33.8] *	13.4 [2.3, 24.5] *
*Significant at p<0.05						

4.2.1.5 Wider impacts of physiotherapist prescribing

Participants were asked to provide additional comments about how NMP may impact the overall level of care that the profession is able to provide. In total, 230 participants provided comments.

Four major themes were identified:

1. Clinical and cost-efficiency
2. Access to prescription medicines
3. Optimal therapeutics and clinical effectiveness
4. Time management

Table 12 lists the number of participants that reported or discussed each theme and provides Illustrative quotations.

Clinical and cost-efficiency

One hundred and eighteen participants commented that the introduction of autonomous physiotherapist prescribing would have positive effects on both clinical and cost efficiencies for patients, clinicians and the health economy. Participants identified the positive impact on the overall patient journey as a potential benefit of NMP by reducing unnecessary appointments with GPs, specialists and surgeons. Specifically, participants recognised the current frequency of referrals from physiotherapists to GPs for analgesic review, access to oxygen therapy, bronchodilators and antibiotics and on-going pharmacological spasticity management. A common sentiment was that if physiotherapists could provide these services themselves, patients could have more timely access to

appropriate medicines, which in turn would complement physiotherapeutic interventions and accelerate patient improvement/recovery. Participants also anticipated that NMP could reduce acute injury recovery times and minimise the risk of chronicity, which in turn could reduce pressures on medical services and end costs to the consumer, Medicare and private health insurers. Further, the presence of physiotherapist prescribers in emergency departments and specialist multidisciplinary clinics was anticipated to reduce waiting times for patients, thus helping to meet performance measures set by governing bodies.

Access to prescription medicines

Seventy-one participants provided comments concerning potential improvements in accessing prescription medicines for all Australians regardless of geographic or other socio-economic factors. Specifically, it was suggested that physiotherapist prescribers in rural and remote regions could issue prescription medications to patients who might otherwise have limited access to medical professionals. However, no participants from rural/remote regions identified this theme within their responses. Participants from metropolitan and regional areas expressed concerns that patients in rural and remote regions may struggle to navigate an over-burdened and expensive healthcare system, frequently waiting for weeks and travelling great distances to see their GP for medications such as analgesics to supplement treatment from their physiotherapists. Participants from all locations identified potential benefits of NMP to healthcare consumers (regardless of location) whose principal healthcare practitioner is a physiotherapist, including persons with physical disabilities and those involved in sports where acute injuries are managed pitch-side by the team physiotherapist.

Optimal therapeutics and clinical effectiveness

Fifteen participants reported the potential for improved optimisation of medicines in-line with physical and psychosocial interventions and therefore enhanced clinical effectiveness. Participants stressed optimal and appropriate use of analgesics across all specialities, especially where adjustments (escalation or de-escalation) to prescriptions are required in-line with physiotherapeutic intervention. It was felt that that the multimodal skills and techniques utilised by physiotherapists would promote a more integrated use of medicines into the overall patient management, with medicines forming just one part of a more comprehensive and coordinated approach. Participants specialising in women's health echoed this statement highlighting the appropriate use of anticholinergics and vaginal oestrogens necessary to holistically treat many of their patients.

Participants agreed that the close working relationships between physiotherapists and their patients, due to the comprehensive time spent completing physiotherapeutic interventions may be used to promote patients' compliance to their prescribed medicines. Physiotherapist prescribers with the appropriate knowledge and skills could legally reinforce the appropriate use of medicines; better recognising poor adherence, dependency, abuse or adverse side effects masquerading as conditions treated by physiotherapists.

Time management

Nine participants suggested that the time requirements needed to train as a physiotherapist prescriber and on-going time required for CPD may be prohibitive to

introducing NMP in Australia. Likely time away from clinical work for education and development and NMP duties were seen to potentially interfere with tasks currently performed by clinicians. Further, participants felt that although greater efficiency and access to medicines may benefit heath consumers, time presently spent treating patients in the current scope of practice would be lost to procedures related to prescribing medicines. In other words, although NMP may decrease medical practitioners' workload, this would instead increase pressures on already understaffed physiotherapy departments and possibly even threaten clinical outcomes.

Table 12. Comments that Reported or Discussed Each Theme & Illustrative Quotations from Registered Physiotherapists (quotations have been copied verbatim)

Theme	Number of comments (n)	Illustrative Quotations
Clinical and cost efficiency	118	……would benefit people financially if they do not have to go back to their GP for medication (Participant 41) Time and cost savings for busy workers, i.e. not having to go to 2 appointments (Participant 127) …. improve patient flow and decrease reliance on medical staff (Participant 490) Working in an Emergency Dept where access and flow are critical……. would improve efficiency and the patient experience (Participant 7) The ability to prescribe would enable more efficient service delivery to patients. A lot of time is wasted back and forth trying to get appropriate pain medication, antibiotics etc. in a timely fashion (Participant 32)
Access to prescription medicines	71	Working in a rural area where it is difficult for a patient to be able to make a GP appointment (typical 2-3week wait) I can see the benefit of streamlining the system by giving prescribing rights to physios who are also primary care professionals (Participant 630) Will reduce burden on overbooked GP's & ED's for people with pain problems, e.g. acute low back [pain] or those with inflammatory injuries (Participant 873) Physiotherapists working in public health help people from different minority groups - indigenous, recent immigrants, people relying on disability pensions, etc. Greater access to simple medications would improve their quality of life and reduce unnecessary attendances at over- worked GP clinics (Participant 12) I work in a country setting where travel times are significant, and it can be difficult to get a doctor's appointment… patients rely on friends, relatives or public transport to reach appointments. This means that a physiotherapy appointment with prescription would become a more efficient use of time and people are more likely to comply (Participant 654)

Theme	Number of comments (n)	Illustrative Quotations
Optimal therapeutics and clinical effectiveness	15	Will allow physiotherapist to adjust medications particularly in management of chronic pain and LBP….” (Participant 333) “There is considerable potential for this to significantly improve adherence to medication regimes (Participant 45) Physios tend to spend more time with patients and often are better skilled to recommend medications than even the registrars…… being able to prescribe anticholinergics and vaginal oestrogens would significantly increase the efficiency of the clinics (Participant 276) ….’de-prescribing’ could potentially be a very important role for Physios (Participant 790)
Time management	9	The time required to keep up to date with medications…. I feel would impact the time available to treat patients…. (Participant 246) Puts extra pressure on appointment time when we already have to deal with full assessment and treatment of the patient’s physical and psycho-social needs (Participant 693)

4.2.1.6 Further Insights

The final question allowed participants to express any additional thoughts and views about physiotherapist prescribing that they deemed important and had not already been captured. Two hundred and sixty-six participants provided comments. Three major themes were identified:

1. Quality and safety: clinical governance, policies and procedures, and education
2. Professional issues
3. Physiotherapy professional priorities

Table 13 lists the number of comments that discussed each theme and subtheme, providing Illustrative quotations from participants.

Quality and Safety

Two hundred and seventeen comments were received regarding quality and safety concerns around NMP. These focussed on clinical governance, policies and procedures and educational requirements for prescribers.

One hundred and forty-four participants proposed that adequate clinical governance, policies and procedures should be in place for physiotherapist NMP to be successful. Participants identified the need for a clear scope of practice linked to a physiotherapy-centric formulary that is endorsed and regulated promoting transparency and safety. Participants raised concerns that statutory processes and procedures defining a limited formulary could quickly become out-dated due to medical advances. Meanwhile, other participants identified that a limited formulary based around the profession's specialist

areas of practice would be safest, protecting clinicians from pressures to prescribe out of scope. Participants were concerned that unless communication channels were maintained between physiotherapist prescribers and GPs, there is a risk that patients could shop around for prescriptions, potentially aiding the abuse of prescription medication, and causing clinical incidents. Participants were also concerned that the increase in professional risk due to physiotherapist prescribing would lead to an increase in indemnity insurance premiums.

Seventy-three comments were received with regards to education. Participants recognised that the scope of practice must be absolutely clear, endorsed and underpinned by a robust clinical education framework. They felt that thought must be given to the process of assessment and selection of appropriately qualified assessors from outside the profession including medical doctors and pharmacists to ensure quality and safe practice among prescribers.

Access to prescribing courses for physiotherapists living in regional and remote areas was highlighted as a potential issue due to the distance to the nearest university. Participants recommended that the regulatory body should dictate compulsory annual CPD hours and periodic reassessment of competency should be mandatory. Participants had varying opinions with regards to when physiotherapists should be able to train and qualify as prescribers, however the participants agreed that current pre-registration physiotherapy programmes should be updated to include pharmacology and therapeutics on their syllabi in preparation for the future.

Professional Issues

Thirty-nine participants provided comments on important professional issues. Participants noted that the introduction of physiotherapist prescribing could change the 'physiotherapy brand', weakening the public's perception of physiotherapists as experts in manual therapy and exercise, leading to potential loss of patients to other emerging healthcare professions. It was suggested that a marketing campaign may be necessary to manage public expectation and minimise consumer confusion.

Inter-professional relationships between physiotherapists, medical practitioners and pharmacists were highlighted as being fragile. Participants warned that members of the Australian Medical Association (AMA) would not support the introduction of physiotherapist prescribing, alluding to the possibility that medical doctors might see the introduction as a direct challenge to their authority and private businesses, leading them to reduce referrals to physiotherapy. Participants specifically identified the impact this may have on practice revenues in the musculoskeletal and sport specialities. That said, other participants reported great support from medical colleagues and the greater multidisciplinary team, citing the streamlining of current clinical services and patient pathways, alongside improved access to medicines as key reasons for positive inter-professional support. Participants warned that although these efficiencies would reduce service costs, establishing physiotherapist prescribing would require an initial co-ordinated investment to ensure appropriate governance, clinical education and safe/quality implementation across Australia.

Physiotherapy Professional Priorities

Forty participants commented on the profession's professional priorities. Participants described the risks of junior physiotherapists under-developing their traditional physiotherapy skills used to treat impairments, and instead depending on medicines. To mitigate these risks, a robust career progression framework would need to be introduced to ensure ongoing high-level professional development across all specialities. To safeguard the good reputation of the profession, participants focused on maintenance of quality and safety for patients and clinicians. Physiotherapist prescribing should be introduced in a structured and organised manner with all physiotherapists supporting each other, even if they do not wish to prescribe themselves. Further, participants also commented that the ability for physiotherapists to directly refer to specialist medical or surgical practitioners and ensuring appropriate patient rebates for imaging would have a positive clinical impact.

Table 13. Additional Comments Reported or Discussed by Participants & Illustrative Quotations from Participants (Registered Physiotherapists)

Theme/ Subtheme	Number of comments (n)	Illustrative Quotations (quotations have been copied verbatim)
Quality and Safety Clinical governance, policy, procedure Education	217	Prescribing medicines is a risk to the physiotherapy profession as there can be a lot of risks to the patient with medications. Prescribing and its scope needs to be carefully planned and managed with introduction to the physiotherapy profession (Participant 379) The physio who is going be a prescriber needs to undergo a certain number of hours of training…… going through an examination process. Continuous on-going training is also important as medications change fairly rapidly (Participant 14) …. professional indemnity is required to protect them in case of errors or mishaps (Participant 89) Risks of 'doctor shopping' of physiotherapists for opioid based drugs without centralised control (Participant 651) The challenge in prescribing is ensuring consumer safety through adequate training of the physiotherapists involved and improved communication across health professions (Participant 56)
Professional Issues	39	I believe that it would create confusion for the public if some physiotherapists could prescribe, while others could not (Participant 227) A cultural change is needed, namely adjusting the public's perception of what allied health professionals can do, in order to effectively utilise non-medical prescribing rights (Participant 380) …. the medical doctors may have their issues with this as it may be seen as a direct challenge to their authority and therefore reduce their use of referral pathways already established (Participant 4) I would be concerned that there may be a conflict that forms between doctors and physiotherapists if physios were given prescribing authority. I think there would have to be some very strict guidelines about managing a patient who may be seeking prescriptions from both a doctor and physiotherapist at the same time (Participant 879)

Theme/ Subtheme	Number of comments (n)	Illustrative Quotations (quotations have been copied verbatim)
Physiotherapy Professional Priorities	40	Physio profession needs to become more progressive with enhanced scope roles, career pathways are currently limited (Participant 412) I think that the physiotherapy profession should spend their resources and energies trying to improve the ability for physiotherapists to order radiological investigations & referrals to specialists which would be far more beneficial in a cost and time saving way then being able to prescribe medications (Participant 78) Potential for increased reliance on pharmaceutical treatments of MSK conditions over traditional physiotherapy management strategies (i.e. manual therapy, exercise prescription) (Participant 701) May potentially de-value other interventions in the management plan (i.e. committing to taking medication as prescribed, but not to exercises prescribed in same session) (Participant 219)

4.2.2 Group 2: Student Physiotherapists

Of the 8943 student physiotherapists enrolled at Australian universities at the time of the survey, 526 (6%) fully completed the online questionnaire.

4.2.2.1 Demographics

Demographic data are presented in Table 14. 56.8% of participants were female with the majority (n=470, 89.4%) aged below 30 years. All States and Territories with at least 1 university offering an entry-level physiotherapy programme were represented (no physiotherapy programmes existed in the Northern Territory or Tasmania at the time of data collection).

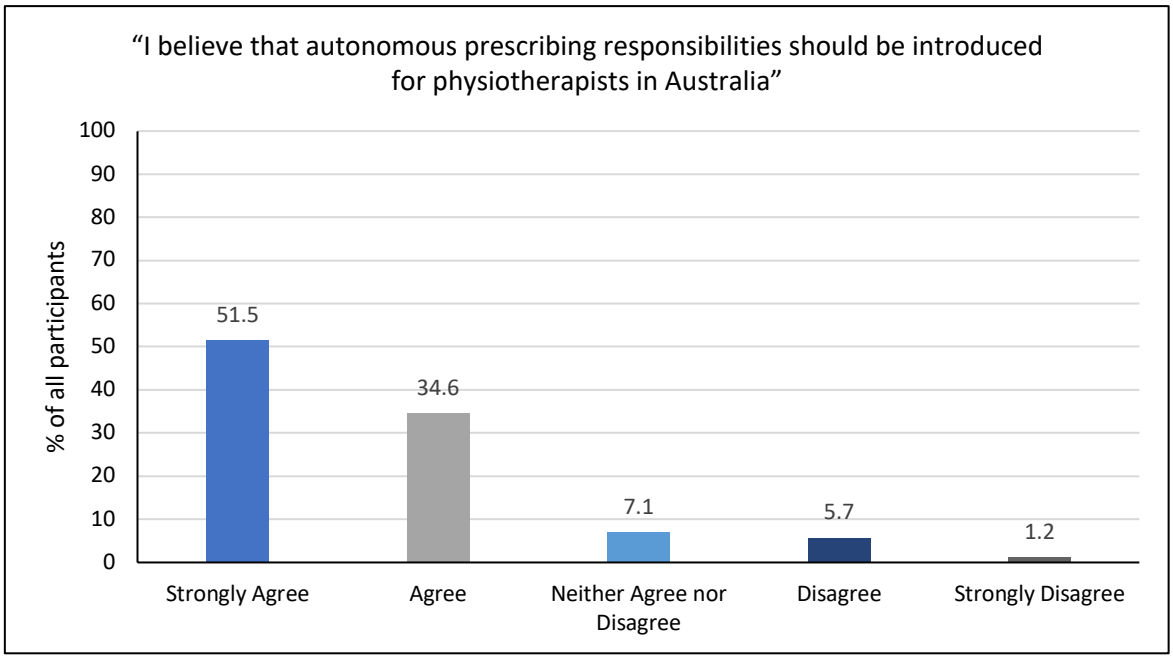
Table 14. Demographic data of the student physiotherapists

Demographic	Student Physiotherapists n (%)
Total Participants	526 (100)
Gender	
Male	227 (43.2)
Female	299 (56.8)
Age	
17-29	470 (89.3)
30-39	42 (8.0)
40-49	12 (2.3)
50-59	2 (0.4)
60+	0 (0.0)
University State or Territory	
Australian Capital Territory	36 (6.9)
New South Wales	139 (26.4)
Northern Territory	0 (0.0)
Queensland	79 (15.0)
South Australia	123 (23.4)
Tasmania	0 (0.0)
Victoria	75 (14.3)
Western Australia	74 (14.1)

4.2.2.2 Participant perceptions of positive and/or negative aspects of physiotherapist prescribing with regards to the profession

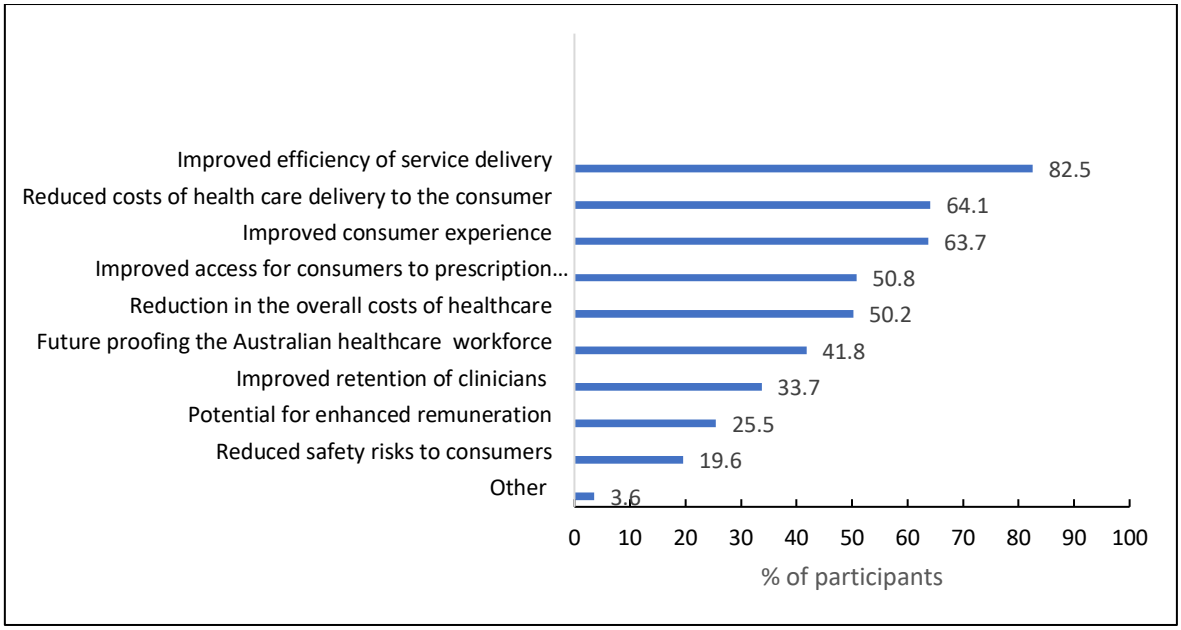
Four hundred and thirty-eight participants (87%) strongly agreed (n=262, 52%) or agreed (n=176, 35%) that autonomous prescribing responsibilities should be introduced for physiotherapists in Australia, with 35 participants disagreeing (n=29, 6%) or strongly disagreeing (n=6, 1.2%) (Figure 23).

Figure 23: Student physiotherapists' opinions on whether autonomous prescribing should be introduced for physiotherapists in Australia



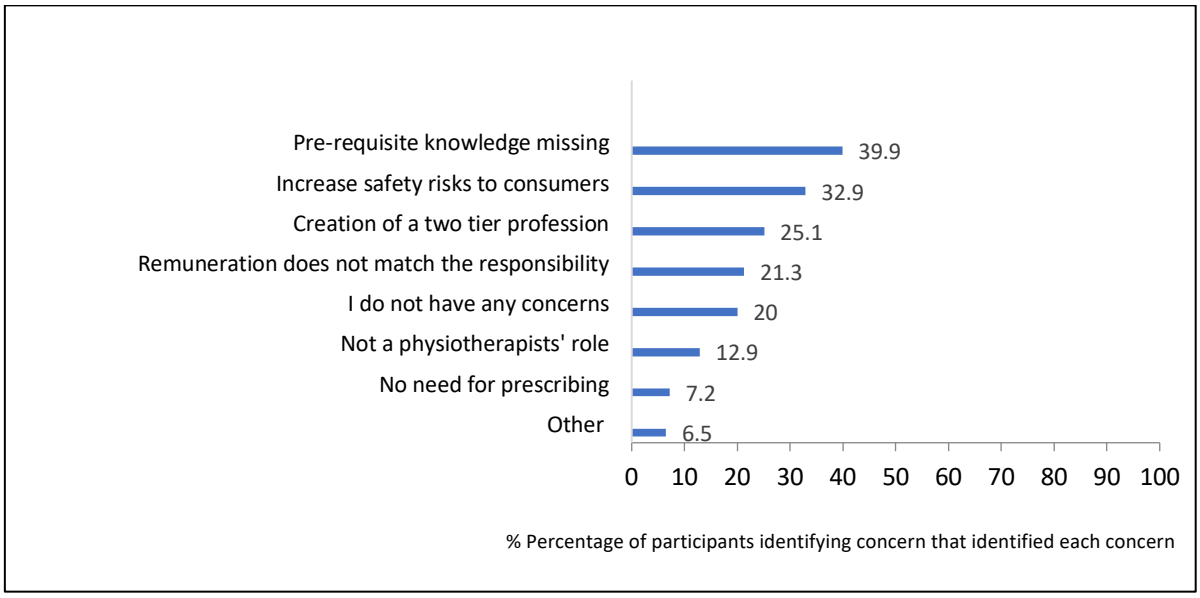
Benefits and concerns from participants are summarised in Figure 24 and Figure 25.

Figure 24: Potential benefits of physiotherapist prescribing in Australia (student physiotherapists)



Key benefits were directly linked to patients: potential improvement in the efficiency of service delivery (n=434, 83%), reduced costs of healthcare delivery for patients (n=337, 64%), improving the overall patient experience (n=335, 64%), and improved access to medicines (n=267, 51%). Participants identified additional potential benefits to be the reduction in currently overloaded GPs caseloads with a more collaborative approach to healthcare.

Figure 25: Participants' Concerns about the prescription of medicines by physiotherapist (student physiotherapists)



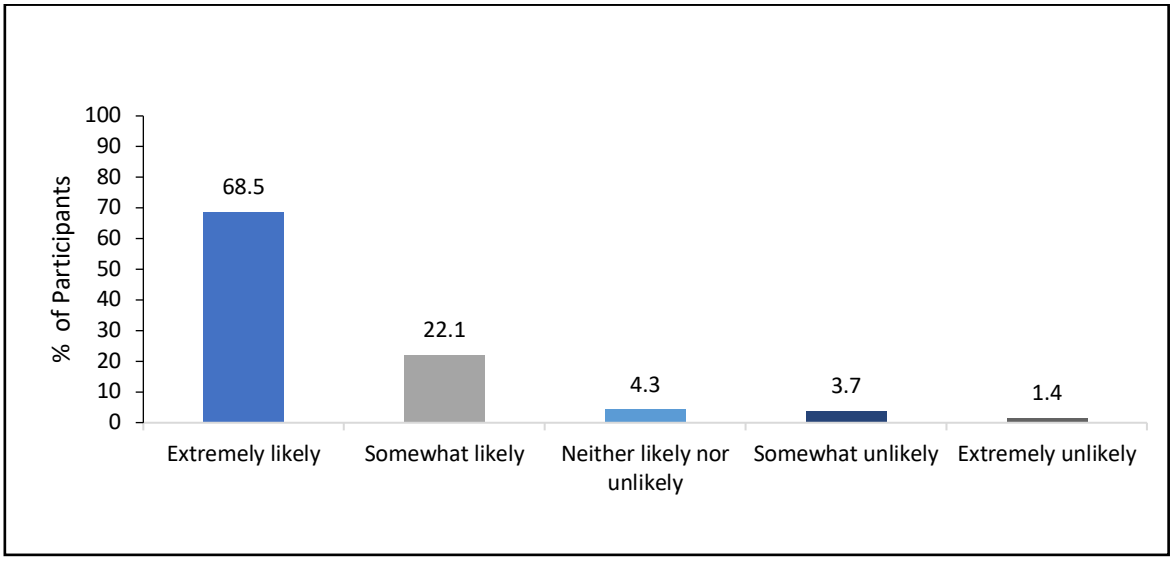
Concerns focussed on a lack of base-level pharmacological knowledge required to successfully complete a NMP course (n=210, 40%) and the potential increased safety risks to the patient (n=173, 33%). Additional comments highlighted a perceived lack of acceptance by older, more experienced physiotherapists, and potential conflict between the medical and physiotherapy professions due to the blurring of traditional roles.

Three hundred and fifty-seven participants (53%) felt that 1-5 years of clinical experience as a physiotherapist was necessary prior to being able to undertake a NMP course, with 41 participants (8%) feeling that >5 years would be preferable. One hundred and seventy-eight participants (36%) reported that prescribing should be included in entry-level physiotherapy programmes; consistent with medicine and dentistry.

4.2.2.3 Participants' perceptions of the impact of physiotherapist prescribing to them as an individual

Figure 26 demonstrates the likelihood of the participants to want to train as a physiotherapist prescriber should a change in Australian federal and state or territory laws and regulations allow. Four hundred and forty-three participants (91%) stated that they were extremely likely (n=335, 69%) or somewhat likely (n=108, 22%) to want to complete an NMP course, with only 25 participants (5%) reporting that they were somewhat unlikely (n=18, 4%) or extremely unlikely to (n=7, 1.4%).

Figure 26: How likely are student physiotherapists to want to train to become a Prescriber



The motivating factors and deterrents to pursuing autonomous prescribing responsibilities identified by the participants are detailed in Figure 27 and Figure 28. The potential for improvements in quality of care (n=450, 97%), alongside improved job satisfaction (n=246, 53%) and strengthened professional reputation (n=310, 67%) were identified as key

motivational factors. Of those that stated that they would not want to train as a prescriber, key reasons were identified as the level of clinical responsibility (n=28, 64%) and inadequate pre-requisite knowledge required to successfully enter and complete a NMP course (n=26, 59%). Participants also highlighted a lack of remuneration for increased stress and responsibility.

Figure 27: Key Motivators for training to be a Prescriber (student physiotherapists)

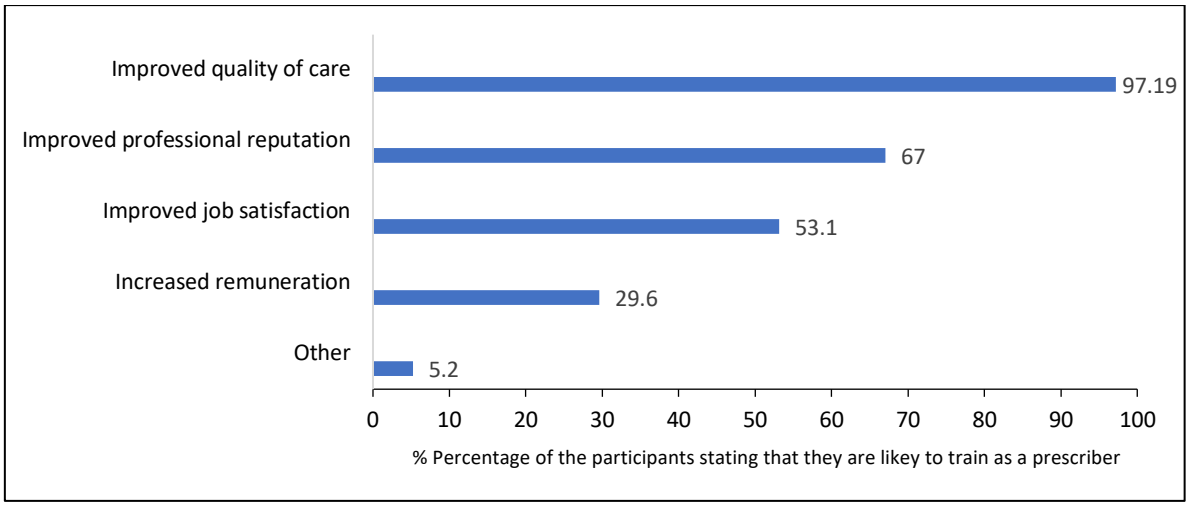
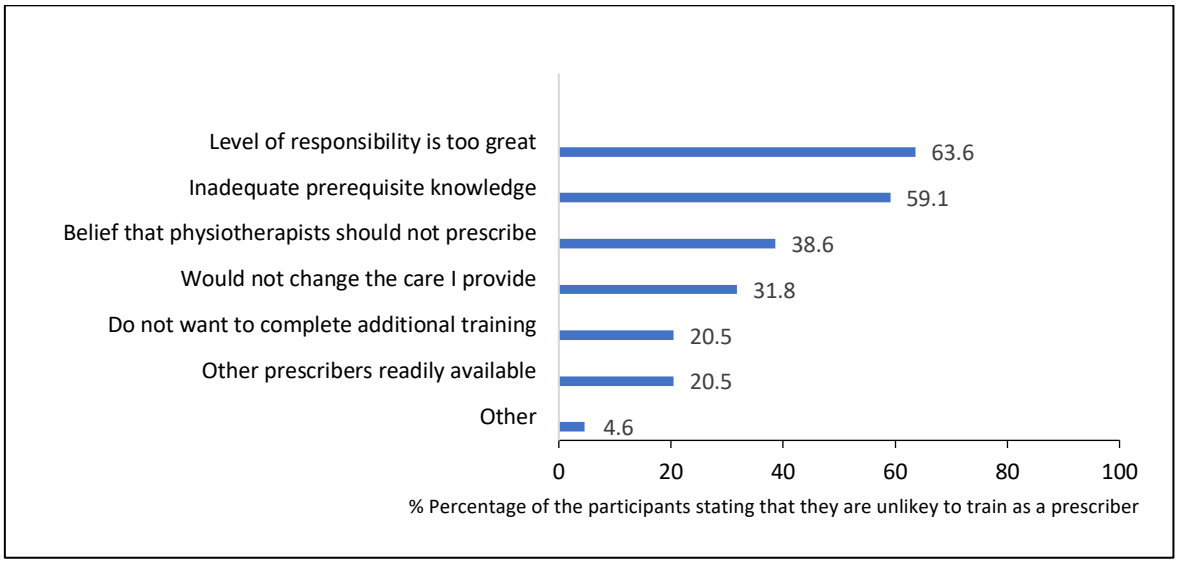


Figure 28: Key deterrents to becoming a prescriber (student physiotherapists)



4.2.2.4 Participants' perceptions regarding the potential wider impacts of physiotherapist prescribing

Participants' perceptions about how physiotherapist prescribing might 'impact the care which the profession is able to provide' were analysed and synthesised into 3 themes:

1. Clinical and cost efficiency
2. Access to prescription medicines
3. Quality of care

Table 15 provides illustrative quotations to demonstrate each theme.

Clinical and cost efficiency

Sixty-one participants commented on the potential for physiotherapist prescribing to improve clinical and cost-effectiveness for physiotherapy consumers and services. Participants felt that with the imminent burden that the ageing population will place on the Australian healthcare system, having physiotherapists that are able to prescribe appropriate medicines could reduce costs resulting from patients attending multiple appointments with multiple practitioners for the same problem. Furthermore, physiotherapists could provide a more holistic approach to treatment, providing a 'one-stop-shop' service for patients. Participants also felt that waiting times would be reduced by off-loading the burden on GPs, emergency departments and specialist services, allowing medical/surgical practitioners to concentrate on other cases. Specifically, participants suggested that the ability to prescribe analgesia would accelerate the recovery of patients with acute conditions presenting in primary care, complementing traditional physiotherapeutic skills, and minimising the risk of developing chronic pain. Participants

noted that, ultimately, improvements in time efficiencies would lead to improvements in cost-effectiveness for Medicare and private health insurers.

Access to prescription medicines

Seventeen participants reported that physiotherapist prescribing would improve access to prescription medicines. Where GPs and specialist medical practitioners have time pressures, physiotherapists could provide appropriate medications for their patients in a timely manner, being especially beneficial in rural and remote locations where access to other healthcare providers may be limited. Specifically, improved access for minority groups such as refugees and asylum seekers were conveyed. It was also noted that physiotherapist prescribers could improve access where physical disability limits travel and where financial barriers prevent multiple appointments with multiple clinicians.

Quality of Care

Thirteen participants commented that the quality of care that physiotherapists are able to provide could be improved if physiotherapist prescribers were optimally utilised. Participants stressed that prescribing should not take precedence over effective manual therapy and pain education. However, when used in conjunction as part of holistic management, physiotherapist prescribing might enhance patients' recoveries. It was emphasised that by reducing the to-and-fro from GPs for medication reviews the patient-therapist relationship would be strengthened. This continuity of care could allow physiotherapists to modify medications in-line with the outcomes of other physiotherapeutic interventions.

Table 15. Comments that Reported or Discussed Each Theme & Illustrative Quotations from Participants (quotations have been copied verbatim), student physiotherapists

Theme	Number of comments (n)	Illustrative Quotations
Clinical and cost efficiency	61	"It will reduce secondary referrals, increase the time doctors in hospitals or GP's can be dealing with other more major illness and reduce burden on the client" (Participant 234) "This is extremely positive for a patient's health care costs" (Participant 78) "It will save people the trouble from moving back and forth between general practitioners and physiotherapists" (Participant 132) "It will be beneficial as patients will not have to see a number of different healthcare/medical workers, streamlining the care they receive" (Participant 15)
Access to prescription medicines	17	"Patients would not have to wait extended periods of time to see their doctor to attain a prescription that their physio had already prescribed/deemed important for their rehabilitation" (Participant 67) "…. improved medication prescription for immigrants whom physiotherapists often build closer relationships through therapy sessions compared to short medical consultations" (Participant 404) "It would positively influence those in rural/regional areas or with less access to healthcare" (Participant 497) "…. could provide a positive impact especially those patients in lower income brackets, and time restricted not requiring a follow up GP appointment as well as a physiotherapist appointment" (Participant 21)

Theme	Number of comments (n)	Illustrative Quotations
Quality of Care	13	"I believe it would increase client satisfaction" (Participant 398) "I feel like it is always a good thing to have more tools available to you" (Participant 501) "Prescription should not take precedence over equally effective manual therapy or pain education" (Participant 65) "It will enhance care because the physio will be able to follow through on explanations of pain to the client - why it hurts, what they can do about it without using medication, and when they do need medication, the best kind and most efficient way to take it, considering the particular condition and particular level of pain they are experiencing" (Participant 178)

4.2.2.5 Further Insights

Fifty-nine additional comments were received in response to the final open question. Table 16 provides Illustrative quotations from participants. Three themes were identified:

1. Risks and responsibilities
2. Education
3. Professional relationships and credibility

Risks and Responsibilities

Thirty-seven participants described the increased risks and responsibilities that could occur with physiotherapist prescribing. Some participants stated that they chose to train as physiotherapists because they did not want the responsibility associated with the prescription of medicines that medical and dental practitioners carry. These participants worried that physiotherapist prescribing would reduce the use of other clinical skills such as exercise therapy. Other participants reported that they would happily take on the responsibility of prescribing, if remuneration reflected that of other autonomous prescribers such as medical practitioners. Participants also raised concerns about 'abuse of the system' by patients 'doctor shopping' to feed addiction, and physiotherapists driven by financial incentives. It was recognised that robust clinical governance, policies and procedures would be essential to limit poor practise, and that appropriate communication technology would be paramount in avoiding clinical errors, duplication of treatment and abuse of the system among healthcare professionals treating the same patient. Further, participants noted that any prescribing errors may be reported in the media, tarnishing the reputation of the profession as a whole.

Education

Nineteen participants commented on the educational requirements for physiotherapist prescribing. Participants recognised the need for a robust and accredited NMP programme that leads to registration with AHPRA as a physiotherapist prescriber. It was felt that prescribing should not be compulsory for all physiotherapists, and participants queried whether they possessed the pre-requisite base-level knowledge of pharmacology to complete a prescribing course. Participants agreed that entry-level physiotherapy programmes should contain a compulsory preparatory pharmacology unit, however warned that this may deter potential candidates from applying to study physiotherapy. Participants studying longer (4-5 years) pre-registration courses felt that these additional units could fit within the current curriculum. This was debated by those on shorter post-graduate entry-level programmes, who were concerned that these units would be taught to the detriment of other skills. Further, it was suggested that any proposed NMP qualification should be transferable internationally, to ensure that future generations of physiotherapists are able to gain experience outside Australia.

Professional Relationships and Credibility

Eleven participants raised the issue of inter-professional relationships and the credibility of the physiotherapy profession. Key thoughts centred around an improved professional image and increased credibility to the public, other health professionals and internationally. Participants were mindful that physiotherapist prescribing might cause conflicts between physiotherapists, medical professionals and pharmacists due to the blurring of professional boundaries but did not see this to be a deterrent.

Table 16. Comments that Reported or Discussed Each Theme & Illustrative Quotations from Participants (quotations have been copied verbatim), student physiotherapists

Theme	Number of comments (n)	Illustrative Quotations
Risks and Responsibilities	37	"Unless a central database was made for every prescriber (doctor and physio) to access the patients complete drug history, it could become another way of people abusing the system and gaining more access to medicines than is necessary" (Participant 22) "There needs to be intense training and accreditation processes which assist physios with gaining the correct accreditation in order to prescribe medications. With this in place it has the ability help patients obtain better quality of care" (Participant 3) "Opens a window for error and serious complications" (Participant 215)
Education	19	"Unless physiotherapists undergo extensive study in relation to medications and prescribing them, I do not think it will be safe for the client" (Participant 144) "There should also be CPD requirements to uphold the prescribing rights" (Participant 51) "I believe that within the 5-year course of physiotherapy that I am studying, there is room to acquire the knowledge to become a non-medical prescriber" (Participant 250) "I think pharmacology subject need to be one of the core physiotherapy modules in all Australian universities" (Participant 399) "Adding therapeutics to the curriculum might put people off studying physio due to extended course duration" (Participant 412)

Theme	Number of comments (n)	Illustrative Quotations
Professional Relationships and Credibility	11	“I don't believe it would decrease the cross-referral to medical doctors, but it would certainly enhance our credibility with our patients and reduce unnecessary or excessive visits to the doctor” (Participant 501) “People will take us more seriously than before” (Participant 13) “It can have a negative impact on Physio as there can be physiotherapists who are negligent and prescribe the incorrect medications. There can also be physios who do not stick to their scope of practice giving the rest of the industry a bad name” (Participant 88) “…further enhances the reputations as primary care practitioners” (Participant 21)

4.2.3 Intergroup Comparison

4.2.3.1 Demographics

A total of 1409 participants completed the online questionnaire. Out of the 30,004 physiotherapists registered with AHPRA, a sample of 883 (3%) completed the online questionnaire. Of the 8943 student physiotherapists enrolled at Australian universities 526 (6%) completed the online questionnaire.

A comparison of the demographics in terms of age and gender are presented in Table 17.

Table 17. Demographic Data Across Groups (AHPRA registered and student physiotherapists)

	AHPRA Registered Physiotherapists %	**Student Physiotherapists %**	**Total Participants %**
Survey Participants	62.7	37.3	100
Gender			
Male	41.4	43.2	42.1
Female	58.6	56.8	57.9
Age			
17-29	29.2	89.4	51.7
30-39	29.4	8.0	21.4
40-49	19.6	2.3	13.1
50-59	14.0	0.4	8.9
60+	7.7	0.0	4.8

4.2.3.2 Participant perceptions of positive and/or negative aspects of physiotherapist prescribing with regards to the profession

Figure 29 demonstrates the between group trends associated with the belief that autonomous prescribing responsibilities should be introduced for physiotherapists in Australia. Concordance between the groups is demonstrated with 78.9% of AHPRA

registered physiotherapists and 86.1% of student physiotherapists stated that they agree or strongly agree that prescribing should be introduced. However, Figure 30 demonstrates that there was variation in viewpoints between the registered physiotherapists and physiotherapy students when it came to the number of years' experience a clinician should have as a qualified physiotherapist prior to being able to train as an autonomous prescriber. Fifty-three percent of student physiotherapists felt that 1-5 years of clinical experience was preferable prior to training to be a prescriber, with nearly 70% of registered physiotherapists believing that a minimum of 3 years is essential.

Figure 29: Between group comparison of the distribution of answers to the survey question: I believe that autonomous prescribing responsibilities should be introduced for physiotherapists in Australia

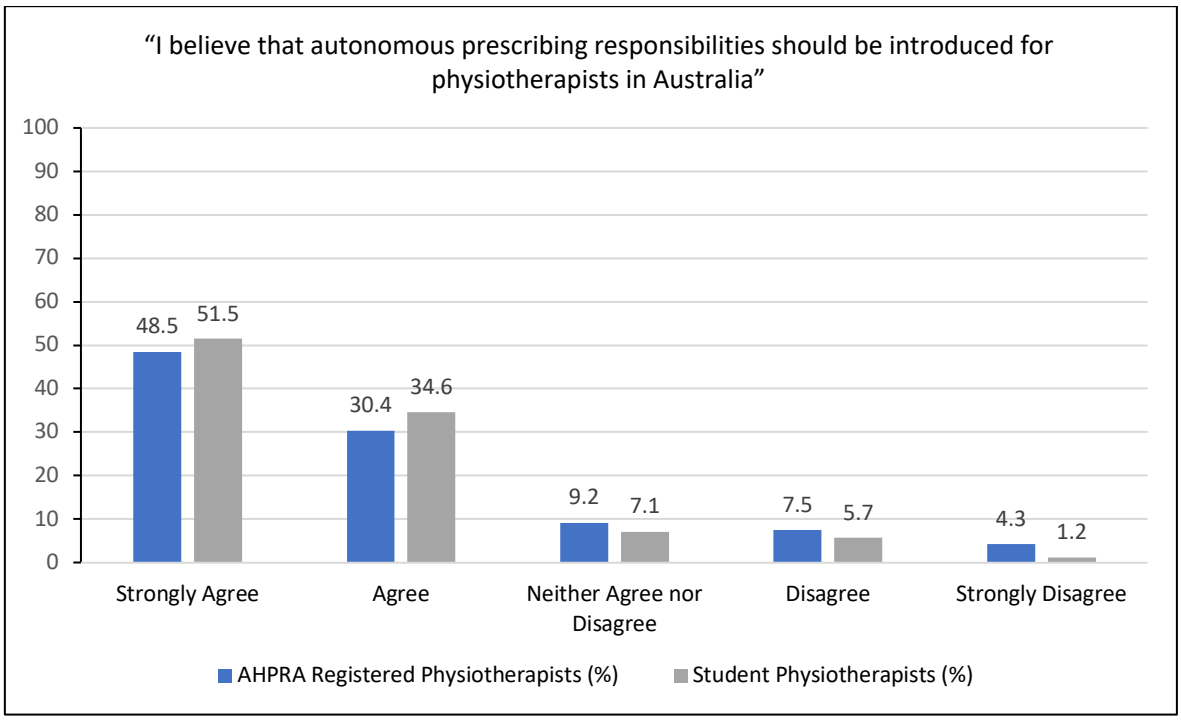
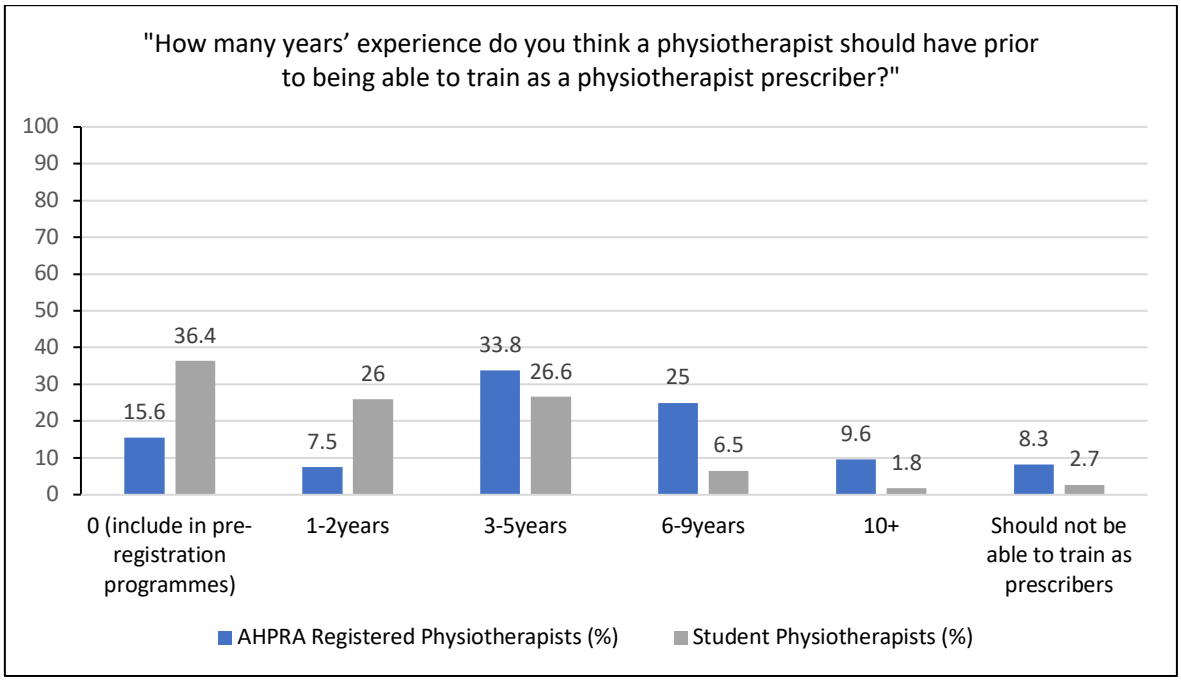


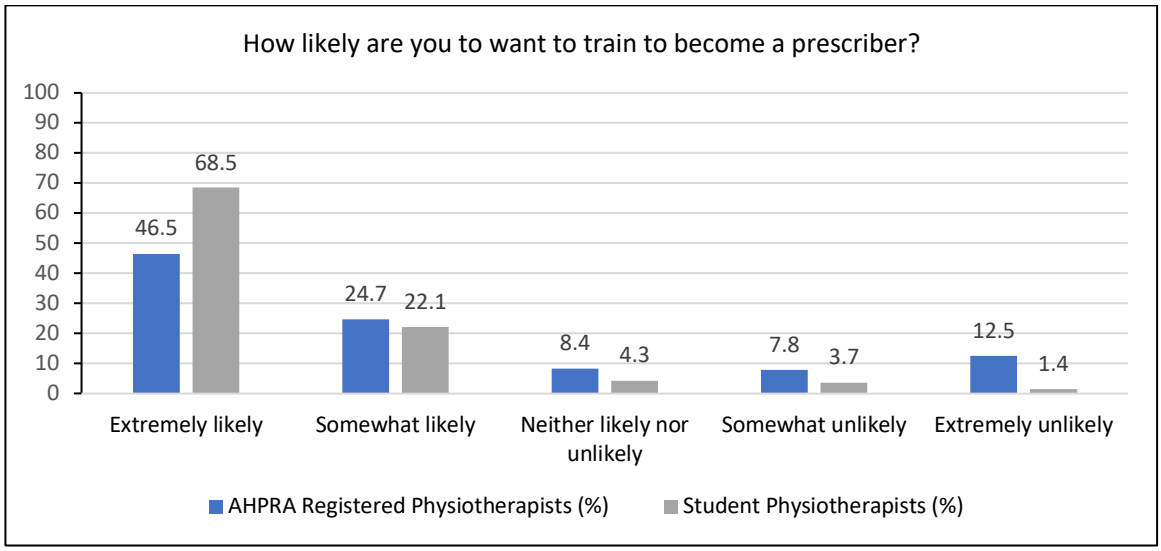
Figure 30: Between group comparison of the distribution of answers to the survey question: How many years' experience do you think a physiotherapist should have prior to being able to train as a physiotherapist prescriber?



4.2.3.3 Participants' perceptions of the impact of physiotherapist prescribing to them as an individual

The majority of registered physiotherapists (71.2%) and student physiotherapists (93.2%) stated that they were likely or somewhat likely to want to train to become a prescriber, demonstrating a common trend across the profession (Figure 31). However, of all the participants that stated they were unlikely to want to train to prescribe, relatively more were registered physiotherapists (20.3%) than student physiotherapists (5.1%).

Figure 31: Between group comparison of the distribution of answers to the survey question: How likely are you to want to train to become a prescriber?



4.3 DISCUSSION

4.3.1 The potential implementation of physiotherapist prescribing in Australia

This is the first study to explore the perceptions of Australian registered physiotherapists and student physiotherapists regarding physiotherapist prescribing in Australia. The majority of participants agreed that autonomous prescribing responsibilities should be introduced for physiotherapists in Australia, due to benefits for patients, clinicians, the physiotherapy profession and the Australian health economy. The benefits to health consumers and services, such as improved clinical and cost-effectiveness due to streamlined clinical pathways, were perceived by participants as paramount, being more important than potential benefits to the profession, such as enhanced recognition. This concurs with literature evaluating the introduction of NMP by other professions internationally and physiotherapy in the UK [25], reporting anecdotal improvements in clinical and cost-effectiveness alongside excellent patient satisfaction [113 195], strengthening

the external validity and transferability of this study's results. Participants' perceptions that physiotherapist prescribing would reduce costs to their patients, healthcare services, and to the health economy as a whole, is supported by an economic review commissioned by the APA. The report predicts savings to the Australian health-economy of over $9.22million per year if physiotherapist prescribing was implemented [53], however this is not currently reflected in the health economics literature.

A robust low risk of bias systematic review investigating the clinical and cost-effectiveness of NMP (Chapter 2) found only 1 inadequately powered pilot RCT investigating clinical effectiveness to date; concluding that the benefit of NMP to the health economy remains unclear [88]. This gap in the literature highlights the need for further robust trials with low risk of bias to rigorously assess the clinical and cost-effectiveness of NMP across professions and clinical specialities [88]. It is proposed that a beneficent approach should be adopted by the physiotherapy profession when identifying trial priorities. Initial trials assessing physiotherapist independent prescribing should aim to evaluate prevalent, disabling and costly conditions such as LBP, that are frequently managed via a multimodal treatment approach including pharmacotherapy alongside other more traditional physiotherapeutic techniques [37 38].

Over 90% of the student physiotherapists and 70% of registered physiotherapists who completed the questionnaire stated that they would train to become a physiotherapist prescriber if prescribing rights were introduced, with potential improvements in quality of care identified as a key motivator. Greater job satisfaction and enhanced professional reputation were also highlighted as motivating factors, potentially improving retention of talented physiotherapists within the profession. This consensus amongst participants

supports the hypotheses outlined within the profession's 'prescribing submission document', proposing the endorsement of registered physiotherapists as autonomous prescribers [39]. Although nurse prescribing has been shown to improve job satisfaction in senior clinicians, increased stress due to the level of responsibility associated with NMP has also been emphasised and is highlighted as a deterrent to training as a prescriber in the nursing and pharmacy literature [122 163]. Participants recognised that these deterrents may be mitigated by increased remuneration [122 127 142]. Further, enhancing remuneration alongside additional clinical responsibility may tackle inter-occupational conflicts and competition due to pay inequalities reported in the health-sociology literature [196]. It is hoped that addressing inequalities in remuneration would facilitate professional equality between autonomous, diagnosing, treating and prescribing professions such as medicine, dentistry, optometry and physiotherapy, further strengthening quality, efficacy and collaborative patient management.

4.3.2 Quality and governance

To guarantee quality development of physiotherapists across the profession, participants called for the creation of a contemporary career-development framework into which prescribing would be integrated, to safeguard mastery of traditional skills, govern quality practice and maintain the 'physiotherapy brand'. This appeal concurs with literature reporting that career frameworks within healthcare help the public understand different clinicians' knowledge, skills and roles within one profession, as well as providing purpose and direction for professionals, promoting engagement and job satisfaction [197 198]. Further, academic qualifications and increased clinical responsibility should lead to enhanced

remuneration if physiotherapists are to adopt prescribing into their clinical practice, as a lack of remuneration has been recognised as a barrier to NMP across other professions [122] [127] [142]. Improvements in recruitment and retention within the profession were anticipated due to improvements in job satisfaction for clinicians and greater recognition and professional reputation, echoing the findings of other NMP professions reported in the literature [122] [123] [133].

The need for urgent and effective management of health inequalities and challenging shortfalls in the number of doctors in rural and remote areas have been acknowledged in both the health literature and Australian health policy [164] [199] [200]. Improvements in access to medicines for all Australians due to the introduction of physiotherapist prescribing, especially those living rurally and minority groups, such as refugees and asylum seekers, was highlighted by participants. However, participants also echoed the findings of the rigorous mixed methods systematic review investigating the barriers and facilitators of NMP (Chapter 3), citing that improved access to medicines via the introduction of physiotherapist prescribing will require robust governance to ensure appropriate, quality and safe practice, process and clinical pathways [163]. Participants' perceptions further concurred with the review's findings, acknowledging that divided opinions within the physiotherapy profession and conflicts with the medical profession would be inevitable if changes in scope were not managed effectively. This would compromise vital medical support and create barriers to the implementation of physiotherapist prescribing.

4.3.3 Experience, geographical location and health sectors

Physiotherapists working in cities and regional areas were consistent in observing that physiotherapist prescribing would improve access to medicines across all regions but would be specifically helpful in rural and remote areas where access to medical prescribers may be limited. However, physiotherapists from rural and remote areas although positive about the introduction of physiotherapist prescribing, were less likely to wish to train as prescribers, identifying potential increased risks when working in geographical isolation owing to a lack of clinical support. Due to a perceived lack of need in the present healthcare environment, participants felt that not all physiotherapists would benefit from undertaking a NMP course. Those working in close multidisciplinary teams with co-located prescribers, or those employed in non-clinical roles such as healthcare managers or academic physiotherapists were found to be less likely to wish to become prescribers than clinicians working in the public and private sectors. There was debate within and between registered physiotherapists and student physiotherapists as to when and who should undertake the training, with no consistency as to whether education should be included in foundation level courses or become a post-registration qualification for those with a specified clinical experience. Further, rural physiotherapists identified that the distance to universities may act as a barrier to training as a prescriber, highlighting the need for educators to consider flexible learning methods such as online education and video teleconferencing to fulfil the academic requirements of a NMP course. It is therefore imperative that a robust, fit for purpose, transparent and future proof education framework is developed to ensure unity within the Australian physiotherapy profession and assurance for all stakeholders that physiotherapists prescribers would be adequately prepared for practice.

4.3.4 Knowledge and education

Unsurprisingly, the educational requirements supporting physiotherapist prescribing were an overt focus for the student physiotherapists. It was felt that prescribing should not be compulsory, with a small number of students identifying prescribing responsibilities as a reason for not pursuing a medical or dental career. To ensure that physiotherapists are equipped to prescribe safely within a multimodal physiotherapeutic context, participants perceived that a contemporary, innovative and robust educational framework should be developed prior to the introduction of physiotherapist prescribing. This perception reflects contemporary educational literature that urges educators to carefully consider the ever-evolving healthcare industry when designing curricula for physiotherapists [165]. Transforming healthcare needs will require the next generation of physiotherapists to be ready to adapt to changes in consumer complexity and expectation, working within new models of care that are organised, funded and delivered in innovative ways. It has been postulated in the literature that a more flexible, broader and deeper clinical expertise will be required by physiotherapists if the Australian physiotherapy profession wishes to succeed as evidence-based and viable health provider in the integrated, value-driven health-industry of the future [175].

The introduction of 'pharmacology and therapeutics' to all physiotherapy programmes to ensure prerequisite knowledge in preparation for post-graduate prescribing education may be a valuable initial step, alongside the review of the academic requirements essential for acceptance onto a pre-registration physiotherapy programme. Nevertheless, developing a revolutionary education framework fit for the next generation of physiotherapists, whilst minimising the loss of time spent studying current evidence-based

content will be challenging. This will require innovation and contemporary programme design in consultation with those driving healthcare reform such as politicians, managers, insurers and patients [165]. The majority of the participants felt that a prescribing qualification should follow a specific number of years of clinical experience. This was deemed essential for development of the physiotherapeutic assessment, treatment and reasoning skills required to ensure an holistic and multimodal approach to patient management, emulating recommendations from the UK where physiotherapist prescribing is now established [201 202].

4.3.5 Intra-professional viewpoints

This study reports both the perceptions of AHPRA registered physiotherapists and physiotherapy students enrolled in educational facilities in Australia about the potential introduction of autonomous physiotherapist prescribing in Australia [178 203]. When compared, both cohorts of participants perceived that autonomous physiotherapist prescribing would lead to improved access to medicines, efficiency of services and reduced healthcare associated costs. Both shared similar concerns about prescribing practices and motivations for training to become a prescriber, however key differences existed regarding the reasons as to why a physiotherapist would be unlikely to choose to train as a prescriber. Registered physiotherapists recognised that prescribing might not enhance their individual roles especially if they already work closely with a prescriber or in a non-clinical role. They also worried about the practicalities of training to become a prescriber, noting additional stress and costs. The student physiotherapists focused on the increased clinical responsibility without enhanced remuneration, with some students recognising potential

deficits in their knowledge that would limit their ability to complete a NMP course successfully. Decision makers using the results from this study when planning for the future should acknowledge these similarities and differences, integrating all viewpoints to ensure the success and longevity of the profession into the future.

4.3.6 Strengths and limitations

This is the first study investigating the perceptions of AHPRA registered physiotherapists and student physiotherapists about the potential introduction of NMP among physiotherapists in Australia, and so provides an important overview of the current associated professional landscape. The study used high quality methods and data analyses to investigate the specific objectives. The data should be used to guide the APA, health departments and political leaders towards successful implementation of physiotherapist prescribing in Australia. As with all survey-based research, limitations are inherent due to selection and response bias [78] [79]. The survey was anonymous, so participants may have biased the results by completing the online questionnaire multiple times. Further, registered physiotherapists and student physiotherapists with strong views or vested interests may be more likely to complete the questionnaire, meaning that their answers may not reflect the views of the wider profession.

A representative survey response rate was achieved [178]. Although only 3% of AHPRA registered physiotherapists responded, this reflected the response rate of a previous national evaluation of physiotherapists [53], where similarly, it was not possible to contact all registered physiotherapists directly due to the AHPRA privacy policy. Physiotherapists who were not APA members at the time of the survey would have been unaware of the

questionnaire unless they were provided with a link to the questionnaire through professional networks. It is impossible to determine why 97% of AHPRA registered physiotherapists did not participate; therefore, the risk of bias remains unknown and should be considered when interpreting the results. Similarly, it is unknown whether the university departments were able to successfully distribute the link to the questionnaire to all students; with only student members of the APA receiving the additional advertisement via their electronic communications.

In-line with recent Australian regulatory data [204], the sample was representative of all registered physiotherapists in Australia in terms of age, gender and state in which they practise. Unfortunately, no national demographic data exists demonstrating the geographic location or health sector of registered physiotherapists' employment. It is therefore likely that the comparable demographic profile of the study's sample to contemporary national evaluations enhances generalisability of the data to the greater physiotherapist population in Australia and reduces risk of bias. Age and gender demographics were characteristic of the greater student physiotherapy population in Australia [205], with students at universities across all states with pre-registration physiotherapy programmes represented. Given this representative demographic profile, it is likely that the results are characteristic of the student physiotherapist population studied. Due to the small number of study participants contributing to the qualitative data, the generalisability and transferability of the thematic analyses may be limited. However, the themes agreed with those identified in the registered physiotherapist population, strengthening the likelihood of good generalisability and transferability.

4.4 CONCLUSION

AHPRA registered physiotherapists and student physiotherapists in Australia perceive that the introduction of autonomous physiotherapist prescribing would be beneficial for the Australian population and should be introduced. Participants recognised the benefits to all stakeholders, highlighting improvements for patients and in turn, health services. It is anticipated that the introduction of physiotherapist prescribing may aid in retaining talent within the profession if the additional responsibility is supported and remunerated appropriately. Acceptance of physiotherapist prescribing and the likelihood of physiotherapists to train as prescribers vary dependent on location and the health sector in which a physiotherapist works. Legislation, regulation and governance around the use of physiotherapist prescribing all require careful consideration and consultation with experts and health consumers to ensure the safety and quality demanded by physiotherapy profession. Rigorous national educational frameworks should be developed within a transparent career development structure to ensure prescribing is used within a multimodal-physiotherapeutic context, safeguarding the professional reputation of physiotherapy.

It is recommended that the APA, health departments and political leaders use the results of this study in conjunction with cost-benefit analyses, risk analysis as well as assessment of the health-requirements and consultation with key stakeholders, to redefine the scope of Australian physiotherapy to include NMP. Stakeholders should use the results of this study in conjunction with the supporting literature to inform planning that should not only focus on the introduction of physiotherapist prescribing but should be visionary, preparing the profession for the future. It is acknowledged that to date no RCTs have investigated

the efficacy of physiotherapist prescribing across specialities or settings, to support or oppose its use in clinical practice. Low risk of bias RCTs are required to formally assess the clinical and cost-effectiveness of physiotherapist prescribing across a range of clinical contexts (specialities and settings) in the UK. Researchers should prioritise conditions with large clinical and economic burdens such as LBP, to facilitate safe, quality implementation of physiotherapist prescribing where there is the greatest potential benefit internationally.

4.5 DISSEMINATION OF RESULTS

The results of the research have been published across two articles in BMJ Open, an international peer review journal (Appendix 17 and 18) [206 207].

Noblet T, Marriott J, Jones T, Dean C, Rushton A. Perceptions about the implementation of physiotherapist prescribing in Australia: a national survey of Australian physiotherapists. BMJ open 2019;9(5): e024991

Noblet T, Marriott J, Jones T, Dean C, Rushton A. Perceptions of Australian physiotherapy students about the potential implementation of physiotherapist prescribing in Australia: a national survey. BMJ open 2019;9(5): e026327

Response to expert reviews comments prior to publication are found in Appendix 19 and 20. Findings were also disseminated at peer reviewed international and national conferences:

Noblet T, Marriott J, Jones T, Dean C, Rushton A. Views and perceptions of Australian physiotherapists and physiotherapy students about the potential implementation of physiotherapist prescribing in Australia. Podium presentation, Australian Physiotherapy Conference NEXT 2018, Oct 2018; Hobart, Australia

Noblet T, Marriott J, Jones T, Dean C, Rushton A. Views and perceptions of Australian physiotherapists and physiotherapy students about the potential implementation of physiotherapist prescribing in Australia. Podium presentation, World Confederation of Physical Therapy Congress 2019, May 2019; Geneva, Switzerland- Award/Prize for best podium presentation WCPT

4.6 FUNDING

No funding from external sources was received to complete this study.

4.7 CHAPTER SUMMARY

This chapter explored the views of Australian physiotherapists and physiotherapy students regarding NMP by physiotherapists in Australia. A cross-sectional descriptive survey using open and closed questions was developed by a panel of subject experts and emailed to all members of the APA. A sample of 1409 participants completed the survey. The majority of participants agreed that autonomous prescribing responsibilities should be introduced for physiotherapists in Australia, owing to potential benefits for patients, clinicians, the physiotherapy profession and the Australian health economy. Quality clinical governance, risk management, regulation of clinicians and the development of an education framework were identified as priorities for successful implementation in the future.

It is advised that decision-makers should consider the results of this survey in conjunction with cost-benefit and risk analysis when planning the introduction of physiotherapist prescribing. Researchers should prioritise conditions with large clinical and economic burdens such as LBP, to facilitate safe, quality implementation of physiotherapist prescribing where there is the greatest potential benefit internationally. Acknowledging this recommendation and the deficit of quality trials highlighted in Chapter 2, the following chapter goes on to evaluate the feasibility, suitability and acceptability of methods for completing a future definitive trial to evaluate the clinical and cost-effectiveness of physiotherapist independent prescribing by MSK APPs for LBP.

CHAPTER 5: INDEPENDENT PRESCRIBING BY ADVANCED PHYSIOTHERAPISTS FOR PATIENTS WITH LOW BACK PAIN IN PRIMARY CARE: A FEASIBILITY TRIAL WITH AN EMBEDDED QUALITATIVE COMPONENT

Chapter overview:

This chapter reports a feasibility trial with an embedded qualitative component evaluating the feasibility, suitability and acceptability of assessing the effectiveness of independent prescribing by APPs for patients with LBP in primary care. This addresses thesis objective 4. Analysis of the data from the trial and embedded qualitative components are presented and assessed against a priori success criteria. The findings are discussed to inform the development of a future definitive trial.

Sections of this chapter are taken verbatim from the following publications in which I am principal author.

Noblet T, Marriott J, Rushton A. Independent prescribing by advanced physiotherapists for patients with low back pain in primary care: protocol for a feasibility trial with an embedded qualitative component. BMJ open 2019;9(4): e027745

Noblet T, Marriott J, Hensman-Crook A, O'Shea S, Friel S, Rushton A. Independent prescribing by advanced physiotherapists for patients with low back pain in primary care: A feasibility trial with an embedded qualitative component. PloS one 2020;15(3):e0229792

To ensure the reader has a clear understanding as to why methodological decisions were made, the methods section of the published protocol article has been extended for clarity and transparency. Due to limitations in word count for publication, the published

discussion of findings was reduced. This chapter provides a fully detailed discussion of the study's findings and further discusses the strengths and weaknesses of the study.

Details of authors' contributions to the published paper (as acknowledged in the article):

TN is a PhD candidate at the University of Birmingham (UK). AR is a reader in Musculoskeletal Rehabilitation Sciences and lead supervisor. JM is a professor of clinical pharmacy and co-supervisor. Both supervisors ensured the rigour of methods and analyses. TN wrote the first draft of this article and led on subsequent drafts with feedback from supervisors and experts to develop subsequent drafts. Patients and the general public were involved in the design of this study via PPI evaluation groups.

5.0 BACKGROUND

LBP is the most prevalent MSK condition in the UK, with 58-84% of the population experiencing LBP in their lifetime [32-34]. At any time, 28.5% of adults over 25 are experiencing LBP [33]. Data indicates that 3.2 million work days are lost per year in the UK, with an average of 16.5 days lost per case [208]. Approximately 20% of those with LBP seek care from their GP [32], with 7% of all GP consultations being due to LBP [34 35].

Despite increased funding for treatments and a growing understanding of the complex biopsychosocial nature of LBP leading to improvements in assessment and management of the condition, up to 7% of the general population in the UK have chronic LBP associated with significant disability [32 33] and the health and function of this demographic continues to decline [209]. In an attempt to address this, novel approaches have been adopted to inform

shared decision-making and stratification tools are being utilised to improve outcomes through recognising clinical heterogeneity, ensuring that all biopsychosocial risk factors are addressed, improving patient management and reducing the overall cost of health care [37] [209] [210]. Early assessment, diagnosis and treatment of LBP has been seen to reduce chronicity [32]. However, the complex and multidimensional nature of LBP combined with a current deficit in the availability of GPs in the UK [211] [212], has prompted the redesign of out-dated traditional LBP clinical-pathways, and the introduction of new treatment models designed to maximise clinical and cost-effectiveness, whilst readying the health services for the future [54] [212] [213].

Physiotherapists are experts in the assessment, diagnosis and treatment of musculoskeletal disorders [21] [24] [170]. For more than 30 years, physiotherapists have been working in advanced practice roles across the country, utilising their scope of practice to optimise patient care, providing support in health services where the availability of medical practitioners does not meet the demands of a local community [20] [21]. Advanced MSK physiotherapists have been shown to be clinically and cost-effective in a variety of settings including orthopaedic and emergency care departments as well as in primary care in MSK interface-services [20] [22] [23]. Recently, the success and experience of these practitioners, alongside changes in demographics and predictions that GP numbers will further reduce by 2020, have prompted successful pilot studies investigating the effectiveness of first contact advanced physiotherapy practitioners (FCPs) in primary care [55] [213]. As a result, Health Education England (HEE), in collaboration with NHS England, the Royal College of General Practitioners (RCGP), the British Medical Association (BMA) and the Chartered Society of Physiotherapy (CSP) have committed to introducing these roles across England [55] [214] [215].

Recently published guidelines from NICE [37] for LBP and sciatica, advocate for a holistic, multimodal approach to assessment and management [34]. Advanced physiotherapists are well placed to provide this care owing to their competency in physical therapies including manual and exercise therapy; knowledge and skills associated with the management of psychosocial factors; and ability to appropriately refer for blood tests, imaging, spinal injections, denervation and surgery [216 217]. Further, the NICE guidelines recommend the use of drugs that are helpful and minimise harm [34 37]. It is therefore envisaged that independent physiotherapist prescribing will be a key competency required for the successful implementation of first contact advanced physiotherapists working in primary care.

Physiotherapist independent prescribing remains relatively new, with the first prescribers qualifying in 2014. Evaluation of physiotherapist and podiatrist independent prescribing has shown good acceptance by patients and a good safety record to date [25]. The recent mixed methods systematic review investigating the barriers and facilitators of NMP detailed in Chapter 3, concludes that the successful implementation and utilisation of NMP is dependent upon adequate preparation and organisation of a range of factors [163]. Considerations such as the use of advanced physiotherapists in primary care were seen to facilitate successful implementation of NMP as long as clinical governance, policy development and service practicalities and logistics are adequately developed and established prior to implementing NMP. To ensure longevity and future growth, education, support and financial factors alongside the management of personal and professional considerations were also deemed paramount [163].

For clinical services to be successful they must deliver positive clinical outcomes in a safe and economically sound manner [218]. Our recent rigorous systematic review investigating

the clinical and cost-effectiveness of NMP across all professions and clinical settings (Chapter 2), identified limited evidence with unclear risk of bias [88]. We concluded that quantifiable benefits of NMP remain unknown and called for adequately powered, low risk of bias randomised controlled trials (RCTs) in specific patient groups, professions and clinical settings [88]. Owing to the contemporary nature of physiotherapist independent prescribing, no trial has examined the clinical or cost-effectiveness of this intervention in the complex context of LBP. Trial design requires careful consideration particularly as physiotherapy independent prescribing is within the process of implementation across private health services and NHS Trusts. A feasibility study is therefore required to inform a multi-centre RCT investigating physiotherapist independent prescribing by APPs for patients with LBP, in primary care. The project will aim to evaluate the feasibility, suitability and acceptability of procedures and outcomes for use in the definitive trial, also assessing the commitment and burden on participants, clinicians and researchers as well as infrastructure and technological requirements.

Aim:

To evaluate the feasibility, suitability and acceptability of assessing the effectiveness of independent prescribing by APPs for patients with LBP in primary care to inform the design of a future definitive stepped-wedged cluster trial.

Objectives:

General Objectives

- To assess the feasibility, suitability and acceptability of the proposed definitive trial [219] including:
    - Eligibility criteria [220-222]
    - Recruitment strategy [220-222]
    - Data collection methods [220-222]
    - Follow up procedures [220 221]

Specific Objectives:

Feasibility:

- To evaluate participant recruitment rates [219-221].
- To evaluate the ease of fitting participants with accelerometers and ease of data collection [220 221].
- To evaluate the capacity (time and effort) of clinicians and researchers to complete trial related tasks [220 221].
- To evaluate the necessary training requirements required by clinicians to successfully implement a definitive trial [220 221].

Suitability:

- To evaluate the range of participants' scores on the Roland and Morris Disability Questionnaire (RMDQ), assessing for floor effects and therefore the appropriateness of outcome measure for use in a definitive trial [219-222].
- To evaluate the suitability of the ActivPal 3 accelerometer to measure physical activity and sedentary behaviour in people with LBP and participant compliance with wearing the accelerometer device [220 221].
- To evaluate the time required to conduct each stage of the protocol [220 221].
- To evaluate the suitability and availability of services and infrastructure such as access to national and institutional communication and information technologies required to undertake a definitive trial [220 221].

Acceptability:

- To evaluate the acceptability (appropriateness and tolerability) of the intervention to patients and the public [219-222].

5.1 METHODS

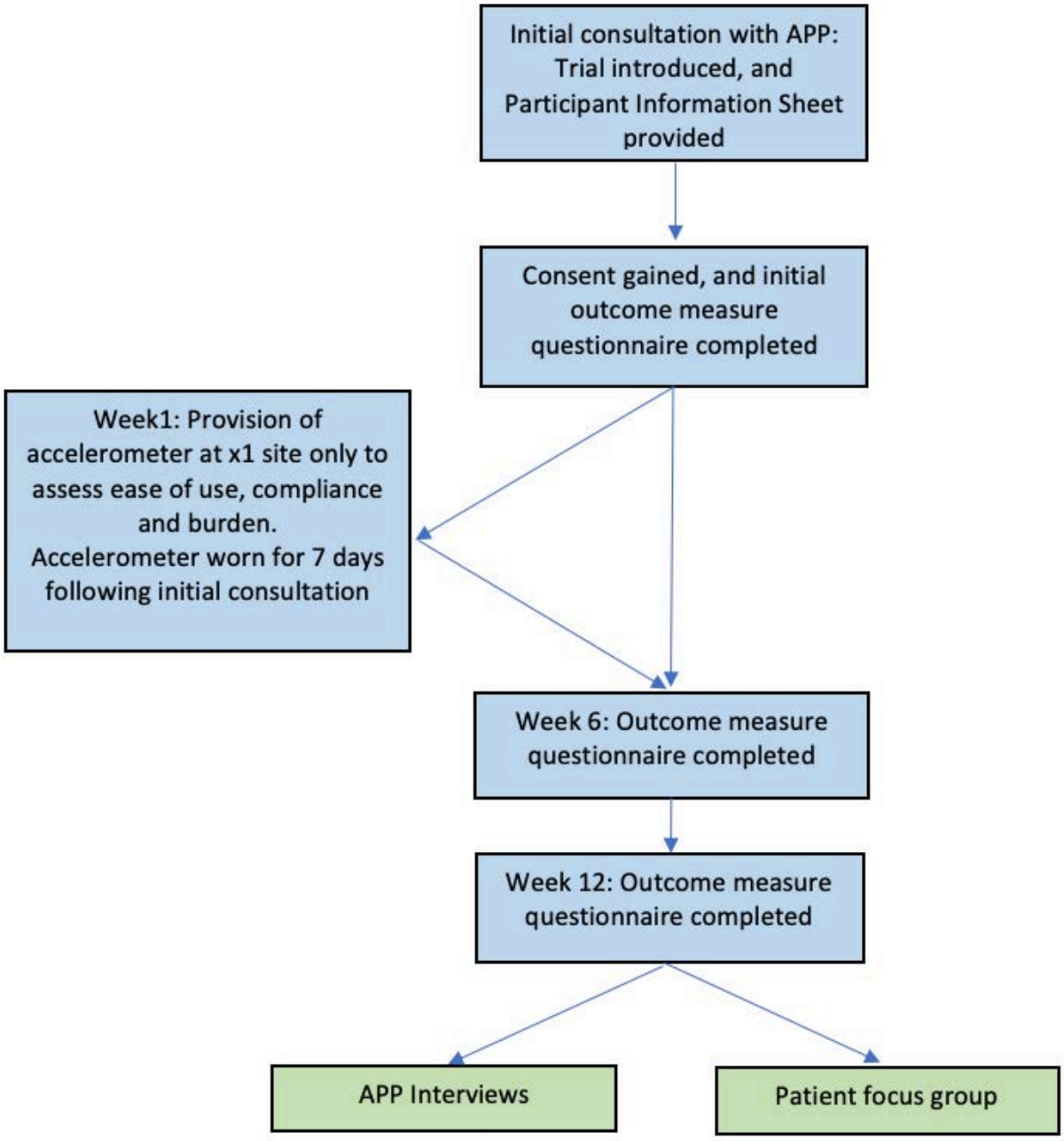
To ensure transparency and reproducibility this feasibility trial protocol was published in BMJ Open [223] (full protocol article is found in Appendix 21) and registered on the ISRCTN database (ISRCTN15516596). For clarity and rigour it is reported in line with the CONSORT 2010 statement: extension to randomised pilot and feasibility trials (CONSORT checklist is found in Appendix 22) [224-226], with all PPI reported in line with the GRIPP2 short form reporting checklist [227 228].

This feasibility trial utilised a mixed methods research approach comprising:

- a quantitative one-armed feasibility trial
- qualitative semi-structured interviews and patient focus groups, using thematic analysis.

Mixed methods designs are recognised to enable a richer synthesis, generating data which will facilitate appropriate change [95-97]. The feasibility trial structure is presented in Figure 32.

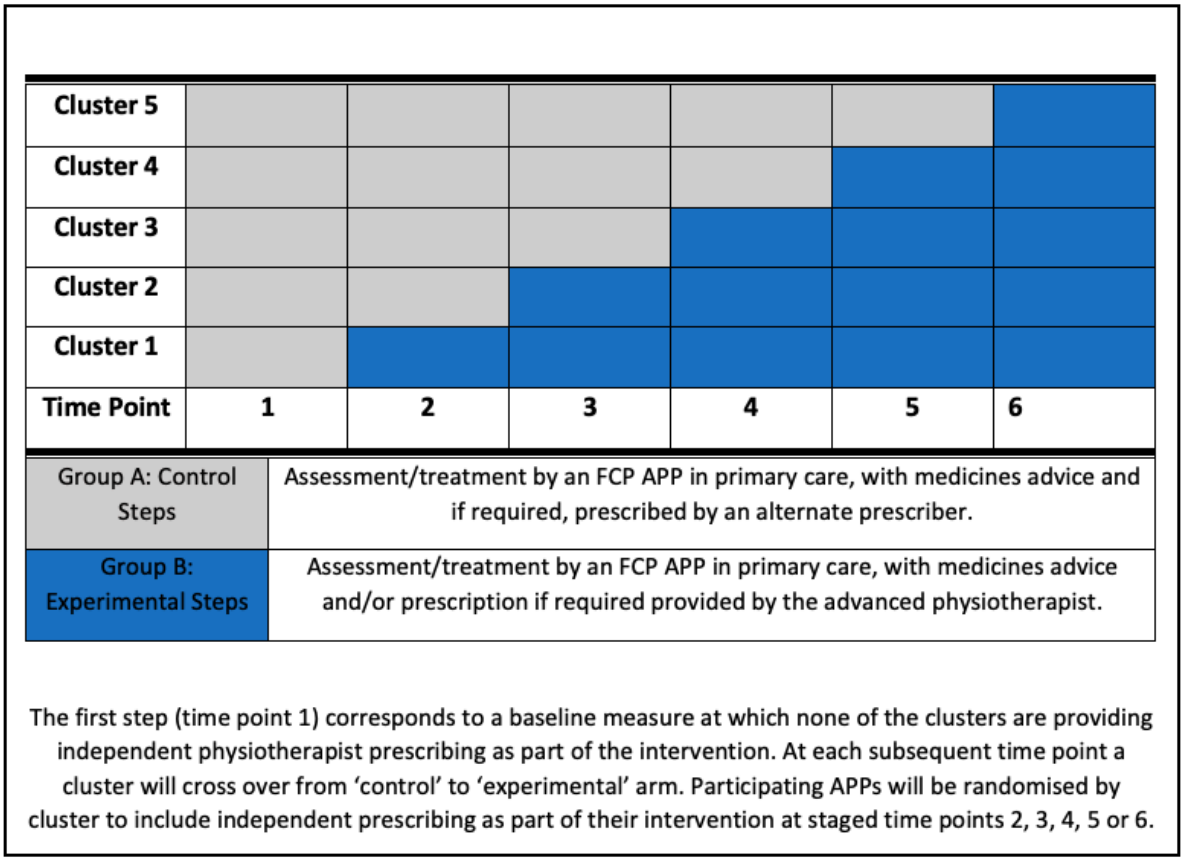
Figure 32: Trial Flow Diagram



5.1.1 Design

RCTs are considered the gold standard for evaluating the effectiveness of an intervention [229]. Cluster RCTs (cRCTs) allowing for randomisation by group have been developed to overcome practical issues in clinical settings, where individual randomisation is not convenient or feasible [229-231]. When evaluating contemporary interventions, parallel designs requiring the new intervention to be simultaneously provided to multiple clusters of participants are often too costly or not practical owing to the necessary clinician training required to deliver the intervention safely [229 230]. A stepped-wedge cluster randomised controlled trial (SWcRCT) design will therefore be used to evaluate the clinical and cost-effectiveness of physiotherapist prescribing for LBP in the future. This design is valuable when evaluating innovative clinical interventions where there is a strong ethical belief that the intervention will benefit patients [230 232 233]. SWcRCTs allow each experimental cluster to begin in the control arm then cross over to the experimental arm at specified time points (Figure 33) [232]. As the implementation of physiotherapy independent prescribing and the utilisation of APPs working as FCPs are both relatively contemporary innovations, there are limited numbers of clinicians currently working in these innovative roles who are registered to prescribe. This research design allows for the use of fewer clinicians than those required for a parallel design and is therefore more reflective of current practice. APPs who are not prescribers will start in the control group and cross to the experimental group following registration as an independent prescriber. APPs who are not prescribers start in the control group and cross to the experimental group [230-233].

Figure 33: The stepped wedge cRCT design for potential use in a definitive trial



Currently no clear framework exists describing the requirements for best practice when completing feasibility trials in preparation for SWcRCTs [234]. Two-arm feasibility trials that have aimed to calculate intra-cluster correlation coefficients (ICCs) required for sample size calculations in preparation for full cRCTs have demonstrated insufficient accuracy, unless the feasibility trial is equal in size as the definitive trial [234]. Therefore, a single-arm feasibility design was employed to test specific aspects of the trial protocol in terms of feasibility, suitability and acceptability on the experimental arm of the future SWcRCT, without sample size estimation [78 220 235].

5.1.2 Trial Component

A prospective, mixed methods, single-group feasibility trial was used to evaluate the trial objectives [222 235]. Participant consent forms (Appendix 23) and patient reported outcome measures (Appendix 24) were completed digitally via an online survey at initial assessment (baseline) and at 6 and 12 weeks (12 weeks is the planned primary endpoint of the definitive trial) following a prescription being issued, to evaluate the feasibility of follow up data collection procedure [78 79]. Follow up time points were selected in line with the prognostic literature showing that 40% of patients presenting to primary care with LBP will be pain free 6 weeks post onset, with 58% pain free by 12 weeks [38 236 237]. The online outcome measures survey was built using REDCap (Research Electronic Data Capture) software (hosted in the Centre for Precision Rehabilitation for Spinal Pain (CPR Spine) at the University of Birmingham, UK), enabling data to be captured and stored in real-time, on a range of electronic devices [238]. Baseline measurements were completed by the participants within the clinical setting. A link to the online outcome measures survey with instructions was then emailed to participants for completion at 6 and 12 weeks. If participants forgot to complete the outcome questionnaire on the required day, a reminder to complete was sent at 24hrs and 48hrs after the deadline to facilitate compliance [78 180]. To evaluate the feasibility of fitting participants with accelerometers in clinic to measure physical activity and sedentary behaviour, the ease of data collection and participant compliance with wearing the accelerometer device [220 221], n=10 participants at one research site were fitted with an accelerometer to wear for 7 days immediately following completion of patient reported outcome measures at the first consultation. Participants were provided with stamped/addressed envelopes in which to return the devices after use.

5.1.2.1 Participants

Potential participants were identified by the APPs at each clinical site, by using the STarT Back Tool at initial assessment, to stratify all patients presenting with LBP [210]. Patients stratified into the medium risk group by the STarT Back tool were eligible for recruitment if they met the inclusion criteria following assessment (Figure 34). This group of patients has been recognised as the predominant cohort presenting for assessment and treatment of LBP in primary care; exhibiting both physical and psychosocial prognostic factors and may require physiotherapist prescribing to optimise their multimodal physiotherapeutic treatment [39 210 239 240]. Convenience sampling was adopted, as this method has the advantages of fluid recruitment and follow up required by feasibility trials, with good retention of participants where time is limited [78 79 221 241]. Patients that were interested in participating were provided with a participant information sheet (Appendix 25) explaining the rationale, content and research dissemination plans to ensure ethical recruitment of participants. The physiotherapist answered any questions and if the patient wished to participate, consent was obtained using an online consent form. Contact details for the research team were provided to give the participants the opportunity to have any further questions answered. Contact details for an independent advisory service (PALS at each site) were also be provided in case external advice was desired by participants. Participants were free to withdraw at any time, without any impact on their care [78 79].

Figure 34: Chapter 5 Participant Eligibility Criteria

Inclusion Criteria
• Male and female patients, aged >18 years. • Non-specific LBP +/- leg pain requiring medication advice and drug prescription on assessment • Classified as Moderate risk using the STarT Back Tool (classified as potentially benefiting from medicines and active physiotherapy treatment[210]) • Able to read/communicate in English (owing to funding restrictions for interpreters and translators) • Capable of following the demands inherent of the study
Exclusion Criteria
• Signs of lumbar nerve root compression[242] • Red Flags including potential spinal fracture, inflammatory disease, infection or malignancy[242] • Spinal stenosis[243] • Suspicion of or confirmed corda equine syndrome[244] • Does not have capacity to consent[245] • Unable to receive email and/or complete online questionnaires

5.1.2.2 Interventions

As the control arm of the definitive trial will be "current normal practice", the intervention designed for the experimental arm of the definitive trial was used to evaluate the feasibility trial objectives [219-222]. As per "current normal practice", an APP acting as an FCP completed the initial assessment and physiotherapeutic treatment of participants as deemed appropriate through evidence based clinical reasoning and best practice (traditional role). In addition to the physiotherapist's traditional role, the APP had the competence and legal ability to prescribe medicines independently. If advice about medication or prescription drugs were required/no longer required within the multimodal physiotherapeutic context, these were prescribed/de-prescribed by the APP immediately, rather than referring the

patient back to their GP for assessment for medications as per current normal practice. The medications provided were to be taken by the patient as prescribed in the time frames discussed in the clinical consultation.

5.1.2.3 Outcomes

The literature reports that the use of a core outcome set assessing pain intensity, health related quality of life and physical function is required for the assessment of non-specific LBP (NSLBP) [246]. However, no consensus exists with regards to the instruments most suitable to measure these domains [246]. The outcome measures selected for use within the trial were informed by a team of subject-experts including physiotherapists, pharmacists, medical practitioners, academics and health-service managers and deemed most appropriate to evaluate the studies objectives whilst attempting to minimise the burden on participants. Two primary outcome measures (detailed below) were selected as they jointly evaluate the core outcome set requirements defined in the literature [246]. Detail of the secondary outcome measures and rationale for selection are found in Table 18. Assessment of sleep via accelerometer was detailed in the published protocol. Unfortunately, sleep was not evaluated due to limitations in the validity of the sleep evaluation functionality of the current technology available [247].

Primary Outcome Measures

- Overall Pain, Numerical Rating Scale (NRS): The NRS is a unidimensional 11-point scale (0-10) used to measure pain intensity, where 0 represents no pain and 10 represents maximum pain (e.g. the worse pain you can possibly imagine) [248].

Patients with pain have been shown to prefer the NRS over other pain measure including the pain Visual Analogue Scale (VAS) owing to simplicity and clarity [248 249]. The NRS has demonstrated good reliability, validity and responsiveness and has been used extensively in pain research [250-252]. A reduction of 2.5 points on the NRS has been shown to be clinically important for chronic LBP [251-253]. Participants scored pain in 3 categories: “worst pain over the last two weeks”, “least pain over the last two weeks” and “average pain level today”.

- Roland Morris Disability Questionnaire (RMDQ): The RMDQ is one of the most widely used outcome measures for LBP, with well-established good levels of validity and reliability [254]. The RMDQ has been selected over its counterparts owing to its superior measurement properties in patients reporting moderate disability demonstrated by those stratified into the medium risk group by the STarT Back Tool [210 253 254]. The 24-item questionnaire takes approximately 5 minutes to complete and includes items assessing: physical activity, sleep, psychosocial factors, activities of daily living, appetite and pain [255]. Scores range from 0 (no disability) to 24 (maximum disability), with a change of 3.5 points deemed clinically significant [253].

Table 18. Secondary Outcome Measures and their Rationale

Outcome	Measure	Rationale
Health Related Quality of Life (QALY)	EQ-5D 5L	The EQ-5D 5L is used to measure health related quality of life demonstrating good reliability and validity through psychometric testing [256]. If feasibility is found this measure will inform cost utility is a full RCT.
Pain Related Fear of Movement	The Tampa Scale- 11 for Kinesiophobia (TSK)	The Tampa Scale for Kinesiophobia (TSK) is a 11-item tool which was developed to measure a person's fear of movement owing to LBP. Ongoing fear of movement has been linked to the development of long term persistent pain [257]. This outcome measure has been found to show good validity and reliability when measuring pain related fear of movement [258].
Physical activity and sedentary behaviour	ActivPal 3 Accelerometer	Anecdotal evidence suggests that decreasing sedentary behaviour in people with LBP may have significant health benefits [240], reducing risks of obesity, metabolic syndrome, type two diabetes and mortality [259]. Systematic reviews have revealed that physical activity of people with LBP is lower or equal to the healthy population [260-262], however there appears to be differing patterns of physical behaviour, with the back-pain population engaging in shorter bouts of physical activity which are not long enough to incur health benefits (>10 minutes) [262 263]. An accelerometer will be used to collect data including: time sitting, standing and walking, steps count and overall activity score [264]. To date no individual brand/model of accelerometer has been identified as gold standard. The ActivPal 3 was selected for use in this feasibility trial as it has been seen to be more precise and sensitive than other accelerometers [264 265].

Outcome	Measure	Rationale
Time to return to work and nature of return to work (e.g. full time, part time, light duties)	Days	Work absence owing to sick leave for work disability is a key issue clinically, socially and economically. The MCIC for time return to work has not been defined due to the specific measurement (days on sick leave) being widely accepted and recognition of the measure's value in social and economic issues rather than an indicator of morbidity [253]. This measure would therefore be useful when conducting economic evaluation of physiotherapist prescribing.
Prescription utilisation, Participant	Days	Time requiring drugs for the treatment of NSLBP discussed/prescribed by the advanced physiotherapists was monitored to evaluate the necessity of this measure for future cost-effectiveness analysis within a definitive trial.
Number of appointments with other healthcare professionals about this episode of LBP	Number of appointments with each type of healthcare professional	The number of appointments with other healthcare professionals about the specific episode of LBP being studied was recorded via a question in the outcome questionnaire to evaluate the necessity of this measure for future cost-effectiveness analysis within a definitive trial.

5.1.2.4 Sample Size

As the number of FCP physiotherapists that are registered to prescribe is currently limited [27], 3 first contact APPs (n=3), across 3 primary care sites representative of English geography (x1 capital city, x1 regional city, x1 rural town), recruited, assessed and treated up to n=10 participants per APP within a 6 month recruitment time period. This enabled the evaluation of recruitment rates across clinicians and the feasibility of the trial methods in both metropolitan and rural healthcare services [220 234 235]. This feasibility trial did not aim to estimate the sample size required for the definitive trial as feasibility trials for cRCTs have been shown not to adequately predict sample size, therefore large numbers of participants are not required [234 266]. The literature recommends that a sample size of n>20 is adequate when testing feasibility objectives for cRCTs however, a total sample of n=30 participants was planned to allow for under-recruitment within the specified time period and participant drop out [220 221 234 235]

5.1.2.5 Data Analysis

A CONSORT diagram was used to describe the flow of participants and loss to follow up rates. This then allowed for analysis of the feasibility of the eligibility criteria, and acceptability of recruitment and follow up rates [224]. Only data from fully completed outcome questionnaires was included in the data analysis, however the number of partly completed outcome questionnaires was noted and reasons for this explored in the embedded qualitative component of the trial. Data from accelerometers were uploaded to ActivPal analysis software (PALanalysis v8, UK) immediately following removal from the participants. Data measuring physical activity and sedentary behaviour including time

sitting, standing and walking, number of steps taken, the number of times the participants stood from a sitting position and an overall activity score (metabolic equivalents-hours) were extracted. All data were tabulated, and primary descriptive analysis of the data was completed to test procedure [78 79 220]. Descriptive analysis was used to determine the distribution of the data, enabling the identification of trends and associations between variables [78 79 267]. Causality was not statistically analysed as this is not within the scope of this feasibility trial [78 79 267]. The distribution of the scores on the RMDQ were evaluated at baseline, 6 and 12 weeks following initial intervention. The percentage of scores equalling 0/24 at 12 weeks were used to measure a potential floor effect [268].

5.1.3 Embedded Qualitative Component

5.1.3.1 Design

An embedded qualitative component was utilised as recommended by current guidance, to address trial objectives and to refine and adapt the proposed definitive trial design following evaluation [269 270]. The methodology was designed and is reported using the Consolidated Criteria for Reporting Qualitative Health Research (COREQ)[271].

Advanced Physiotherapy Practitioners

Semi-structured in-depth face-to-face interviews with all of the APPs (n=3) were used to evaluate their views and experiences about the feasibility, suitability and acceptability of the trial, specifically evaluating trials objectives [219-222 272 273]. Interviews were undertaken by one researcher (TN) following completion of participant data collection, to evaluate the

research objectives and to gather qualitative data regarding the participants' views, perceptions and experiences about taking part, future risks and how the trial might be improved [220 221]. Question design was informed by the methodological literature and developed by a team of experts in the fields of physiotherapy, primary care, NMP, health policy and trial methodology [78 241]. The topic guide can be found in Appendix 26. A PPI group reviewed the questions for appropriateness and clarity [274]. Prior to completing the interviews, the APP participants were provided with an information sheet and had the opportunity to ask the researcher any questions about the interview process. Consent to taking part was gained using a consent form (Appendix 27). Interviews were recorded and transcribed verbatim. Transcripts were returned to participants for inspection, comments and corrections prior to analysis, to ensure all views and thoughts were captured [272].

Patients

A focus group of patients took place following the 12 week assessment point, specifically to evaluate the research objectives [220 275]. Focus groups are recognised to produce data on collective views, generating a rich understanding of participants' experiences [276]. A purposive sample of 6 patients, representative of ages and gender was used to evaluate the feasibility trial objectives across the diverse LBP population [277 278]. This sample size is reported in the literature as the optimum [275]. The focus group met in a closed meeting room at Windermere Health Centre, ensuring confidentiality. The focus group was conducted by 2 researchers (facilitator and observer) using a predetermined topic guide designed to assess the research objectives, developed by a team of experts in the fields of physiotherapy, primary care, NMP, health policy and trial methodology and informed by the methodological literature [78 241]. The topic guide (Appendix 28) was reviewed by a PPI

group to ensure appropriateness and clarity [274]. Consent to participate in the focus group was taken prior to the focus group commencing. The participants received an information leaflet and had the opportunity to have any questions answered by the researchers. The focus group was recorded and transcribed verbatim. Transcripts were returned to participants for comments/correction to ensure all views are represented [271].

5.1.3.2 Analysis and Findings

To fulfil the trial objectives a thematic analysis approach was used to analyse and synthesise the qualitative data [78 279 280]. This systematic, inductive and interactive method is recognised to be useful in identifying the key thoughts and views of the population being studied. The method is useful where there are likely to be both similarities and diversity of opinion and where the intervention is novel, often providing explanations alluding to how the concerns may be resolved or processed in preparation for a definitive trial [279-282]. Focus group and interview transcripts were coded line-by-line using NVivo 11 software (QSR International, Melbourne, Australia) by one researcher (TN) and verified by a second researcher (AR) [79 280 281]. Rigorous comparative analysis was completed by one researcher (TN) to identify similarities and differences within the data, informing the development of descriptive categories which were linked, merged or split to synthesise a conceptual understanding of the data [280 281]. To avoid single researcher bias, a second researcher (AR) re-interrogated the data to validate or contradict findings [280]. Outcomes were then discussed with a panel of experts for confirmation and agreement [279 280 282].

5.1.4 Integration: Feasibility, Suitability and Acceptability

Following data analysis of the trial and embedded qualitative components, the quantitative and qualitative data were assessed against success criteria outlined a priori (Table 19). As no validated success criteria framework exists for use in feasibility trials, the predetermined success criteria were developed by a team of experts in the fields of physiotherapy, primary care, NMP, health policy and trial methodology and informed by the methodological literature [78 221 241 283]. Trial objectives were considered successful if the success criteria were satisfied following the integration of the quantitative and qualitative findings [221 283].

Table 19. Success Criteria

General Objectives	Success Criteria
Eligibility criteria	A favourable number of patients fit the eligibility criteria to enable the stipulated recruitment rate
	APPs agreed with the eligibility criteria
Recruitment strategy	Participants were recruited within the time constraints of the local clinical environment
	Patients and APPs report that they were happy with the recruitment strategy
Data collection methods	Data were collected with ease via RedCap and no complications were experienced
	Data completeness of ≥ 80 %
	Patients and APPs report that they were happy with the data collection methods
Follow up procedures	100% of participants were contacted for follow up
	≥80% completion of follow up outcome measures
	Patients and APPs report that they were happy with follow up procedures

Specific Objectives	Success Criteria
Feasibility	
Participant recruitment rates	Recruitment target of n=10 per clinician met in the time available (6 months)
Ease of fitting accelerometers	Accelerometers were fitted within the allocated clinical time allowed with the FCP APP
	Patients and APPs report that accelerometers were fitted with no issues
Accelerometer data collection	RedCap was able to capture the data from the accelerometers with no errors or data loss
	Patients report that they were happy with data collection using accelerometers/ burden within subjectively appropriate limits
Capacity (time and effort) of clinicians' complete trial related tasks	APPs report that adequate time was allowed to complete all tasks required by them during the trial
Training requirements required by clinicians	APPs report that they had adequate training to be able to complete the tasks required by them during the trial
Suitability	
Outcome measures	Data completeness of ≥ 80 %
	Patients and APPs report that the outcome measures were appropriate and self-explanatory
Compliance with wearing the accelerometers	Data collected ≥ 80 % of the requested time (16hrs/day for 7 days)
Time required to conduct each stage of the protocol	APPs report having adequate time to complete each stage of the protocol
Service infrastructure	Recruitment targets met. Data completeness of ≥ 80 %
	APPs report that adequate service infrastructure is in place to allow for a definitive trial to be completed
Acceptability	
Intervention	Patients and APPs report that the intervention was appropriate/ satisfactory

5.1.5 Patient and Public Involvement (PPI)

Patients with LBP were part of the research team and co-investigators to ensure the patient perspective is central. There was a PPI representative on both the Trial Management Group and Trial Steering Group to ensure that patients and the public were involved at all steps in the research process.

Patients reviewed the trial protocol and contributed to the development of the interview and focus group questions, participant information sheet, consent form; and importantly to the processes of data analysis and interpretation and producing a lay summary of findings.

5.1.6 Data Storage

All data were electronic and stored in password protected computer files that could be accessed only by study investigators at the University of Birmingham. Participants who chose to disclose personal details were additionally protected via coding on data files. This coding was kept in a password protected computer file on the University of Birmingham server, only accessible to the research team ensuring confidentiality [78 179]. These personal data and participant contact details (stored during study to arrange focus groups and interviews) were securely destroyed at the end of the study. No participants were identifiable in data presentation or dissemination. The confidentiality of data was preserved when the data were transmitted to sponsors and co-investigators by maintaining the de-personalised data format and ensuring that no data were traceable to an individual participant. The password-protected files will be retained for 10 years, in a confidential, locked storage unit, satisfying university code of practice.

5.1.7 Ethical Considerations

The feasibility trial was conducted in accordance with the principles of the Research Governance Framework for Health and Social Care. To ensure that the trial was conducted in an ethical manner within best research practice, ethical approval was granted (IRAS project ID: 250734, Protocol number: RG_18-101, REC reference: 18/LO/1793) (Appendix 29) and HRA approval obtained (Appendix 30), with R&D permission from all sites (33, 34). Approval was granted on 30th October 2018. Participants' inclusion within the study was entirely voluntary, with no incentives offered to participants to minimise bias [78] [79]. Participant consent was gained using an online consent form following the provision of information explaining the rationale, content and research dissemination plans to ensure ethical recruitment of participants [78] [179]. Participants were free to withdraw at any time [78] [79].

5.2 RESULTS

5.2.1 Trial Component

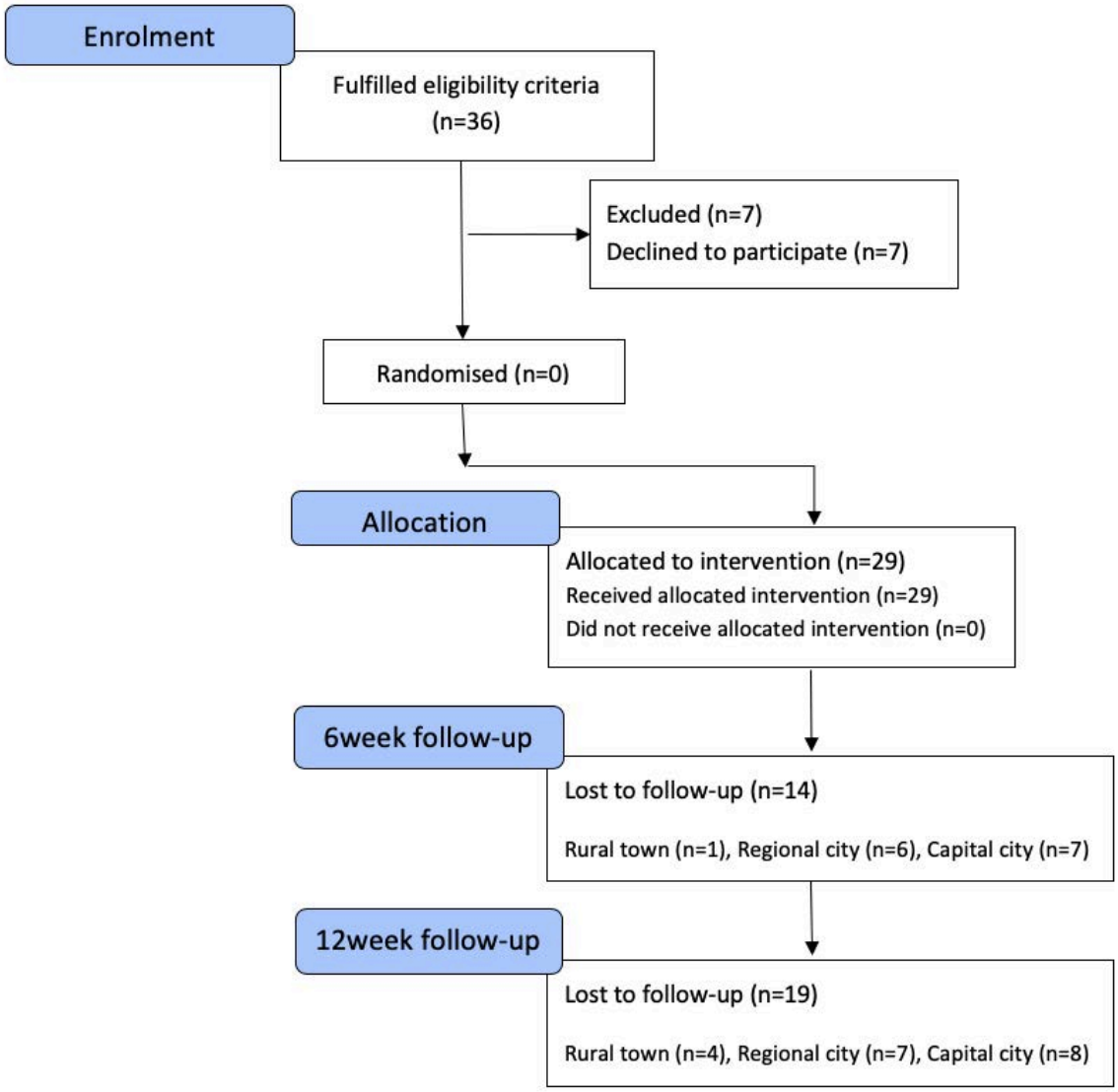
5.2.1.1 Demographics and participant flow

Demographic and recruitment data are presented in Table 20. n=29 participants (n=12 male, n=17 female) were recruited. The mean recruitment rate was 1.07 participants/week. Two sites recruited the pre-defined n=10 participants within the 6-month recruitment period (3 and 4.5 weeks). Forty-eight percent of participants were lost to follow up at 6 weeks, with 65.5% at 12 weeks (Figure 35). One site had a loss to follow up of 89%, suggestive of site-specific issues. No patients refused to participate owing to the inability to complete the outcomes measure survey online.

Table 20. Demographic and recruitment data for the trial component

Gender		
Male	12	
Female	17	
Age		
18-29	3	
30-39	8	
40-49	5	
50-59	5	
60 or older	8	
Recruitment rates		
Location	Time to recruit (weeks)	No of participants (n)
Rural town	4.5	10
Regional city	3	10
Capital city	20	9
Mean (SD)= 9 (9.41)		Total=29

Figure 35: CONSORT flow diagram



5.2.1.2 Outcome measures survey

Table 21 presents mean primary and secondary outcome measure data collected from the outcome measure questionnaire with variability reported by the use of standard deviations (SD). Reductions in pain were found for all pain categories as time progressed. Mean scores on the RMDQ reduced from 9.21 (SD 5.58) at base line to 8.07 (SD 5.82) at 6 weeks, then increased to 9.70 (SD 5.33) at 12 weeks. Between baseline and 12-week, improvements were seen across all components of the secondary outcome measures other than anxiety

and depression (EQ-5D 5L) which increased with time. No participants scored the distinct lower limit in any of the outcome measures; therefore, no floor effects were found. As primary and secondary outcomes improved, absence from work and prescription utilisation reduced.

Table 21. Primary and secondary outcome measures data

Outcome measure	Baseline Mean (SD)	6 weeks Mean (SD)	12 weeks Mean (SD)
Pain			
Worst pain over the last 2weeks (0-100)	81.17 (18.18)	59.87 (27.84)	58.20 (31.88)
Least pain over the last 2weeks (0-100)	43.48 (25.72)	34.07 (23.88)	25.70 (20.01)
Average pain level today (0-100)	55.89 (23.18)	42.53 (23.61)	40.40 (28.86)
RMDQ (0-24)	9.21 (5.58)	8.07 (5.82)	9.70 (5.33)
EQ-5D 5L			
Mobility (0-5)	2.45 (0.99)	1.93 (0.96)	2.20 (0.79)
Self-care (0-5)	1.76 (0.83)	1.53 (0.74)	1.60 (0.84)
Usual activities (0-5)	2.66 (1.01)	2.40 (0.99)	2.50 (0.85)
Pain/discomfort (0-5)	3.24 (1.02)	2.33 (0.72)	2.60 (0.80)
Anxiety/depression (0-5)	1.66 (0.72)	1.80 (1.21)	2.00 (1.33)
Health today (0-100)	74.72 (27.18)	68.20 (15.65)	59.60 (21.37)
TSK-11 (11-44)	25.66 (7.99)	24.13 (8.64)	22.2 (7.92)
Absent from work (DAYS- between each survey)	8.52 (20.04)	7.07 (17.38)	1.00 (3.16)
Total prescription utilisation (DAYS)	-	17.47 (17.30)	25.30 (37.08)
Number of appointments with other health professionals (between each survey)			
General Practitioner	-	3	0
Advanced Physiotherapy Practitioner		1	1
Spinal surgery team		1	0
Pain Management team		0	1

5.2.1.3 Accelerometery

Ten participants (n=2 male, n=8 female) wore an ActivPal accelerometer 24 hours a day for 7 days. Data collected by the accelerometers are displayed in Table 22. There were no missing data. Participants spent an average of 18.57hrs (SD=1.54) sitting per day, 4.14hrs (SD=1.17) standing and 1.3hrs (SD=0.39) walking. Participants completed 5884.66 steps per day (SD=2255.11), with a mean activity score of 32.94MET.h (SD=1.03).

Table 22. Accelerometer Data across 7 days

Participant	Sitting (hrs)	Standing (hrs)	Walking (hrs)	Steps	Sit-Stands	Activity Score (Metabolic Equivalents- hours (MET.h))
1	17.60	4.66	1.77	9720.86	49.57	34.47
2	18.13	4.36	1.53	6386.29	64.00	33.19
3	15.67	6.49	1.86	8680.29	55.71	34.38
4	19.67	3.43	0.90	3461.71	32.00	31.90
5	21.80	1.71	0.50	1808.29	33.57	30.98
6	18.34	4.31	1.36	5966.00	56.29	33.00
7	18.54	4.16	1.32	6003.90	48.52	32.99
8	18.54	4.16	1.32	6003.90	48.52	32.99
9	18.67	4.09	1.25	5472.91	48.37	32.77
10	18.75	4.05	1.22	5342.43	46.14	32.72
Mean Total-over 7 days	18.57	4.14	1.30	5884.66	48.27	32.94
SD	1.54	1.17	0.39	2255.11	9.74	1.03

5.2.2 Embedded Qualitative Component

5.2.2.1 Interviews: Advanced Physiotherapy Practitioners (APPs)

Demographics

Demographic details of the APPs can be found in Table 23. APPs all had a post-graduate qualification in the musculoskeletal speciality. The number of years qualified as a physiotherapist ranged from 15- 28 (mean= 21 years).

Table 23. Demographic data of interview participants

No:	Job title	Gender	Years registered as a physiotherapist	Post graduate qualifications
1	Advanced Physiotherapy Practitioner	Male	15	MSc Musculoskeletal Physiotherapy Non-medical Prescribing
2	Advanced Physiotherapy Practitioner	Female	28	MSc Musculoskeletal Medicine Non-medical Prescribing
3	Advanced Physiotherapy Practitioner	Female	20	MSc Musculoskeletal Physiotherapy Non-medical Prescribing

The APPs' (n=3) views, perceptions and experiences related specifically to the trial objectives were analysed and synthesised into 3 themes and associated subthemes:

- **Trial design, conduct and processes**
    a) Eligibility criteria, recruitment strategy and follow up procedures
    b) Capacity (time and effort required)
    c) Training requirements
- **Data Collection, outcomes and measures**
    a) Data collection tool and accelerometery
    b) Equipment, services and infrastructure
- **Adequacy of the feasibility trial**

Table 24 provides illustrative quotations to demonstrate each theme.

Table 24. Interviews, comments that reported or discussed each theme and illustrative quotations from APPs (quotations have been copied verbatim)

Theme	Illustrative Quotations
Trial design, conduct and processes	"I think it's quite time intensive with the clinician doing it [recruitment] in real terms, mid-clinic, to collect all of that data." (APP1) "The reasons it [recruitment] was slow was, I didn't prescribe much, and I think the biggest reason was because patients didn't want to take medication for their back pain……." (APP 3) "rather than having 20-minute slots for these patients, I would want a good 30-40 minutes for them, so that I didn't rush those elements [clinical assessment]." (APP 1) "The ideal situation, I think, would be for the first contact practitioner to identify the patient and then create a list for a research assistant to then take over, to put the bits and bobs on and to sit with them to do the questionnaire." (APP2) "…… most of them kind of knew how to use a tablet, but I definitely couldn't just ignore them to let them get on with it in the waiting room…" (APP 1) "You definitely need a research assistant. If you're going to sit with somebody, then I think the clinician doesn't really have enough time to do that." (APP 2) "Time was massive, time, restricted anyway with 20 minutes, appointments, and I felt that it did cause me to run over." (APP 3) "…. in the demographics, with all due respect, that we were in, I didn't really want to give them a brand-new tablet to take away and do it because there was the potential that that wouldn't come back." (APP 1) "… there were 10 subjects, on average round about five minutes I would say. Some were a bit less, there was one or two patients who were a good 10 minutes or so, really, who weren't tech savvy." (APP 1)

	"Time factor, they [patients] didn't want to [be recruited] … they were maybe happy to do the first questionnaire, but they didn't want to then do the follow up questionnaires, they couldn't commit to it." (APP 3) "A way round it [time restrictions] would have been to recruit an admin staff or an assistant and for them to go through it in person with those patients, the questions, and their input." (APP1) "I think having someone there with them, not to bias the answers but to just read it along with them, was useful." (APP 1)
Data Collection, outcomes and measures	"… these are standardised questionnaires and they're robust and they've been well studied, but they still did ask questions and they were not 100% sure of what they should do." (APP 1) "I thought the content was good, there wasn't anything particularly in there that I thought shouldn't have been in there." (APP 2) "It felt like it was set up on an Apple and then put on an Android because it was clunky software." (APP 1) "I think the questions that are on there are all well-studied, reliable, robust measurement tools, as robust as we can have." (APP 3) "I thought the content was good, there wasn't anything particularly in there that I thought shouldn't have been in there." (APP 2) "… if you think about back pain and all the contributing factors…. so, lifestyle and sleep [should be added]." (APP 3) "I think the accelerometers are really good at doing what they're supposed to do in terms of activity, lying down, standing up. It would be quite interesting to correlate that to actual activity." (APP 2) "I think the benefits of electronic and automatic…. getting it [surveys] uploaded…. would be good, I think that would be preferential, over paper." (APP 1)

	"I quite like the slidey things, but the vertical slidey thing doesn't work on an iPad, it just moves the whole pad up and down" (APP 2) "Yeah, the age demographic didn't play out necessarily. Some of my older patients could fly through it." (APP 1) "I'd be keen for you to collect information about what drugs were we looking at, what exact prescribing decisions we would be making." (APP1) "I liked it being electronic. I thought, having the patient information sheet in paper was quite good because you could go through that together. But I thought in terms of the actual rest of it, I thought it was fine." (APP 3) "They [patients] were given prescription advice, or de-prescribed… that was the bulk of my work… And getting them to take medication correctly." (APP 1) "There was one particular section that I needed to explain to patients, it was the bit where they were looking at patient statements of pain." (APP2) "You've definitely got different categories and yeah, you've got those ones… it's quite different the ones you've written the prescription to, to those ones that are just over the counter. Or GP has given you this, but actually you're not quite taking it right. That would reflect what we really do." (APP 3)
Adequacy of feasibility trial	"…. the biggest part of it, it's about advising about what pain is and about how it can be managed and it's not dangerous and about how activity is more beneficial to them than not being active. It's about rehabilitating, psychologically and physically back to full function." (APP 2) "… people that come and they're on opiates when they don't need to, beforehand, if you weren't qualified in prescribing, you might not know that they're inappropriate and you might not have the confidence to venture into that and challenge that prescription decision. That patient would continue to take a drug that might be doing more harm for them than benefit, which is not great." (APP 1)

	"A minimal amount of my prescribing might be in the acute things, episodes where they might need a prescribed drug, but you can then quickly bring them off that drug. Also, more importantly, is the fact that when people are put onto, say opiates, for example, an FCP is more likely to take the person off the opiates, by de-prescribing or they can reduce the pain medications down in a graded kind of way to make sure they're safe and then go onto over the counter drugs." (APP 2) "I thought the information sheet was really thorough and I thought it was clear and the patients seemed to understand it." (APP 1) "I liked it being electronic. I thought having the patient information sheet in paper was quite good because you could go through that together." (APP 3) "I think the questions that are on there are all well-studied, reliable, robust measurement tools, as robust as we can have." (APP1) "I do think it'll work; I think it's good but again, the de-prescribing part needs to be in it." (APP 2) "It's about rehabilitating, psychologically and physically back to full function. And pain management can be hot or cold. It doesn't have to be as in medication although medication is part of the whole thing and it is used, but I think that that's a small part of the patient's recovery for their back pain." (APP 2) "Being able to de-prescribe I think has been probably the most beneficial part of doing that role and then prescribing, you're enabling patients to get on board with their treatment and therapy." (APP 1) "Overall, I think it's very beneficial to have those skills and the ability to tap into them is really useful. It increases my own self-confidence when exploring drug histories and putting the bigger picture into place. Rather than having a niche of physio and not daring venture into medication because of medico-legal processes, I'm happy to stray into those topics. I think the patients holistic care is better for that." (APP 1)

Trial design, conduct and processes

a) Eligibility criteria, recruitment strategy and follow up procedures

APPs felt that a definitive trial should enable the evaluation of all stratifications of NSLBP +/- leg pain. They advocated for a definitive trial that include participants across all LBP stratification groups defined by the STarT Back tool. This would allow for both intra- and inter-group comparisons evaluating the effectiveness of independent prescribing by APPs for patients with LBP in primary care across the spectrum. The APPs advised that variation would exist regarding the utilisation of skills within the scope of independent prescribing across each of the STarT Back stratification groups due to patient-specific factors such as the length of time the participant has experienced LBP, associated psychosocial factors, previous treatments and experiences and related medical history. Therefore, it was felt that the specific prescribing skills used, such as prescribing medicines, de-prescribing, advising about the use of over-the-counter medication and medicines management, should be captured throughout the individual patient journey. All APPs expressed that the trial methods tested by the feasibility trial would enable appropriate comparison of STarT Back stratification groups, however they highlighted that the complex nature of persistent LBP would require follow up for longer than the 12-week period tested, demonstrating the need to consider increasing the primary endpoint in a definitive trial.

All the APPs felt that the recruitment strategy was suitable, although recognised that recruitment rates could potentially differ between APPs in a definitive trial due to varying experience of clinicians working in FCP roles and proficiency and/or confidence in prescribing medicines. Two of the clinical sites (regional city and rural town) recruited n=10 participants over 3- and 4.5-week periods respectively. The third site (capital city) used the

full 6-month recruitment period to recruit n=9 participants. The APP from the capital city site reported that patients were frequently excluded from participation due to language barriers. Additionally, English-speaking young professionals in the area often declined recruitment, declaring that they were too busy to commit to complete the 6 and 12-week follow up surveys. Recruitment was curtailed across all sites by patients consistently stating that they did not want to take analgesia for their LBP, preferring to engage in other conservative management strategies such as exercise and manual therapies. This was cited as the key benefit of consulting a physiotherapist for their LBP rather than their GP.

To optimise recruitment rates in a definitive trial, it was suggested that posters and social media posts might encourage patient interest. Administrative staff could be utilised to highlight potential participants when booking appointments and provide patients with participant information leaflets prior to seeing the APP. APPs across both city-based sites recognised the risk associated with participants using data collection equipment unsupervised, fearing that there was potential for theft or damage. Patient's literacy was highlighted as a potential barrier to independent completion of the online outcome measures surveys, and thus a barrier to recruitment of a sample representative of the LBP population. All APPs highlighted that due to restricted consultation time in FCP practice, the use of research assistants to recruit and consent participants identified by the APP during consultations, could further optimise recruitment rates. APPs postulated that research assistants at each site, recruiting, consenting and aiding patients with completing the online outcome measures survey, would not only simplify recruitment and follow up procedures but would also minimise risk, especially at locations where multiple APPs are recruiting to a definitive trial. The APPs advised that to improve compliance with follow up procedures, participants should be asked to consent to reminder telephone calls from the

research team, with the choice of completing the follow up outcome measures survey online, on paper, independently or face-to-face with a researcher or research assistant. It was proposed that these changes would increase the likelihood that patients would consent to participating in the trial and minimise drop-out due to non-compliance.

b) Capacity (time and effort required)

Twenty-minute FCP consultations were scheduled at each site. The APPs stated that the recruitment and consent of each participant and completion of the initial outcome measures survey took approximately 10-15 minutes. If the application of an accelerometer was required, this took an additional 5-10 minutes dependant on the "tech savvy nature" of the individual participant. Additional time was also required to answer participants' questions, confirm data entry and upload data to the REDCap server. All APPs described the time pressures as "stressful", causing their clinics to run late. Further, all APPs reported "rushing" clinical assessments if they were aware that they needed to recruit a patient to the trial. It was recommended that if APPs are to be used to recruit, consent, aid in the completion of the initial outcome measures survey and apply an accelerometer in a definitive trial, 30-40-minute consultations would be necessary. Unfortunately, all of the APPs agreed that healthcare service commissioners would not agree to extended appointment times to allow for research activity. Therefore, a definitive trial would require a research assistant at each site to ensure appropriate clinical and administrative capacity.

c) Training requirements

All APPs reported that they felt prepared and confident to lead the recruitment of participants and initial data collection processes. Each APP reported acting as principal investigators for previous clinical trials and observed that less experienced clinicians may require additional training in ethical recruitment and consent procedures, documentation and data management. All recruiting clinicians would require training to effectively apply accelerometers to participants and to educate participants on the re-application should dressings become unsealed or cause a skin reaction. For future trials it was recommended that peer support and clinical mentorship would be essential for new prescribers and less experienced APPs. This would ensure best practice and assist in managing variation in clinicians' confidence to prescribe.

Data Collection, outcomes and measures

a) Data collection tool and accelerometery

All of the APPs agreed that the outcome measures within the survey were suitable and encompassed the majority of the multi-faceted dimensions of LBP. Two of the APPs recommended that tools evaluating sleep, lifestyle and confidence with global physical activity could further improve the richness of data collected in a definitive trial. Although the APPs recognised that the outcome measures within the survey were validated and tested for reliability and reproducibility, it was reported that some of the participants required help to complete all questions in the survey. However, no common question was

identified. It was suggested that this variation in understanding was due to differing participant literacy levels.

The survey logic was reported as user-friendly other than an issue with one question ("Number of days taken off work?") as this question was not applicable to participants who were part-time, retired or registered as disabled. The APPs all commented that the difficulty in the ability to capture data about the wider use of the independent prescribing qualification was a weakness. The use of prescribing, de-prescribing and medicines advice and management were deemed fundamental to the effective use of NMP within the FCP role. APPs were also interested in capturing data around what, as well as how drugs are currently being prescribed for the management of LBP by APPs in primary care across the country.

No problems were reported regarding the fitting of accelerometers. Participants were happy to be taught to re-apply accelerometers themselves should the dressings become loose or need replacing. No issues were reported to the APPs regarding self-removal of accelerometers by participants after 7 days, and all units were returned in a timely manner without damage. No adverse effects or compliance issues were reported. It was highlighted that all participants lived locally to the clinic and returned the accelerometers in person. If participants lived further away from clinical sites it was deemed acceptable for participants to return accelerometers by post following provision of a padded pre-paid envelope.

b) Equipment, services and infrastructure

Overall, the APPs agreed that the services and infrastructure tested by the feasibility trial were suitable and would enable the completion of a robust definitive trial. All of the APPs disclosed technical issues with the tablet computer provided for data collection. One APP stated that the tablet was not sophisticated enough to optimally run the REDCap application. The others described the application as "clunky", reporting significant issues with the vertical sliding visual analogue scale (VAS) within the EQ-5D 5L tool. The security of the tablet computer was a concern if the outcome measures survey was to be used outside of the consultation room. It was recommended that the tablet computer should be securely attached to a wall in a quiet waiting area to stop theft, however it was accepted that participant privacy and dignity may preclude this solution from being a valid alternative.

Adequacy of the feasibility trial

Each of the APPs interviewed stated that the feasibility trial was adequate for assessing the feasibility suitability and acceptability of the trial methods. The clinicians all agreed that iNMP enables better holistic care by FCPs for LBP in primary care, therefore a definitive trial is essential to evaluate efficacy. The APPs deemed all ethical conduct and trial documentation (including participant information sheet, consent form) acceptable for use in a definitive trial. The use of digital consent and data collection was seen to be positive, securely storing participant data and enabling the blinding of the analytical research team.

To better inform clinical decision making, the clinicians enquired as to whether collaboration with NHS digital might further streamline data collection. It was felt that connectivity between data collection technology and the participant's digital clinical notes, might highlight psychosocial factors not identified by clinicians in a time-pressured consultation, further improving management of the 'whole patient'.

5.2.2.2 Focus Group: Patients

Demographics

Focus group demographic data are presented in Table 25. Six participants from the trial component of the feasibility trial consented to participate in the focus group. Purposive sampling enabled a representative spread of ages. Sixty percent (n=4) of the participants were female.

Table 25. Demographic data of focus group participants

Demographic Descriptor	Number of Participants
Male	2
Female	4
Age (years)	
17-29	1
30-39	1
40-49	1
50-59	1
60 or older	2
	Total number of participants n=6

Patients' views, perceptions and experiences related specifically to the trial objectives were analysed and synthesised. Data were synthesised into 3 themes:

- **The use of physiotherapist independent prescribing by APPs**
- **Trial conduct and processes**
    a) Recruitment processes
    b) Follow up processes
- **Data Collection**
    c) Accelerometery
    d) Outcome measure survey

Table 26 provides illustrative quotations to demonstrate each theme.

Table 26. Focus group, comments that reported or discussed each theme and illustrative quotations from patients (quotations have been copied verbatim)

Theme	Illustrative Quotations
The use of physiotherapist independent prescribing in FCP clinics	"When you go to a doctor and say, "I've got back pain," they'll sort of say, "Right… I'll give you some painkillers to take for a couple of weeks,", Whereas if you're with [APP 2}, she will say… "do X, Y, Z and if you can't manage it, then come back and we'll try something," and vice versa. So, you get more information on how the drugs will work for you if you need them…." (Participant 3) "The general practitioner will try to refer on if they're not sure what's going on. Whereas your MSK consultant [FCP] is looking after your pain, your physiotherapy and your forward treatment. I think it's good in the one package." (Participant 2) "It seems you're getting a solution to the problem rather than having to wait and wait and wait and see other people that you have to explain the same thing to every time you meet them." (Participant 6) "Sometimes, you need medication to take the pain away so that you can do strengthening exercises and then when you go back, you've got a better range of movement, so you don't need the tablets, you know, whichever way round." (Participant 1) "If you're pain free, you can get back to work, they [APPs who can prescribe] get you back to work as quickly as possible." (Participant 5) "… and they're [GPs] sitting there typing, "Okay, right. Well, just take the co-codamol for a couple of weeks," you know, sort of thing. I don't mean it as harshly as that but that's how it is, it can be." (Participant 4) "It's more of a holistic view." (Participant 1) "It [LBP] is like a specialist subject…… it's not really suited to general practice" (Participant 2) "If it's soft tissue, they [GPs] send you off for an MRI or CT and say, "We'll give you a referral in three weeks' time," whereas the APP would say, "I think it's this. I want to give you treatment for this and we're going to give you some medication, some exercises and follow-on care." (Participant 2)

	"I love doctors, don't get me wrong but as I say, it's like a 10 minute [appointment] and they don't really know you and it's, "Oh well, I'll just write you out a prescription," …." (Participant 4)
Trial conduct and processes	"I think so long as it's explained to the patient in the beginning that it is a trial and you have to complete it. Even if you've got better in the middle of it, you've still got to fill in the surveys to say, "I got better". Because a lot of people don't bother." (Participant 2) "...ask the patient initially how they would like to be contacted, you know, whether they would mind having a reminder call of some description……" (Participant 4) "…. some folks are social media savvy and would be okay to contact them by email or by MSN. Or, if they joined a closed group on a Facebook site, where there was a community and reminders came on that. But for an older patient, it could be difficult to interface. If they don't have a computer themselves, they'd have to rely on someone else logging on for them……" (Participant 5) "….. a lot of patients, especially the older ones just don't go on the internet, don't want to know anything about it. So, you'd have to have a different way of communicating." (Participant 3) "… the wider sort of rurality. You know, so you've still got have options. You do when you join a website, they say, "How would you like to be contacted?" So, if you've got all the options, you can pick one or all of them and you can always change them at any time." (Participant 1) "Well, it obviously doesn't work for everyone, but you could have a liaison point in the surgery." (Participant4) "I don't know whether it [the trial] needs a proper clinic advert/poster. I mean, I know the receptionists tell… and obviously, people say by word of mouth but just that extra…" (Participant 6) "[to aid in recruitment] …. What about the use of the television screen in the waiting room?" (Participant 5) "[To promote retention in the trial] …. I would just sell the message that completing the survey is not about an individual case, it's about back pain." (Participant 1)

	"I think so long as it's explained to the patient in the beginning that it is a trial and you have to complete it. Even if you've got better in the middle of it, you've still got to fill in the surveys to say, "I got better." Because a lot of people don't bother." (Participant 3) "Well, I think it's people [those not completing follow up surveys] who, if they get better, they think they don't need to carry on." (Participant 5)
Data Collection	"You just got used to it and you forgot it was there and mine didn't roll or peel, you know, because you gave me a spare dressing in case it rolled up but it was absolutely fine; you forget it's there." (Participant 1) "I was walking like five, seven miles a day and I was swimming probably two miles, three miles a week, something like that, with it on." (Participant 6) "I have very sensitive skin so when I first put it on, I wondered if I'd get eczema, because that's what I suffer from. Not a bit of it, just forgot about it. And it came off easily in the end." (Participant 2) "Well, that was another thing that I remember flashed across my mind at the time. If it had come off, did it matter where it was put back on? You know, does it have to go back in exactly the same place, or could you move it?" (Participant 3) "It did for about the first couple of days but then you forget about it, so I thought, "Well, there's no point deliberately doing anything," because that's not giving a true thing." (Participant 1) "No, it didn't worry me. It's just that I wasn't quite sure what its purpose in life was, if you see what I mean…... I'd forgotten what had been explained to me!" (Participant 4) I'm sure that it was explained to me, otherwise I wouldn't have had it attached to my person……. but when I got home, I thought, "What is it doing on my leg? And why is it doing it?" you know, it had just sort of gone over the top by the time I'd got home." (Participant 2) "It was the one [digital VAS] where… yeah, we had when it was vertical. It just kept moving up and you couldn't do it. So, that would probably be better horizontal." (Participant 6)

	"I don't like questions that have like a scale. I can't think what percentage out of 100 is… "(Participant 1) "….one to 100 is quite a big range. At least one to 10, you've got so many points you can think of…" (Participant 3) "You need a timescale of some description as to what point of the day you're answering that questionnaire. Because I know I did mine at night. Well, at night, my back pain is absolutely horrible. If I'd done it a 9:00 in the morning, you'd have probably got different answers" (Participant 4) "I was filling it in at work and I had to take a phone call and then I came back and there was a problem with it, I couldn't restart it. I had to start it from the beginning again." (Participant 6)

The use of physiotherapist independent prescribing by APPs

The participants expressed that they were happy with the introduction of physiotherapist independent prescribing and felt confident in the APPs' skills. All participants agreed that physiotherapists are experts in the management of LBP. APPs were felt to provide a more detailed assessment than GPs, listening to patients' problems prior to developing a holistic treatment plan alongside the individual patient. All participants agreed that they would prefer to utilise non-pharmacotherapy methods to manage their LBP. If analgesia was required by a patient to facilitate management and rehabilitation, the APP was able to advise why the medication was needed and how best/ when to take the medication within the context of their social and family life, work commitments and associated treatments, including exercise therapy and physical activity. It was recommended by participants that more clinicians in similar roles should be employed across the whole spinal pain pathway, particularly within urgent care centres and emergency departments.

Trial conduct and processes

a) Recruitment processes

The participants reported that they were happy with the ethical conduct throughout the feasibility trial. They deemed the participant information sheet to be satisfactory and suitable for use in a definitive trial. All participants were happy with the recruitment process and could not identify any adverse effects or risks to being involved in the trial. It was proposed that the use of posters, social media and advertising on waiting room television screens might encourage participation in a definitive trial. Further, the focus

group recommended marketing aimed to involve all NHS patients in research activity. It was thought that this broader marketing strategy would reduce fear of participation and increase public awareness about the social responsibility for participation in health research.

b) Follow up procedures

All participants agreed that the follow up procedure used in the feasibility trial was acceptable however, participants in a definitive trial would benefit from choice of communication options. Participants agreed that personal preference would vary between patients, some preferring contact via telephone or post rather than email. They requested that each clinical site should have a liaison point for face-to-face discussion if required, with the option to complete the follow up outcome measure surveys digitally or on paper, over the telephone, via video call or face-to-face with a member of the research team. These options should be offered to the participants during the consent procedure with the participants being able to change their preference during participation in the trial if required. It was posed that the probable reason for non-response to the 6 week or 12-week follow up survey was that the participants were no longer suffering from LBP. It was felt that the clinicians recruiting participants to a definitive trial should be explicit about the necessity to complete all follow up surveys whether LBP had resolved or remained present. It was felt that reminders from a research assistant would further assist compliance.

Data Collection

a) Accelerometery

Participants agreed that all aspects of the feasibility trial testing the use of accelerometery were suitable and acceptable. They reported that the APP's explanation regarding the application, reapplication and rationale for use of the accelerometer was clear and understandable. Participants felt confident to reapply the accelerometer with a fresh dressing if required. However, this was not necessary across the trial participants. Three participants reported worrying about re-positioning the devices if re-application was necessary, however were happy that they could seek help from their APP if required. It was recommended that a further patient information sheet should be developed demonstrating the use, application and removal of the accelerometer to prompt a participant's memories.

Participants reported that the devices were easily fitted, and none experienced any adverse effects. One participant reported slight skin irritation in the final hours wearing the device but did not feel this was bad enough to warrant a change of dressing. Another participant stated that although wary of her sensitive skin during application, she had no reaction to the device-cover or adhesive dressing. Participants all concurred that the use of accelerometers attached to the skin enabled them to forget that they were wearing the device and continue with normal activity. It was felt that the device did not prompt additional activity after the first 24 hours and were no problem during land- or water-based exercise. Participants reported that attaching the accelerometer to the skin was preferable to wearing a device around the wrist, ankle or on their clothing, as these types of devices might prompt additional physical activity that they would not have otherwise undertaken.

It was felt that removable accelerometers might provoke feelings of stress due to a sense of constant examination and worry that results would be skewed if the device was removed and not replaced immediately.

b) Outcome measure survey

All participants agreed that the outcome measures survey was suitable for assessing the progression of their LBP. Completing the initial survey on a tablet was acceptable as long as help was available from a researcher or research assistant if required. The participants describe the tablet as “clunky”, explaining the problem with using the vertical sliding scale within the EQ-5D 5L tool.

Some participants reported difficulty in understanding the wording contained within the Tampa Scale for Kinesiophobia, other than this all other questions within the outcome measures survey where deemed clear and understandable. Participants debated the use of a 10-point or 100-point NRS, however no consensus in preference was reached, concluding that both numerical scales are acceptable. They warned that participant’s answers may vary dependent upon the time at which the survey is completed relative to a patient’s diurnal pain pattern and the timing of analgesia. However, participants also acknowledging that dictating a specific time for survey completion would not be feasible due to variation in participant’s daily lives. Overall, the participants agreed that the survey evaluated their LBP journey well but recommended the formal assessment of sleep within a full trial.

5.2.3 Integration: Feasibility, Suitability and Acceptability

For the 'general' trial objectives 90% of the success criteria were met, with 64% met for the 'specific' trial objectives. Both the general and specific objectives demonstrated good overall feasibility, suitability and acceptability. Table 27 displays evidence demonstrating the extent to which success criteria were met and potential improvements to trial design.

Table 27. Evidence demonstrating the extent to which success criteria were met

General Objectives	A Priori Success Criteria	Achieved Yes/No	Evidence/Comments
Eligibility criteria	A favourable number of patients fit the eligibility criteria to enable the stipulated recruitment rate	Yes	The eligibility criteria were reported as suitable and acceptable by all recruiting APPs and enabled a feasible recruitment rate. Barriers to recruiting all eligible patients are reported in the qualitative component synthesis.
	APPs agreed with the eligibility criteria	Yes	All APPs agreed with eligibility criteria for the feasibility trial. Qualitative data highlights that all STarT Back stratification groups should be included in a definitive trial.
Recruitment strategy	Participants were recruited within the time constraints of the local clinical environment	Yes	All participants were recruited within clinic time constraints. However, APPs felt the time pressures were stressful and recommended increasing appointment times or use of research assistants.
	Patients and APPs report that they were happy with the recruitment strategy	Yes	The recruitment strategy was deemed acceptable to both patients and APPs. However, APPs cited a lack of time as the major challenge to recruitment, recommending the use of research assistants in a definitive trial.

General Objectives	A Priori Success Criteria	Achieved Yes/No	Evidence/Comments
Data collection methods	Data were collected with ease via REDCap and no complications were experienced	Yes	REDCap collected the data well with no errors.
	Data completeness of ≥ 80 %	Yes	100% data completeness was achieved.
	Patients and APPs report that they were happy with the data collection methods	Yes	Patients and APPs deemed all data collection methods acceptable. It was highlighted that the REDCap application was “clunky” on the tablet, therefore investment in higher spec tablets for a definitive trial was recommended. Participants also recommended the use of horizontal VAS scales over vertical due to difficulties with screen scrolling.
Follow up procedures	100% of participants were contacted for follow up	Yes	100% of participants were contacted.
	≥80% completion of follow up outcome measures	No	Loss to follow up: 6 weeks, 48% 12 weeks, 65.5%
	Patients and APPs report that they were happy with follow up procedures	Yes	Patients and APPs reported that the follow up procedures were acceptable. However, recommended reminder telephone calls and the option to complete the follow up outcome measure surveys: digitally, on paper, over the telephone, via video call or face-to-face with a member of the research team.

Specific Objectives	A Priori Success Criteria	Achieved Yes/No	Evidence/Comments
Feasibility			
Participant recruitment rates	Recruitment target of n=10 per clinician met in the time available (6 months)	Yes x2 No x1	At x2 sites the stipulated n=10 participants were recruited within the 6 month recruitment window. At the capital city site n=9 participants were recruited. Reasons for slower recruitment are described in the synthesis of the interview data.
Ease of fitting accelerometers	Accelerometers were fitted within the allocated clinical time allowed with the FCP APP	No	Additional time or use of research assistants was recommended by the APPs.
	Patients and APPs report that accelerometers were fitted with no issues	Yes	No issues or adverse reactions were reported.
Accelerometer data collection	REDCap was able to capture the data from the accelerometers with no errors or data loss	No	Specific ActivPal applications were required to collect and store accelerometer raw data. Once downloaded, the data was transferred to the university server, as per ethical approval.
	Patients report that they were happy with data collection using accelerometers/ burden within subjectively appropriate limits	Yes	Patients all reported that they were happy with the use of accelerometery and felt no increased burden.
Capacity of clinicians' complete trial related tasks	APPs report that adequate time was allowed to complete all tasks required by them during the trial	No	APPs reported significant time pressures, recommending the use of research assistants or increased appointment times in a definitive trial.
Training requirements required by clinicians	APPs report that they had adequate training to be able to complete the tasks required by them during the trial	Yes	APPs all felt adequately trained, however identified that less experienced clinicians would require training around ethical consent. All APPs in a definitive trial would require training for fitting and using accelerometers.

Specific Objectives	A Priori Success Criteria	Achieved Yes/No	Evidence/Comments
Suitability			
Outcome measures	Data completeness of ≥ 80 %	Yes	100% achieved.
	Patients and APPs report that the outcome measures were appropriate and self-explanatory	Yes	Patients and APPs stated that the outcome measures were suitable. APPs advised the use of a sleep and physical activity questionnaire to accompany accelerometer data. Patients stated that some participants in a definitive trial might require help interpreting questions dependent on literacy levels.
Compliance with wearing the accelerometers	Data collected ≥ 80 % of the requested time (16hrs/day for 7 days)	Yes	100% compliance achieved.
Time required to conduct each stage of the protocol	APPs report having adequate time to complete each stage of the protocol	No	More time required to recruit, consent and fit accelerometers recommended.
Service infrastructure	Recruitment targets met. Data completeness of ≥ 80 %	No	One site did not attain the recruitment target. 100% data completeness was achieved.
	APPs report that adequate service infrastructure is in place to allow for a definitive trial to be completed	Yes	Infrastructure was described as suitable.
Acceptability			
Intervention	Patients and APPs report that the intervention was appropriate/ satisfactory	Yes	All participants in the qualitative component reported that the intervention was acceptable, appropriate and satisfactory.

5.3 DISCUSSION

5.3.1 Principal findings

This feasibility trial evaluated the feasibility, suitability and acceptability of assessing the effectiveness of independent prescribing by APPs for patients with LBP in primary care, to inform the design of a future definitive SWcRCT. Over a recruitment period of 6 months, 29 participants were recruited across 3 clinical sites. The average age range of participants was 40-49 years, reflective of international demographic data for LBP [277 284 285]. Trial objectives were evaluated against predefined success criteria. Ninety percent of the success criteria were met. Specific objective benchmarks evaluating adequate time to complete 'trial-related tasks' and recruitment and retention targets were not met. Forty-eight percent of participants were lost to follow up by 6 weeks with 65.5% lost to follow up by 12 weeks. Both the planned primary and secondary outcome measures were feasible and acceptable.

5.3.2 Acceptability of interventions

Ninety percent of the success criteria were met indicating that the methods tested are feasible, suitable and acceptable for use in a definitive trial. The data further strengthens trends found in the literature, demonstrating that healthcare service users are accepting and satisfied with NMP and have confidence in clinicians' NMP skills and competence [50 141]. Specifically, participants welcomed the APP's ability to include prescribing as one part of a comprehensive and holistic management plan. The clinicians all agreed that NMP enables better holistic care by APPs in FCP roles, for LBP in primary care.

5.3.3 Eligibility criteria

The eligibility criteria were designed to enable the recruitment of patients experiencing medium risk LBP, as stratified by the STarT Back tool. The majority of patients stratified to the medium risk group are acute or subacute in nature, potentially benefitting from a multimodal management approach including the use of analgesia [37 210]. APPs participating in the feasibility trial agreed that the eligibility criteria were suitable to allow the evaluation of the trial objectives. They echoed the literature in recognising that the condition is the predominant MSK problem presenting at primary care clinics potentially requiring analgesia as part of its management [39 210 239 240]. Synthesis of findings support amendment of the eligibility criteria for a definitive trial to include LBP patients across all three STarT Back stratification groups. Epidemiological literature highlights that for first episodes of LBP, pain is seen to improve rapidly in the first 4-6 weeks and is commonly fully resolved by 12 weeks [277 278]. This is not the case for the majority of patients with recurrent episodes or persistent LBP. In these patient groups, pain is often accompanied by more prominent psychosocial drivers, with patients commonly developing issues which require a clear long-term individualised psychosocial management plans [277 278]. If a definitive trial is to include all STarT Back stratification groups, additional longitudinal follow up procedures should be incorporated, rescheduling the trial primary endpoint to 1 year to allow for evaluation of patients in the long term.

The eligibility criteria specified that only patients with NSLBP +/- leg pain requiring medication advice and drug prescription qualified for inclusion. Findings highlighted that the scope of iNMP includes not only the prescription of medicines but de-prescribing and medicines advice and management. Clinicians advised that these key skills are the

prescribing skills most frequently optimised across the spectrum of LBP. The NHS spent £17.4 billion on prescription medications in 2016/17, with prescribing of analgesia for MSK pain significantly increased compared to the previous decade [36]. The APPs reported that they are frequently required to de-prescribe inappropriate and/or potentially harmful analgesia provided by other clinicians, or to optimise the use of drugs already prescribed to enhance rehabilitation potential. These observational findings emphasise the inappropriate overuse of paracetamol, non-steroidal anti-inflammatory drugs (NSAIDs), opioids and gabapentinoid medications for the treatment of pain reported in the literature, despite published prescribing guidelines [37 286]. In the UK, 24 million prescriptions for opioids were issued in 2017 [287], with gabapentinoid prescribing tripling over the last decade. Many of these drugs were prescribed for persistent LBP +/- leg pain [288]. Although it is hoped that these drugs are prescribed appropriately within governance frameworks, it is postulated that repeat prescriptions alongside insufficient clinical follow up, propagate prolonged use of these potentially dangerous drugs [289]. There is a current deficit in research evaluating how physiotherapist independent prescribing is used to manage LBP. It is imperative that a definitive trial collects and evaluates data inclusive of the whole scope of physiotherapist independent prescribing (including what is prescribed, de-prescribed or advised), with eligibility criteria enabling the inclusion of all patients with NSLBP +/- leg pain.

5.3.4 Recruitment

Recruitment rates were found to vary between the sites where identical weekly appointment slots were available. The rural and regional city sites took approximately 1 month to recruit 10 participants with the capital city site recruiting 9 participants over the

full 6-month recruitment period. Interestingly, the key reason identified for the slower recruitment rate was that patients fulfilling the eligibility criteria at this location did not want to take medication for their pain. Instead, participants reported that access to a physiotherapist for assessment and management permitted an alternative to the pharmacotherapy provided by the GP. This reflects the literature evaluating the use of direct access to physiotherapy in primary care. Physiotherapeutic holistic assessment for MSK conditions and joint decision-making regarding the appropriate management plan for the individual, has been shown to provide greater levels of patient satisfaction when patients are able to seek care directly from a physiotherapist without prior mandatory medical-input [290 291]. Completion of an adequately powered trial would be feasible using recruitment rates based on the rural and regional sites not that obtained in the capital city. However, it is posited that with the expansion of the proposed eligibility criteria to include all patients with NSLBP +/- leg pain, the full scope of physiotherapist prescribing and the adoption of additional recruitment capacity via research assistants and administrative staff, that recruitment rates at all sites would be acceptable for an adequately powered trial. To safeguard quality, recruitment rates should be re-evaluated following revision of the trial's eligibility criteria, interventions and recruitment procedures to ensure success criteria are met prior to completion a definitive trial.

5.3.5 Follow up procedures and retention

Poor clinician time capacity is a recognised barrier to conducting clinical trials [74 78 86]. Both patients and APPs advocated the use of research assistants to aid with trial recruitment, consent and follow up administration. Offering participants the opportunity to complete

the outcome measures survey over the telephone in a definitive trial would limit the results, as many of the outcome measure tools used in the survey are not validated for telephone use [292] [293]. To improve retention, participants recommended reminder telephone calls and one-to-one appointments where participant literacy levels limited completion of follow up surveys. Further, it was proposed that research assistants would improve retention by acting as a consistent point of communication, encouraging smooth participant flow through the trial.

Previous literature has linked the use of a combination of recruitment and follow up strategies, with improved retention rates [86] [294]. This improvement is attributed to sustained, frequent contact with participants as they move through a trial. Adequate statistical power and good external validity rely on sufficient participant numbers [74] [78] [86]. As loss to follow up in this feasibility trial was higher than the 20% deemed acceptable within research methods literature [86] [294], it is essential that the design of a definitive trial engages several strategies to improve retention. Modified procedures must be evaluated to ensure participant retention rates meet success criteria prior to a definitive trial. The literature proposes that a minimum of 3 communication channels should be provided by each participant, including contact through friends and relatives, with regular updates, 'check in' communication via text, email and telephone and face-to-face appointments if preferred. 'Branding' the trial with a recognisable name and logo embossed on all trial documents and correspondence may also improve retention owing to inferred credibility, enabling participants to build a bond with the research [86] [294].

5.3.6 Outcome measures and data collection methods

The literature reports that the use of a core outcome set assessing pain intensity, health related quality of life and physical function is required for the assessment of NSLBP [246]. As optimal tools are not defined in the literature, the primary and secondary outcome measures were selected and agreed upon by a group of clinical and academic experts. The appropriateness of the selected outcome measures for use in a definitive trial were evaluated. All APPs and patients agreed that the outcome measures were suitable and acceptable. However, the patients recommended that the option of completing the survey on paper would be beneficial for those with limited access to email or poor IT skills. Data demonstrated graduated improvements in pain, function, disability and activity over the 12-week assessment period, mirroring the trends for medium and low risk LBP reported in the literature [278 284 285]. No floor effects were detected across the outcome measures used. One hundred percent data completeness was achieved by using an online survey. Data collection via an online survey was deemed acceptable and feasible by both the clinicians and patients, supporting the literature that demonstrates better and quicker response times with fewer missing responses across both open and closed survey questions [295 296].

This feasibility trial aimed to evaluate participant compliance through assessments of wearing an accelerometer alongside the ease of fitting the devices and data collection. Treatment effect was not assessed. Participants fitted with accelerometers achieved 100% compliance and 100% data completeness, demonstrating feasibility of use in a definitive trial. Participants and APPs reported that the devices would be useful to include in a definitive trial. They were fitted easily and owing to their positioning participants did not feel that the devices prompted them to increase activity levels after the first 24hrs. This is

consistent with the accelerometer literature which demonstrates that removable accelerometers worn on the wrist, ankle or clothing may prompt increased physical activity and might lead to poor data completeness owing to participant removing the devices and forgetting to replace them [297-299].

The published protocol for the feasibility trial detailed the assessment of 'quality of sleep' via accelerometer data. Unfortunately, this was not evaluated owing to limitations in the available technology [300]. This deficit was highlighted by the APPs, who recommended the addition of a questionnaire-based outcome measure assessing participants' sleep. Fifty to sixty percent of people experiencing either acute or persistent low back pain experience high levels of sleep disturbance [301]. Poor sleep over long periods of time may lead to depression, obesity, diabetes and cardiovascular disease [301 302]. Patients with LBP suffering with sleep disturbance have been reported as twice as likely to be hospitalised owing to their pain [303]. The literature demonstrates that improved sleep modulates pain intensity [304], with poor quality sleep associated with increased pain intensity, fatigue, decreased function and psychological stress. Although perceived sleep quality has been shown to be different to the objective reality assessed via polysomnography or actigraphy, subjective assessment via sleep questionnaires and diaries have been shown to be valuable where objective evaluation is not possible [305]. Based on this rationale, it would be suitable to add a validated and reliable sleep questionnaire into the outcome measures survey for use in a definitive trial.

Findings from this feasibility trial indicate that a definitive SWcRCT is feasible following some minor modifications:

i. The definitive trial should include all patients presenting with NSLBP +/- leg pain and capture data representative of the full scope of physiotherapist independent prescribing.
ii. Limited clinician capacity and time restrictions dictated by job plans and service specifications, should be navigated through the use of research assistants to recruit, consent, aid in data collection and complete follow up and administrative tasks.
iii. Recruitment and follow up procedures should be modified in accordance with the feasibility trial data prior to the completion of a definitive SWcRCT.
iv. The online outcome measures survey should be revised to include a validated sleep evaluation tool, and the survey logic updated.
v. Revised procedures and both online and paper versions of the survey should be piloted across all LBP stratification groups to evaluate successful modification before use in a definitive SWcRCT.

5.3.7 Strengths and limitations

This feasibility trial used rigorous systematic methods including analysis and synthesis strengthened by an imbedded qualitative component and the engagement of expert trial management and steering groups including clinicians, healthcare managers, academics and patient and public representation. This combination ensured specialist knowledge of physiotherapist independent prescribing and LBP alongside specific primary care perspectives, facilitating a rigorous analytical process. There were no adverse effects to the treatments or methods evaluated. Individuals recruited to the qualitative component of the trial were observed to be comfortable throughout the process, expressing their thoughts and opinions openly. This feasibility trial is limited by the small samples used in both the trial and qualitative components; however, samples did satisfy the theoretical representation of the population essential to evaluate the trial objectives. No guidelines

exist defining best practice for feasibility trials evaluating trial methods prior to SWcRCT. Although this may limit the trial, the authors have utilised transparent, integrated best practice from aligned guidelines, whilst ensuring robust consultation with subject and methodological experts and representatives from the public, throughout trial design.

5.4 CONCLUSION

A definitive SWcRCT is feasible with some minor modifications. Methods evaluated are feasible, suitable and acceptable for use in a definitive SWcRCT. The SWcRCT should include all patients presenting with NSLBP +/- leg pain and capture data representative of the full scope of physiotherapist independent prescribing, including the prescription of medicines, de-prescribing and medicines advice and management. To navigate limited clinician capacity and time restrictions dictated by job plans and service specifications, researchers should consider the use of research assistants to recruit, consent, aid in data collection and complete follow up and administrative tasks. As part of designing a definitive full SWcRCT, recruitment and follow up procedures should be modified and further evaluated in accordance with the feasibility trial data. The online outcome measures survey should be revised to include a validated sleep evaluation tool, and the survey logic updated. Revised procedures and both online and paper versions of the survey should be piloted across all LBP stratification groups to evaluate successful modification before use in a definitive full SWcRCT.

5.5 DISSEMINATION OF RESULTS

The protocol for the feasibility trial has been published in BMJ Open an international peer review journal (Appendix 21) [223].

Noblet T, Marriott J, Rushton A. Independent prescribing by advanced physiotherapists for patients with low back pain in primary care: protocol for a feasibility trial with an embedded qualitative component. BMJ open 2019;9(4): e027745

Response to expert reviewers' comments prior to publication are found in Appendix 31. An article detailing findings have been published in PLOS One [306]. The response to reviewer's comments can be found in Appendix 32.

Noblet T, Marriott J, Hensman-Crook A, O'Shea S, Friel S, Rushton A. Independent prescribing by advanced physiotherapists for patients with low back pain in primary care: A feasibility trial with an embedded qualitative component. PloS one 2020;15(3):e0229792

Findings have also been dissemination at a peer reviewed national conference:

Noblet T, Marriott J, Rushton A. Independent prescribing by advanced physiotherapists for patients with low back pain in primary care: a feasibility trial with an embedded qualitative component. Poster and podium presentation, Physiotherapy UK 2019, Nov 2019; Birmingham, UK

5.6 FUNDING

Identification of the trial funders is disclosed to provide transparency and accountability:

- Health Education England (HEE) funding allowed for the procurement of accelerometers and the associated IT programmes to ensure that innovative physical measures could be evaluated alongside patient reported outcome measures.

- The Private Physiotherapy Educational Fund allowed for the procurement of x3 tablet computers for use in data collection and 7.5hrs per week of the principal Investigator's time for 18 months.

The funders had no direct role in trial design, conduct, data analysis and interpretation, manuscript writing and dissemination of findings. There were no conditions attached to funding.

5.7 CHAPTER SUMMARY

In light of the findings from Chapters 2-4, this feasibility trial was designed to evaluate the feasibility, suitability and acceptability of assessing the effectiveness of physiotherapist independent prescribing for LBP in primary care; informing the design of a future definitive SWcRCT. A definitive SWcRCT was found to be feasible with some minor modifications. Methods evaluated were found to be feasible, suitable and acceptable for a definitive SWcRCT. It was advised that the future SWcRCT should include all patients presenting with NSLBP +/- leg pain and capture data representative of the full scope of physiotherapist independent prescribing.

The following chapter will discuss findings across the thesis reflecting a programme of work as a whole. Each component of the programme of research is critically evaluated in the context of the thesis objectives. The whole programme of research is appraised within the contemporary context. Recommendations for future research are discussed and priorities are considered.

CHAPTER 6: DISCUSSION OF THE THESIS

Chapter overview:

This chapter revisits the thesis' aims and objectives set out in Chapter 1. The whole programme of research detailed in this thesis is appraised in the light of the thesis' aim/objectives and within a contemporary context. Each component of the programme of research is critically evaluated, and the fulfilment of the thesis' objectives assessed. The thesis' contribution to knowledge is detailed and recommendations for future research are made in view of the contemporary physiotherapist independent prescribing landscape, addressing thesis objective 5.

6.0 Fulfilment of the thesis aim

The aim of this thesis was to evaluate the effective implementation and utilisation of NMP across professions internationally, to inform the successful, safe and effective implementation of physiotherapy independent prescribing across clinical specialities, settings and jurisdictions. It is asserted that this aim was met by this programme of research and is demonstrated with the generation of new knowledge from the empirical studies reported in Chapters 2-5. All studies contributing to this programme of work are novel and original. Gaps in the evidence base were recognised, aims and objectives generated, studies completed, and reports written by the author of this thesis.

All individual studies were designed to use rigorous systematic mixed methods to address specific pre-determined aims and/or objectives generated from identified gaps in the literature, extending and strengthening the previously limited evidence base. Mixed methods were utilised throughout this programme of research, allowing integration and

triangulation within and across qualitative and quantitative data, enriching the depth and breadth of the studies' findings [94 95 97 98]. Mixed methods designs symbiotically benefit from the strengths of both quantitative and qualitative methods, which in turn mutually off-set the inherent limitations of one another [94 95 97 98]. The use of the mixed methods study designs was therefore imperative to the production of a valid, reliable and transferable body of evidence.

To minimise risk of bias and optimise quality, all study protocols were developed in consultation with essential stakeholders. Protocols were reviewed and critiqued by panels of experts specialised in NMP within and across professions, encompassing academics, methodological experts and public and patient representatives [63]. Where a registry exists, protocols were registered and or published in international peer reviewed journals prior to study commencement to ensure transparency and reproducibility [64 68]. Individual studies were all reported in line with the appropriate reporting guidelines to safeguard quality and rigour [66 67 176 177 224]. All study samples met minimum sizes defined in the literature to ensure good external validity and transferability. All methods, analyses, results and conclusions contained within this thesis have been rigorously scrutinised via peer review processes for publication in quality international peer reviewed journals and presented at peer reviewed international conferences. Politicians, policy and healthcare managers, and clinical professionals internationally may now use the knowledge accumulated across this body of evidence when considering the safe, quality and successful introduction or use of physiotherapist prescribing in the future.

The implementation of physiotherapist independent prescribing remains an important and current topic internationally, however, it is evolving most quickly in the UK where it has

already been legislated. Owing to the part time nature of the author's PhD programme and in view of developments in the field, limitations must be acknowledged regarding the contemporary nature of the thesis' objectives in the present-day. In Australia the implementation of physiotherapist prescribing has stagnated due to the complexities of the relevant legal frameworks at both federal and state level. The HPPP was developed as a model for all health professions to prescribe under the 'National Registration and Accreditation Scheme' but had never been implemented or tested [45]. The bureaucratic and legislative detail of each step in the HPPP process is being detailed reactively, meaning that the process has not progressed since the submission of the proposal for the endorsement of registered physiotherapists as autonomous prescribers, to the Physiotherapy Board of Australia in 2015 [39]. Although research exploring the views of Australian physiotherapists and physiotherapy students regarding NMP by physiotherapists in Australia was essential to enable preparatory clinical, educational and policy work to proceed [307-309], experience indicates that further research within the UK identified as a result of the studies within this thesis (detailed in section 6.5), could have been prioritised over the surveys completed in Australia. Nevertheless, this programme of research is sound and has extended and strengthened the evidence base.

The objectives detailed in Chapter 1 supported the overall aim of the thesis. The extent to which each objective has been met by this programme of research, the implications for clinical practice and recommendations for future research are now considered.

6.1 Objective 1

To evaluate the clinical and cost-effectiveness of NMP internationally across NMP professions.

Objective 1 was met in Chapter 2, with the evidence published in the journal PLOS One [88]. To evaluate the clinical and cost-effectiveness of NMP, a systematic review of the literature was conducted according to a rigorous pre-defined protocol informed by the Cochrane handbook [63]. The clinical and cost-effectiveness of NMP was evaluated across professions and clinical settings. The systematic review's key findings and recommendations are detailed in Figure 36.

Figure 36: Key findings and recommendations from Chapter 2

Key findings:

- Limited and moderate quality evidence (assessed using GRADE) [89] evidence supports that NMP is safe and can provide beneficial clinical outcomes.
- Benefits to the health-economy remain unclear, with the cost-effectiveness of NMP assessed by a single RCT of low risk of bias [82].

Recommendations:

- Adequately powered low risk of bias RCTs evaluating clinical and cost-effectiveness are recommended in order to evaluate physiotherapist prescribing across clinical specialities and settings.
- The development and testing of a minimum dataset of outcome measures is recommended to ensure comparability of data when analysing and assessing physiotherapist independent prescribing.

Limitations in the number of trials available for inclusion, the overall unclear risk of bias of the included trials and the inability to complete meta-analysis owing to limited

homogeneity across data, limits the external validity of the review across all NMP professions, specialities and locations. Consideration of the study's limitations enabled the generation of explicit recommendations. The recommendations were later endorsed and rigorously evaluated in Chapter 5 as part of the feasibility trial.

The original database searches detail in Chapter 2 were completed in May 2015, with searches re-run prior to publication [88] and thesis submission. No additional trials met inclusion criteria, indicating that the systematic review remains contemporary.

The overall risk of bias of this systematic review was self-assessed using the AMSTAR 2 (A MeaSurement Tool to Assess systematic Reviews, version 2) [310 311]. Revisions of the original AMSTAR tool focused on improving evaluation of the risk of bias in systematic reviews and led to the production of the AMSTAR 2 [311]. The AMSTAR 2 was developed to enable appraisal of both systematic reviews of RCTs and non-randomised studies, using 16 items over 10 domains and has be shown to have good inter-rater reliability [311]. This systematic review fulfils all applicable criteria, indicating an overall low risk of bias (Table 28).

The systematic review identified limited evidence with moderate quality and unclear risk of bias evaluating the clinical effectiveness of NMP across all professions and clinical settings. It was clear that current clinical and cost-effectiveness literature was limited in its ability to provide motivation for the use of physiotherapist independent prescribing, potentially perpetuating resistance to funding and poor uptake by service delivery bodies. Consequently, it was noted that future quality implementation would benefit from the exploitation of facilitating factors, whilst acknowledging and planning for potential barriers [47 48]. Chapter 3 went on to investigate these factors in detail.

Table 28, AMSTAR 2 Checklist, Chapter 2

AMSTAR 2 Checklist Criteria	Achieved
Did the research questions and inclusion criteria for the review include the components of PICO?	Yes
Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?	Yes
Did the review authors explain their selection of the study designs for inclusion in the review?	Yes
Did the review authors use a comprehensive literature search strategy?	Yes
Did the review authors perform study selection in duplicate?	Yes
Did the review authors perform data extraction in duplicate?	Yes
Did the review authors justify exclusions?	Yes
Did the review authors describe the included studies in adequate detail?	Yes
Did the review authors use a satisfactory technique for assessing the risk of bias (RoB)/quality in individual studies that were included in the review?	Yes
Did the review authors report on the sources of funding for the studies included in the review?	Yes
If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results?	N/A
If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?	N/A
Did the review authors account for RoB/quality in individual studies when interpreting/ discussing the results of the review?	Yes
Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?	Yes
If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?	N/A
Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?	Yes

6.2 Objective 2

To evaluate the barriers to and facilitators of iNMP internationally across NMP professions.

The second objective was met in Chapter 3, with evidence published in the Journal of Physiotherapy [163]. To establish an evidence base identifying previously reported existing barriers to, or facilitators of, the implementation and or utilisation of iNMP, a pragmatic mixed methods systematic review utilising a sequential exploratory approach was designed and conducted according to a pre-defined protocol. Forty-three qualitative and 7 quantitative studies from 3 countries (n=12,117 participants) were included. Identified barriers and facilitators from the qualitative studies were synthesised into 4 themes (subthemes): systems (government and political, organisational, formulary); education and support (NMP courses, CPD, support requirements); personal and professional (medical profession, NMP professions, service users); and financial factors. Rigorous analysis of the quality of the evidence collected employed a validated framework specifically developed for mixed methods designs, with a synthesis strengthened by the engagement of a multidisciplinary research team. Data from the quantitative studies corroborated qualitative themes. Integration of the qualitative themes and quantitative data enabled the development of an NMP implementation framework reflecting all key themes. The mixed methods systematic review's key findings and recommendations are detailed in Figure 37.

Figure 37: Key findings and recommendations from Chapter 3

Key findings:

- Barriers to, and facilitators of the implementation and utilisation of NMP are multifactorial and context specific within the four explicit themes: system factors; education and support factors; personal and professional factors; and financial factors.
- When factors are acknowledged and planned for, they become facilitators, but when they were not, they could become barriers.

Recommendations:

- The NMP implementation framework should be core to the implementation strategy of individuals, health services and physiotherapy professional bodies wishing to adopt NMP practice.

Barriers to, and facilitators of the implementation and utilisation of NMP were evident within the literature and demonstrated multifactorial and context specific variables within the 4 explicit themes. It was clear that in the context of NMP implementation, when factors are acknowledged and planned for, they become facilitators, but when they were not, they could become barriers. The resulting NMP implementation framework detailed the importance of personal and professional factors, including the effects of views, knowledge and perceptions of individuals within a profession and the overall standpoint of the profession itself. It was recommended that where physiotherapist prescribing is currently outside the legal scope of practice, the resulting NMP implementation framework (developed from the best existing evidence) should be core to the implementation strategy of physiotherapy professional bodies wishing to adopt NMP practice.

The original database searches detailed in Chapter 3 were completed in May 2015, with searches re-run prior to publication [163] and thesis submission. No additional studies met inclusion criteria, indicating that the systematic review remains contemporary. It is important to highlight that most included studies were limited to nurse prescribing, representing a narrow group of clinical specialities and settings, potentially limiting transferability of the findings to physiotherapy. Acknowledging that some factors may be profession dependent, speciality specific and that views and feelings may change with time, researchers should explicitly evaluate the barriers to, and facilitators of physiotherapist independent prescribing as the skill becomes more commonly embedded within the UK health service.

The overall risk of bias of this mixed methods systematic review was self-assessed using AMSTAR 2 [310 311]. This systematic review fulfils all applicable criteria, indicating an overall low risk of bias (Table 29).

The evidence based NMP implementation framework developed from the rich mixed methods systematic review data, clearly identified the importance that personal and professional factors (including the views and perceptions of individuals within a profession) can have on the successful implementation of NMP. Acknowledging this important finding, Chapter 4 went on to rigorously evaluate the views and perceptions of the Australian physiotherapy profession about the potential introduction of physiotherapist prescribing in Australia.

Table 29, AMSTAR 2 checklist, Chapter 3

AMSTAR 2 Checklist Criteria	Achieved
Did the research questions and inclusion criteria for the review include the components of PICO?	Yes
Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?	Yes
Did the review authors explain their selection of the study designs for inclusion in the review?	Yes
Did the review authors use a comprehensive literature search strategy?	Yes
Did the review authors perform study selection in duplicate?	Yes
Did the review authors perform data extraction in duplicate?	Yes
Did the review authors justify exclusions?	Yes
Did the review authors describe the included studies in adequate detail?	Yes
Did the review authors use a satisfactory technique for assessing the risk of bias (RoB)/ quality in individual studies that were included in the review?	Yes
Did the review authors report on the sources of funding for the studies included in the review?	Yes
If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results?	N/A
If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?	N/A
Did the review authors account for RoB/quality in individual studies when interpreting/ discussing the results of the review?	Yes
Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?	Yes
If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?	N/A
Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?	Yes

6.3 Objective 3

To explore the views of Australian physiotherapists and physiotherapy students regarding NMP by physiotherapists in Australia.

The third objective was met in Chapter 4 with evidence published in BMJ Open [206 207]. The study aimed to: (1) explore the views of Australian physiotherapists and physiotherapy students regarding potential implementation of NMP, (2) evaluate how the geographical location and health sector in which a clinician works may influence their perceptions, (3) explore similarities or differences in the views of student physiotherapists and registered physiotherapists of differing years' experience, about the potential implementation and application of NMP by physiotherapists in Australia and, (4) evaluate the perceptions of Australian physiotherapists and physiotherapy students about how physiotherapist prescribing might impact the care that the profession can provide. A cross-sectional descriptive survey using open and closed questions was developed by a panel of subject experts and used to investigate the study's aims and objectives. A representative sample of 883 AHPRA registered physiotherapists working across all states and territories, and 526 physiotherapy students from universities across all states with entry-level programmes, completed the online questionnaire. The study's key findings are presented in Figure 38.

Figure 38: Key findings from Chapter 4

Key findings:

- The participants felt that the introduction of physiotherapist prescribing would be beneficial for the Australian population and should be introduced.
- Participants recognised the benefits to all stakeholders, emphasising improvements for patients and in turn, health services and the health economy and reflecting the high-quality evidence developed in the prior mixed methods systematic review.
- Acceptance of physiotherapist prescribing and the likelihood of physiotherapists to train as prescribers varied dependent on location and the health sector in which a physiotherapist was working.
- Appropriate legislation, regulation and governance are required.
- Educational frameworks require development.
- Further consultation with all stakeholders is necessary.

Findings echoed and strengthened those discussed in Chapter 3 (used to develop the NMP implementation framework), recognising the need for appropriate legislation, regulation and governance around the use of physiotherapist prescribing, educational frameworks and consultation with all stakeholders to ensure the safety and quality demanded by the physiotherapy profession. The professional demands established within this study are fundamental in informing key stakeholders about the future of physiotherapy in Australia and confirms that the implementation framework developed in Chapter 3 should be core to implementation strategies across federal and state governments, health services and physiotherapy professional bodies.

Owing to the small number of study participants (n=1409) contributing to the qualitative data, the transferability of the thematic analyses may be limited. However, the themes generated agreed across the registered and student physiotherapist populations and states and territories, strengthening the likelihood of good generalisability and

transferability. The data that were analysed and synthesised were collected in 2017. It is acknowledged that views, perceptions, opinions, preferences and professional prioritise change with time. As the progression towards physiotherapist prescribing in Australia has stagnated since 2015, a further study may be warranted to capture more contemporary opinion, reflective of the present-day. However, owing to the stagnation in progression of physiotherapist prescribing in Australia, it is advised that immediate future research should be prioritised in the UK whilst national governance processes and professional/ educational frameworks are developed.

In recognition of the study's strengths and limitations, it is recommended that prior to redefining the scope of physiotherapy in Australia to include NMP, the findings should be used in conjunction with wider reaching and more up to date consultation of stakeholders, risk analysis using the implementation framework developed in Chapter 3 and future definitive low risk of bias RCTs evaluating clinical and cost-effectiveness as recommended in Chapter 2. Chapter 5 went on to conduct the first feasibility trial to evaluate the methods necessary to complete a low risk of bias trial.

The overall risk of bias of this study was not self-assessed as no validated risk of bias assessment tool has been developed for online survey studies that use both quantitative and qualitative methods and analyses. A combination of the STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) checklist [312] and the Standards for Reporting Qualitative Research (SRQR) [313], were adopted to assess the quality of the reporting of the quantitative and qualitative phases of the study respectively. Both checklists were developed to evaluate the broad quality of the reporting of studies, however specific items reflect elements evaluating risk of bias including "selective

outcome reporting" and the evaluation of "other sources of bias" [76 77 312 313]. Both checklists have been shown to demonstrate good inter-rater reliability [312 313]. The completed STROBE checklist can be found in Appendix 33 and the SRQR checklist in Appendix 34. The reporting of this study satisfies all applicable criteria across both reporting checklists, indicating high quality reporting and low risk of bias for the included elements.

6.4 Objective 4

To evaluate the feasibility, suitability and acceptability of the methods required for completing a future definitive trial to evaluate the clinical and cost-effectiveness of physiotherapist independent prescribing.

Objective 4 was met by the feasibility trial detailed in Chapter 5. The feasibility trial protocol was published in BMJ Open and a full article detailing the findings was published in PLOS One. In view of the findings of the systematic review presented in Chapter 2, identifying the limited number of quality trials evaluating the efficacy of NMP; a mixed methods, single-arm feasibility design was employed to evaluate the feasibility, suitability and acceptability of assessing the effectiveness of independent prescribing by APPs for patients with LBP in primary care to inform the design of a future SWcRCT.

The feasibility trial objectives were evaluated via two components: (1) trial component, (2) an embedded qualitative component. In the trial component participants with medium-risk LBP +/-leg pain were recruited across 3 sites representative of English geography. Physical activity and sedentary behaviour were assessed over 7 days using accelerometery. Outcome measures were completed at baseline, 6 and 12 weeks to assess feasibility of follow up and data collection procedures. A CONSORT diagram analysed recruitment and follow up rates. Descriptive analysis evaluated procedure and floor-effects. In the

embedded qualitative component, focus groups and semi-structured interviews evaluated the views and experiences of patients and APPs about the feasibility, suitability and acceptability of the proposed future trial. Thematic analysis was used to analyse and synthesise the qualitative data. Findings were evaluated against a priori success criteria. Key findings from the feasibility trial are detailed in Figure 39.

Figure 39: Key findings and recommendations from Chapter 5

Key findings:

- 90% of the success criteria were met.
- Specific objective benchmarks evaluating adequate time to complete 'trial-related tasks' and recruitment and retention targets were not met.
- 48% of participants were lost to follow up by 6 weeks with 65.5% lost to follow up by 12 weeks.
- Both the planned primary and secondary outcome measures were deemed feasible and acceptable.

Recommendations:

- A definitive trial should include all patients presenting with NSLBP +/- leg pain and capture data representative of the full scope of physiotherapist independent prescribing.
- Limited clinician capacity and time restrictions dictated by job plans and service specifications, should be navigated through the use of research assistants to recruit, consent, aid in data collection and complete follow up and administrative tasks.
- Recruitment and follow up procedures should be modified in accordance with the feasibility trial data prior to the completion of a definitive trial.
- The online outcome measures survey should be revised to include a validated sleep evaluation tool, and the survey logic updated.
- Revised procedures and both online and paper versions of the survey should be piloted across all LBP stratification groups to evaluate successful modification before use in a definitive trial.

The methods evaluated were found to be feasible, suitable and acceptable for use in a definitive SWcRCT. It was recommended that a definitive trial should include all patients presenting with NSLBP +/- leg pain and capture data representative of the full scope of physiotherapist independent prescribing. Further, the use of research assistants was proposed to overcome limited clinician capacity. To ensure completion of a future, low risk of bias definitive trial, further piloting of modified recruitment and follow up procedures and updated outcome measures survey was advised.

Subsequent to the completion of the feasibility trial, publication of the NHS long term plan [28 30] has mandated the introduction of FCP roles in primary care, leaving the design of FCP services to local discretion, to be based on local population need [28 30]. The potential heterogeneity of service designs across locations may impact the choice of methods required for a quality definitive trial evaluating independent prescribing by APPs for patients with LBP in primary care. The longitudinal nature of a definitive trial designed to evaluate physiotherapist independent prescribing for patients with high risk LBP (as recommended by the feasibility trial), also requires further consideration, as clinical pathways for this patient group may now vary from the low and medium risk groups, depending on local interpretation of recommendations published in the National Back Pain and Radicular Pain Pathway [314]. In view of the current uncertainty within primary care and across back pain clinical pathways, it may be advantageous to defer further evaluation until governance structures for MSK FCP (due for publication in the spring of 2020 [315]) are established and clinical standards are enacted [315].

The overall risk of bias of this feasibility trial was not self-assessed as no validated risk of bias tool has been developed for mixed method feasibility trials. To evaluate the quality of

the reporting of the feasibility trial, the CONSORT checklist (developed for use in trials) and the COnsolidated criteria for Reporting Qualitative studies (COREQ): 32-item checklist (developed for use with interviews and focus groups), were adopted for evaluation of the trial component and the embedded qualitative component respectively [224-226] [271]. Both checklists were designed to assess the broad quality of the reporting of studies, however specific items reflect elements evaluating risk of bias including "selective data and outcome reporting" and the evaluation of other potential "sources of bias" [77] [224-226] [271]. Both checklists have been shown to demonstrate good inter-rater reliability [224-226] [271]. The completed CONSORT checklist is found in Appendix 22 and the COREQ checklist in Appendix 35. The reporting of the feasibility trial satisfies all applicable criteria across both reporting checklists, indicating an overall high quality of reporting and low risk of bias for the elements included.

6.5 Objective 5: Recommendations for future research

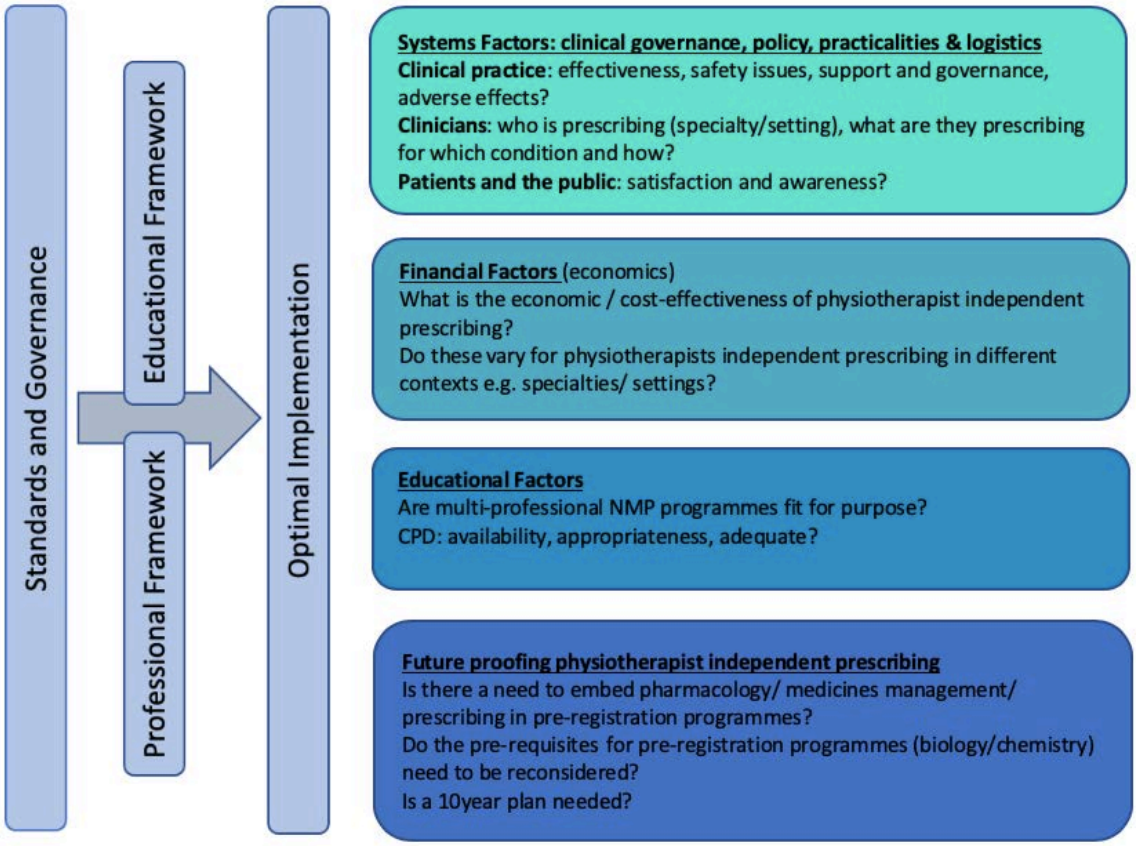
To propose future research priorities relating to the implementation and evaluation of physiotherapist independent prescribing in the UK

Subsequent to the completion of objectives 1-4, recommendations for future research will now be considered. Future proofing high quality, safe and effective physiotherapist independent prescribing within the context of the ever-developing physiotherapy profession is implicit in helping to manage the health demands of the changing population. The use of physiotherapist independent prescribing remains in its infancy, with a deficit of evidence evaluating the efficacy of practice (including clinical and cost-effectiveness), current 'common practice' (which medicines are being prescribed, in what settings for

what problems) and how physiotherapists are using their prescribing qualification in clinical and non-clinical settings. Patient awareness and satisfaction within and across services utilising physiotherapist independent prescribing remains under evaluated. Career and educational frameworks, including CPD requirements and the availability of physiotherapy specific content, have not yet been evaluated in the UK and are not yet developed in Australia or other nations interested in introducing physiotherapist prescribing into their scope of practice.

Driven by the NMP implementation framework and informed the complete programme of research, an overview of recommendations for a future programme of research within the physiotherapist independent prescribing field is summarised in Figure 40. The research recommendations generated in each thesis chapter are formulated into an implementation and utilisation model and are grouped into 4 categories: systems factors (clinical governance, policy, practicalities and logistics), financial factors, educational factors and future proofing physiotherapy independent prescribing. Future research priorities informed by the implementation and utilisation model are considered below.

Figure 40: Programme of research: implementation and utilisation model



6.5.1 Systems and financial Factors: clinical and cost-effectiveness

Low risk of bias RCTs should be completed to formally assess the clinical and cost-effectiveness of physiotherapist independent prescribing across a range of clinical contexts in the UK.

Chapter 2 demonstrates that limited and moderate quality evidence exists evaluating clinical and cost-effectiveness of NMP across professions and clinical settings [89]. Consequently, to ensure safe and quality implementation of physiotherapist prescribing in the future, it is recommended that low risk of bias RCTs should be completed to formally assess the clinical and cost-effectiveness of physiotherapist independent prescribing across a range of clinical contexts in the UK.

Trials should evaluate the safe, appropriate and effective use of medicines within the context of multimodal physiotherapeutic patient management. Economic evaluation should consider longitudinal effects across whole patient pathways and the wider sociological economic impacts, not just focus on additional costs added to traditional physiotherapeutic intervention if a prescription is issued. In order to examine the efficacious nature of physiotherapist independent prescribing in a quality manner, researchers should consider the use of a minimum dataset of generic outcome measures for all specialities, setting and locations, alongside use of outcome measures specific to the health problem being investigated. This would allow for the pooling of data and meta-analysis when evaluating physiotherapist independent prescribing across and between populations, settings and patient pathways.

It is accepted that the evaluation of physiotherapist independent prescribing is required across the clinical specialities, however, the magnitude of this task is acknowledged. It was demonstrated in Chapter 5 that a definitive RCT to assess the effectiveness of independent prescribing by APPs for patients with LBP in primary care is feasible, suitable and acceptable. Recommendations for modifications to the outcome measures survey and recruitment and follow up procedures should be actioned and evaluated against a priori success criteria, once governance structures for MSK FCP are established and clinical standards enacted. If successful, a definitive trial should be commenced. Further, the findings from the feasibility trial should be used to inform the design and implementation of trials evaluating physiotherapist independent prescribing for other conditions, specialities and locations as many of the findings are transferable.

6.5.2 Systems and financial Factors: current practice

A multi-site, prospective, observational service evaluation should evaluate how physiotherapists working in the MSK speciality utilise their NMP skills.

Annually in the UK, more than 30 million working days are lost due to MSK conditions [31]. The NHS spent £17.4 billion on prescription medications in 2016-17, with prescribing of analgesia for MSK pain significantly increased compared to the previous decade [36]. Physiotherapists complete regulated, accredited courses to enable them to prescribe medicines including analgesia for MSK conditions. APPs are therefore well positioned to ensure that the most appropriate analgesics are used at the right time, alongside other helpful treatments such as exercise, psychological interventions and manual therapy. The overuse of opioid and gabapentinoid medication for the treatment of pain has hit crisis point across many countries, despite published prescribing guidelines [37 286]. The misuse of the analgesia leads to both individual and societal problems [316]. In the UK, 24 million prescriptions for opioids were issued in 2017 [287], with gabapentinoid prescribing tripling over the previous decade [288]. Evidence demonstrates that opioid medication is no better than non-opioid for long-term pain-related-function [289]. Unfortunately, many patients persist with opioids and or gabapentinoids longer than clinically indicated; leading to harmful effects, potential dependence and increased NHS costs [317].

It is recommended that patients prescribed opioids and or gabapentinoids should be monitored closely with timely de-escalation or de-prescription [289]. Recent research has shown that for long-term pain related function, the use of opioid medication is no better than that of no non-opioid medication [289]. There are significant risks of harm and limited clinical benefits found when opioids are used for more than 16 weeks [317]. Equally, it is

recommended that if insufficient improvements are seen after two months on a gabapentinoid, doses should be gradually reduced to minimise symptoms of withdrawal and then stopped [318]. Unfortunately, owing to a plethora of reasons, such as limited GP appointment availability, poor patient compliance and inadequate patient-centred medicines management, there is a concerning trend that patients are persisting with analgesia longer than they are clinically indicated, potentially leading to harmful effects and unnecessarily draining the NHS of valuable funds.

Secondary to the contemporary nature of physiotherapist independent prescribing, little is known about how physiotherapists are using their prescribing skills within patient management. Qualitative data detailed in Chapters 3, 4 and 5 illustrate that the benefits of the independent prescribing qualification may not be limited to the ability to provide a prescription for medicines in a one-stop-shop model of clinical practice [56] [319], but additionally the ability to de-prescribe medicines that are no longer clinically favourable or indicated. The qualification also enables the clinicians to offer medicines advice and education to patients, optimising the use of prescription, over the counter and off-the-shelf medications, within a holistic clinical context.

To date no study has evaluated the prescribing practice of APPs working in the MSK speciality. Following completion of the programme of research for this thesis a prospective, observational service evaluation was designed to evaluate the objectives listed below:

- Evaluate how physiotherapists utilise their independent prescribing qualification.
- Evaluate the methods used to prescribe or administer medications (e.g. supplementary prescribing, independent prescribing, patient group direction).
- Evaluate for which conditions physiotherapists are prescribing medications.

- Evaluate what medications physiotherapists are prescribing for musculoskeletal conditions.

Ethical approval was granted by the University of Birmingham and 8 physiotherapist independent prescribers working in the MSK speciality, in 8 health services across England have commenced data collection.

6.5.3 Educational Factors: MSK physiotherapy

A mixed methods sequential study, comprising a cross-sectional national descriptive online survey followed by semi-structured interviews should be utilised to evaluate the perceptions and experiences of physiotherapist independent prescribers of prescribing within their management of MSK conditions.

Data from the feasibility trial presented in Chapter 5 has established that the ability to de-prescribe is key in the management of LBP by APPs in primary care [223]. Qualitative data from the feasibility trial presented in Chapter 5 highlights that physiotherapist prescribers frequently reduce the dose of medicines taken by patients rather than prescribing new medicines [223]. The literature highlights that de-prescribing is a sensitive and complex process that many clinicians feel under-prepared to manage [320]. Survey data reports that >50% prescribers are not confident when de-prescribing guideline-recommended therapies, especially those originally prescribed by another clinician [320]. Evidence presented in Chapters 3 and 4 identifies that deficit of speciality specific education and CPD and lack of support may reduce prescribers' confidence to fully utilise their prescribing qualification [163 206 207].

To date no study has evaluated the prescribing practice of MSK APPs, availability of appropriate CPD and clinicians' confidence to prescribe and critically de-prescribe.

Assessment of these factors is essential to ensure APPs are prepared to effectively prescribe medicines for MSK conditions, and therefore reduce the inappropriate use of opioids and gabapentinoids.

To enable the completion of this study a research project grant application was submitted to the Physiotherapy Research Foundation (Part of the CSP Charitable Trust registered charity 279882). It is hoped that policymakers, healthcare managers and clinicians will use the study's findings as part of their planning for the introduction or use of physiotherapist independent prescribing in their MSK services. Education providers will use the findings when designing CPD opportunities to optimise physiotherapists' prescribing skills. Insight into how, what and why physiotherapists are prescribing will allow education providers to utilise the findings when designing educational and CPD opportunities to optimise physiotherapist prescribing skills for management of MSK conditions. Further, understanding of de-prescribing practice will help address overuse of opioid and gabapentinoid medicines in the UK.

CHAPTER 7: CONCLUSIONS

This PhD thesis has synthesised novel knowledge and insight into the effective implementation and utilisation of NMP across professions internationally, to inform the successful, safe and effective implementation of physiotherapy independent prescribing across clinical specialities, settings and jurisdictions. Through rigorous evaluation it was established that the benefit of NMP to the health economy remains unclear and limited evidence exists evaluating the clinical effectiveness across all professions and clinical settings. As 'best practice' remains unknown, politicians, policy and healthcare managers and clinicians should use the NMP implementation framework to ensure the safe and successful adoption, implementation and utilisation of physiotherapist independent prescribing. The high-quality evidence used to synthesise the framework supports that when factors are acknowledged and accommodated, they become facilitators, but may become barriers when they are not.

Low risk of bias RCTs are required to formally assess the clinical and cost-effectiveness of physiotherapist prescribing across a range of clinical specialities and settings. High-quality feasibility trial data demonstrates that completion of a low risk of bias trial to evaluate the clinical and cost-effectiveness of physiotherapist independent prescribing for LBP in primary care is feasible, suitable and acceptable using the methods examined with some minor modifications.

Robust research methods were used to establish a quality body of evidence that can now be used as a foundation to promote further investigation into the use physiotherapist

prescribing across specialities, health sectors and locations. When evaluating effectiveness, the minimum core dataset of outcome measures evaluated should be used to allow future analysis across trials, evaluating within and across individual clinical fields, professions, and across international healthcare boundaries. Insight into how, what and why physiotherapists are prescribing is now required to optimise physiotherapist prescribing skills and design adequate and appropriate educational and CPD opportunities.

APPENDICES

8.1 Appendix 1: PRISMA Checklist, Clinical and cost-effectiveness of non-medical prescribing: a systematic review of randomised controlled trials

Section/topic	#	Checklist item	Reported Yes/No
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	Yes
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	N/A
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	Yes
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	Yes
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	Yes
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	Yes
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	Yes

Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Yes
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	Yes
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	Yes
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	Yes
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	Yes
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	Yes
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	Yes
Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	Yes
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	Yes
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	Yes
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow up period) and provide the citations.	Yes

Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	Yes
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	Yes
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	Yes
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	Yes
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	Yes
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	Yes
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	Yes
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	Yes
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	Yes

8.2 Appendix 2: Article, PLOS One, Clinical and cost-effectiveness of non-medical prescribing: a systematic review of randomised controlled trials

Noblet T, Marriott J, Graham-Clarke E, Shirley D, Rushton A. Clinical and cost-effectiveness of non-medical prescribing: A systematic review of randomised controlled trials. PLOS ONE 2018;13(3): e0193286. doi: 10.1371/journal.pone.0193286

PLOS ONE

RESEARCH ARTICLE

Clinical and cost-effectiveness of non-medical prescribing: A systematic review of randomised controlled trials

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Abstract

Objective

To evaluate the clinical and cost-effectiveness of non-medical prescribing (NMP).

Design

Systematic review. Two reviewers independently completed searches, eligibility assessment and assessment of risk of bias.

Data sources

Pre-defined search terms/combinations were utilised to search electronic databases. In addition, hand searches of reference lists, key journals and grey literature were employed alongside consultation with authors/experts.

Eligibility criteria for included studies

Randomised controlled trials (RCTs) evaluating clinical or cost-effectiveness of NMP. Measurements reported on one or more outcome(s) of: pain, function, disability, health, social impact, patient-safety, costs-analysis, quality adjusted life years (QALYs), patient satisfaction, clinician perception of clinical and functional outcomes.

Results

Three RCTs from two countries were included (n = 932 participants) across primary and tertiary care settings. One RCT was assessed as low risk of bias, one as high risk of bias and one as unclear risk of bias. All RCTs evaluated clinical effectiveness with one also evaluating cost-effectiveness. Clinical effectiveness was evaluated using a range of safety and patient-reported outcome measures. Participants demonstrated significant improvement in outcomes when receiving NMP compared to treatment as usual (TAU) in all RCTs. An

Competing interests: All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

associated cost analysis showed NMP to be more expensive than TAU (regression coefficient p = 0.0000), however experimental groups generated increased QALYs compared to TAU.

Conclusion

Limited evidence with overall unclear risk of bias exists evaluating clinical and cost-effectiveness of NMP across all professions and clinical settings. GRADE assessment revealed moderate quality evidence. Evidence suggests that NMP is safe and can provide beneficial clinical outcomes. Benefits to the health economy remain unclear, with the cost-effectiveness of NMP assessed by a single pilot RCT of low risk of bias. Adequately powered low risk of bias RCTs evaluating clinical and cost effectiveness are required to evaluate NMP across clinical specialities, professions and settings.

Registration

PROSPERO (CRD42015017212).

Introduction: Rationale

Non-medical prescribing (NMP) contributes to the effective management of both acute and chronic conditions which require prescription of appropriate medication in a timely manner, without the service users' needs being affected by health services' staffing deficiencies, financial concerns or geographical location [1]. It is utilised by a range of professions, with limited consistency regarding definition and terminology internationally [2]. In recent years, the UK government has expanded the scope of NMP that now includes nursing, pharmacy, podiatry, radiography, optometry, physiotherapy and dietetic professions, with the potential to expand further to include paramedicine [3].

With the ever-increasing financial challenges faced by health services, in part due to ageing populations and rising levels of chronic disease, the potential financial efficiencies gained through the use of NMP are of paramount importance [3, 4]. A range of robust studies utilising survey designs have concluded that NMP practice is both safe and appropriate, exhibiting good patient satisfaction [5–9]. Despite this, the implementation of NMP in the UK remains at a relatively slow pace [3]. Although the reasons for this are unclear, it is argued that this is caused by a lack of persuasive high quality evidence demonstrating the clinical and economic benefits of NMP in comparison to current models of healthcare [3]. As demand for healthcare increases, it is likely that policy makers and healthcare departments will become increasingly interested in optimising the skills of all health professionals to streamline patient care [3]. Employing non-medical prescribers within healthcare services has the potential to make savings across a range of health specialties, providing more holistic patient care within an individual profession's scope of practice [3, 4, 10].

For NMP to become more widely accepted, healthcare managers, clinical care quality and safety agencies, as well as the general public require evidence of the overall value of NMP; through the implementation of services that are patient-centred, improving the quality and safety of patient care, while simultaneously reducing costs and improving efficiency of treatment and patient-outcomes [3, 11]. A robust evaluation of NMP is imperative to ensure quality, and appropriate and efficient use of medicines [12]. The advantages, although anecdotal,

are evident in results from case studies and clinical audits which demonstrate that NMP has a good safety record and benefits both patients and clinical services [3, 5]. A recent Cochrane review compared resource utilisation and assessed for non-inferiority in clinical outcome measures and patient reported outcomes of NMP to medical prescribing, concluding that non-medical prescribers provide comparable care across a range of clinical specialties [13]. This systematic review included high risk of bias evidence from controlled trials (Randomised controlled trials (RCTs), cluster-RCTs, controlled before-and-after (CBA) studies and interrupted time series analysis). The future development of NMP across professions internationally is dependent on low risk of bias evidence regarding clinical and cost-effectiveness; without which, it is difficult to demonstrate that NMP offers quality care and patient safety [3]. To date, no systematic review has synthesised this existing evidence.

Objective

To evaluate the clinical and cost effectiveness of NMP.

Methods

A systematic review was conducted according to a pre-defined protocol informed by the Cochrane handbook [14–17], and is reported in accordance with the PRISMA statement [17, 18]. The systematic review protocol was registered with PROSPERO (CRD42015017212) to ensure transparency [15, 19]. This article reports objective 1 of the published protocol.

Eligibility criteria

Inclusion criteria

Studies. Randomised controlled trials (RCTs) or pilot RCTs that evaluated the clinical or cost effectiveness of NMP.

Participants. Health service users receiving treatment from non-medical prescribers from any professional group with appropriate authority to prescribe medicines via supplementary or independent prescribing mechanisms [20].

Intervention. Non-medical prescribing provided by a professional group with appropriate authority to prescribe medicines via supplementary or independent prescribing mechanisms [20]

Comparators. Inter- or intra-profession comparisons of clinical and cost effectiveness, pre and post intervention comparisons of clinical outcomes [14, 21].

Outcome Measures. Measurements reported on one or more outcome of: pain, functional impairment, disability, health, social impact, patient safety, associated costs analysis, quality adjusted life years (QALYs), patient satisfaction, clinician perception of clinical and functional outcomes [14].

Exclusion criteria. studies not written in English [18].

Information sources

The literature search employed sensitive topic-based strategies designed for each of the sources identified in Fig 1.

Search

Pre-defined search terms and combinations, with database specific standardised vocabulary were employed to ensure all relevant studies were retrieved [14, 21–23]. Fig 2 illustrates an

Databases Search:
CINAHL, EMBASE, MEDLINE, AMED, NHS Economic Evaluation database, NICE, Medicines Complete
Cochrane Central Register of Controlled Trials
Selected internet sites:
PUBMED, Turning Research into Practice, Current Controlled Trials website (York), Google Scholar, the Royal college of Nursing, Royal Pharmaceutical Society, King's Fund, National Institute of Clinical Excellence, Department of Health, National prescribing Centre, Chartered Society of Physiotherapy, Society of Chiropodists and Podiatrists, American Association of Nurse Practitioners, Australian College of Nurse Practitioners, Canadian Pharmacists Association, Optometry Australia, British Optometry Association.
National Research Register
Expert Opinion
Hand searches- key journals

Fig 1. Information sources utilised.

https://doi.org/10.1371/journal.pone.0193286.g001

example full electronic search strategy for studies investigating clinical effectiveness in Medline OvidSP. Where a pilot study was identified, the definitive study was sought, or the authors contacted to determine whether further published or unpublished research had been undertaken. The reference lists of the identified literature were searched to ensure no studies were missed [21, 23]. In addition, experts in the area were consulted to detect any further studies [14, 21–23].

Study selection

Two investigators searched information sources (TN/EGC) and independently assessed studies for inclusion by grading each eligibility criterion. In the event of a selection disagreement a third reviewer (AR, methodological expert) was available to mediate any conflict [19, 22]. Both reviewers independently evaluated studies by title and abstract for potential eligibility. Following discussion between reviewers, if a study could not explicitly be excluded on the basis of its title and abstract, its full text was reviewed [15, 17]. All potentially relevant studies proceeded forward to the review of full text. The two independent reviewers made independent judgements as to whether or not an individual study was included in the review based on the study's full text fulfilling the eligibility criteria. The numbers of studies included and excluded at the different stages were recorded [14, 19, 21].

Data collection process

Data extraction was performed by the primary reviewer (TN) and checked and agreed by the secondary reviewer (EGC). Data extraction utilised pre-determined data extraction sheets specific to the review objective which had been piloted, refined and agreed by the researchers prior to use, ensuring that all relevant data were extracted [19, 21]. Any differences were resolved at a consensus meeting of all authors [22], and the third reviewer (AR) checked for consistency and clarity.

Data items

Study design, profession of prescribers, type of non-medical prescribing, participants (patient groups) and indications, interventions, study settings, timing of assessments, and outcome measures were extracted [14], to allow for assessment of homogeneity [14, 21].

Risk of bias

Each reviewer independently assessed the internal validity of each included trial using the Cochrane Risk of Bias Tool [14, 24]. This tool was selected as it was developed to specifically assess bias within RCTs [14, 24]. The tool has been evaluated and has been shown to exhibit good inter-rater reliability [25]. Results were tabulated to demonstrate of the risk of bias across included trials [24].

Summary measures and synthesis of results

An explanation of each included trial's characteristics and outcome data were tabulated. Within and between studies analyses was undertaken in the context of risk of bias [15, 18].

1. independent* prescrib*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
2. supplementary prescrib*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
3. nurs* prescrib*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
4. pharmac* prescrib*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
5. podiatr* prescrib*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
6. chiropad* prescrib*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
7. radiograph* prescrib*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
8. optometr* prescrib*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
9. physiotherap* prescrib*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
10. physio* prescrib*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
11. autonomous prescrib*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
12. non-medical prescrib*.mp.
13. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12
14. Clinical effective*.mp.
15. Treatment outcome*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
16. Error*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
17. clinical effectiveness/
18. medication error/
19. 14 or 15 or 16 or 17 or 18
20. 13 and 19

Fig 2. Full electronic search strategy for Medline OvidSP (clinical effectiveness). Originally undertaken: 25th May 2015. Most recently undertaken: 1st November 2016.

https://doi.org/10.1371/journal.pone.0193286.g002

Results

Study selection

The search strategy identified 373 potentially relevant studies. Following screening for duplicates, 61 citations remained. No relevant unpublished studies were found and no further studies were identified from the Internet searches, reviews of the national research register or via experts in the field. Reviewing by title and abstract excluded 158 studies that were not RCTs. The full texts of the remaining 3 trials [26–28] were examined in detail and evaluated as meeting the inclusion criteria. A further article [29] retrieved when examining the reference lists of retrieved studies was included as it presented additional data to an included RCT. The data from the two articles were considered as one pilot trial (The PIPPC pilot trial) [26, 29]. Therefore, 3 trials (2 definitive trials and 1 pilot trial) were included (Fig 3). All included trials investigated clinical effectiveness (n = 3) [27–29]; 1 trial investigated cost effectiveness [26]. Fig 3 presents the number of studies at each stage of the selection process. 100% inter-reviewer agreement was achieved following open discussion at each stage. Third reviewer mediation was not required.

Study characteristics

Study characteristics and descriptive data for the 3 included trials are summarised in Table 1. All 3 trials involved pharmacy as the NMP profession evaluated in the experimental arms of trials. The setting for one trial was the UK [26, 29], and for two was Australia [27, 28]. All included trials compared pharmacist prescribing within a service or specific patient population to usual care.

A total of 932 participants with an age range of 18–89 years, were randomised across the 3 trials. Details regarding the participants' specific diagnoses were not disclosed. Participants were either: admitted to a tertiary hospital for surgery, involving an overnight stay [27, 28], or received regular prescriptions for medication for chronic pain within a primary care setting [26, 29].

Two trials were completed at single site surgical departments of tertiary hospitals in Australia (Brisbane, Queensland and Newcastle, New South Wales)[27, 28], with a third trial undertaken in primary care across six general practices in the UK (England and Scotland). The type and scope of non-medical prescribing utilised by the pharmacists varied. One trial guided by protocols, used supplementary prescribing to prescribe the patients' regular medication [28]. One trial used independent prescribing only, where the scope of prescribing was to either continue or withhold regular medications and to prescribe VTE prophylaxis in accordance with local and Australian guidelines [27], and a single trial, owing to regulations in place at the time of study, utilised supplementary prescribing to prescribe controlled drugs and independent prescribing for all other required medications [26, 29].

The prescribing pharmacists in two trials were registered independent pharmacist prescribers having completed an Independent Pharmacist Prescribing Course accredited by the General Pharmaceutical Council, UK [26, 27, 29]. An amendment to the Queensland Health (Drugs and Poisons) Regulation 1996 enabled the qualified pharmacists to prescribe in Queensland, Australia [27]. There was no disclosure of the mechanisms (qualification/credentialing/accreditation) that were required for the pharmacists to undertake legal supplementary prescribing in the trial completed in New South Wales, Australia [28].

Outcomes: Clinical effectiveness

Primary outcome measures assessing clinical effectiveness varied. Bruhn et al (2013) used the SF12v2 and the Health Utilities Index (HUI). However, because licencing costs were required

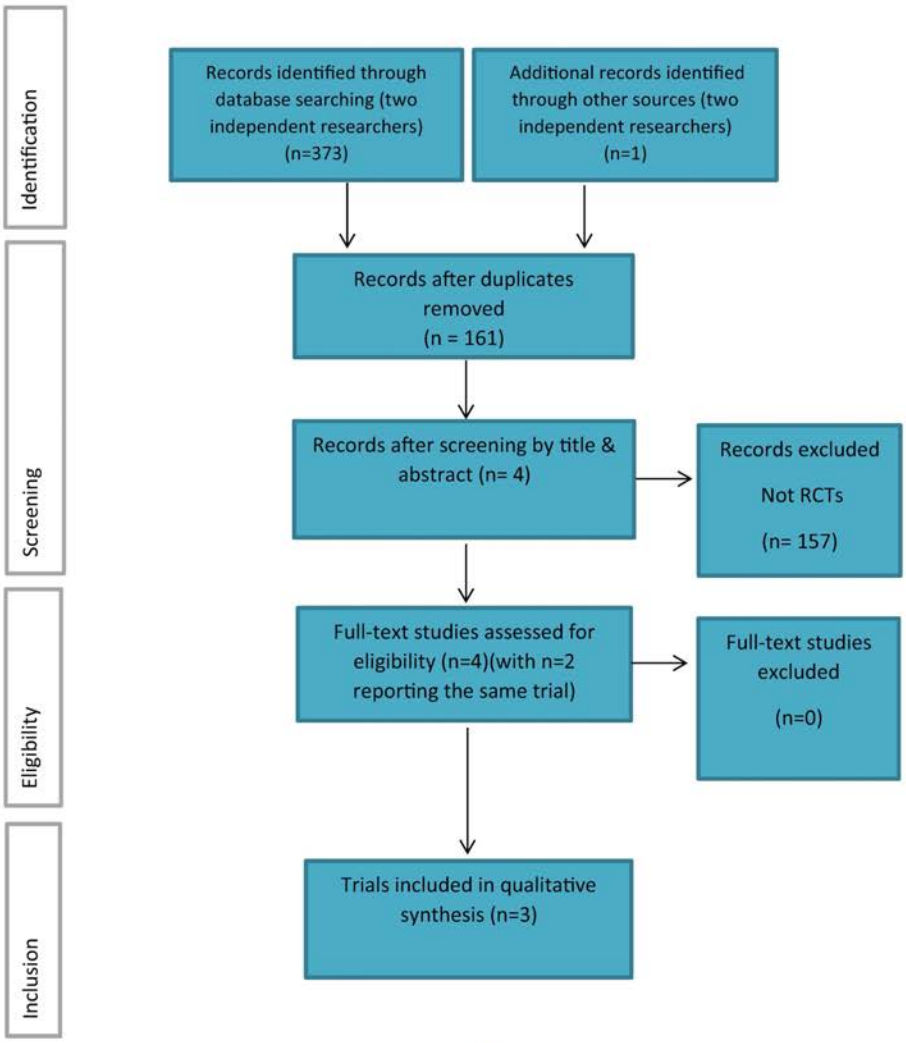

Fig 3. Study selection flow diagram (adapted from Moher et al, 2009)[18].

https://doi.org/10.1371/journal.pone.0193286.g003

to score the data, the HUI was not subsequently analysed. Hale et al (2013) and Marotti et al (2011) did not specify a validated patient reported outcome measure, however they analysed the safety of NMP practice, assessing the frequency of omission and prescribing errors when compared against a patient's medical history, and the number of medication doses inappropriately missed during an inpatient stay respectively.

Table 1. Study characteristics of included trials.

Trial	Design	Participants & Indication	Intervention & Setting	Outcome Measures	Between Group Results	Additional Information
The PIPPC Trial (Neilson et al, 2015, Bruhn, 2013)[26, 29]	Pilot RCT: Three Groups: A. Pharmacist medication review plus face-to-face prescribing B. Pharmacist medication review with GP prescribing C. Treatment as usual Recruitment March-June 2010	• Patients >18 years, living independently, receiving regular prescribed medication for pain. • Patients must have received ≥2 acute prescriptions within the preceding 120 days for an analgesic and/or NSAID. • GPs excluded patients with severe mental illness, recent bereavement, alcohol/drug addiction and cancer pain Baseline: A. n = 68 B. mean (SD) age 66.1 (12.1), C. 54.4% female n = 62, age 65.7 (14.2), 46% female n = 63, age 64.9 (11.6), 37% female	A: Face-to-face pharmacist prescribing, with pre-consultation paper-based medication review; patients completed a pain diary. All non-controlled drugs issued via IP. Controlled drugs issued by SP (regulations at the time). B: Pharmacists undertook paper-based medication reviews focussed on pain related prescription medications, implementation by GPs. C: Treatment as usual GP care X6 pharmacist prescribers utilised *Setting*: • GP practices, primary care pharmacies. • UK (Scotland & England)	*Primary Clinical outcome*: SF12v2 Health Utilities Index (data not analysed due to licencing laws) *Secondary Clinical*: CPG HADS *Primary Economic*: Costs associated with: • Intervention (source- PSSRU 2009/2010) • pain related hospitalisation (source- IDS Scotland March 2010) • primary care visits for chronic pain (source- PSSRU 2009/2010) • primary care telephone contacts for chronic pain (source- PSSRU 2009/2010) • OTC pain related medication: Source- BNF 61, March 2011 *Secondary- Effect of pharmacist-led intervention*: QALYs- based on SF-6D	*Clinical outcomes*: SF12v2: no statistical significant difference between groups. CPG: Statistically significant improvement for group A compared to groups B&C for intensity (p = 0.02) but not disability (p = 0.55). HADS: Statistically significant improvement in HADS scores for group A compared to group B&C (A: p = 0.022; D: p = 0.045) *Cost effectiveness outcomes*: *Resource use and costs*: Positive incremental mean cost differences reported for groups A&B compared to C, indicating group A&B interventions are more expensive than group C. *QALYs*: After adjusting for baseline SF-6D scores, baseline costs/controlling for baseline patient characteristics, QALYs for groups A&B were largely unchanged relative to group C.	NMP Qualification: Independent Pharmacist Prescribing Course accredited by the General Pharmaceutical Council, UK. NMP- Pharmacists Independent Prescribing, supplementary prescribing. Exploratory trial to estimate the sample size for full trial- no formal power calculation. Optimal trial size estimated at 780 per group for full study.
Hale et al, 2013[27]	RCT: Two Groups: A. Pharmacist generated medication chart/plan for peri-operative medication/ prescribed VTE prophylaxis. B. TAU. Post consent, patients randomised using computer-generated randomisation in blocks of 10. Independently prepared sealed envelopes containing 1 or 0 then determine allocation. Conducted between June-Sept 2009.	All patients > 18 years, who attended the PAC. Patients were excluded if unable to communicate due to language barrier or undergoing day surgery. Baseline: A. n = 190, mean (mean range) age 57.6 (18–89), 58% male B. n = 194, mean (mean range) age 55.8 (18–86), 59% male	*Intervention*: Group A: Patients seen by a nurse, prescribing pharmacist, RMO and anaesthetist. (Pharmacist prior to RMO). Pharmacist undertook duties as per usual care, plus prescribing. The scope of prescribing: continuing/ withholding regular medications & prescribing VTE prophylaxis according to local & national guidelines. Group B: all 4 professionals consulted in no particular order. Prescribing was the responsibility of the RMO. X1 Pharmacy Prescriber utilised. *Setting*: • X1 Tertiary Hospital • Elective Surgery Preadmissions clinic (PAC) at Princess Alexandria Hospital, Brisbane, Australia.	*Primary clinical outcome*: Frequency of omission & prescribing errors when compared against patient's medical history. The clinical significance was also analysed. *Secondary clinical outcome*: Appropriateness of VTE prophylaxis prescribing.	*Clinical outcomes*: Significantly less unintended omissions of medications by group A compared to group B. Significantly less prescribing errors involving selection of drug, dose or frequency by group A compared to group B. VTE prophylaxis on admission to the ward approx. 93% group A & 90% group B, revealing no significant difference. No difference in appropriateness of VTE prophylaxis on admission between the two groups.	NMP Qualification: Independent Pharmacist Prescribing Course accredited by the General Pharmaceutical Council, UK. NMP- Pharmacists Independent Prescribing. An amendment was facilitated to the Queensland Health (Drugs and Poisons) Regulation 1996 to enable the qualified pharmacists to prescribe in Queensland, Australia. Power calculations based on pilot data used to calculate sample size.

(*Continued*)

Table 1. (Continued)

Trial	Design	Participants & Indication	Intervention & Setting	Outcome Measures	Between Group Results	Additional Information
Marotti et al, 2011 [28]	RTC: Three Groups: A. Pharmacist medication history plus supplementary prescribing. B. Pharmacist medication history taking, prescribing through usual process. C. TAU. Blinded computer-generated randomisation. Conducted between Nov 2008- March 2009	All adults (no definition) elective surgery patients excluding orthopaedics. Patients excluded if: no regular medications, unable to provide consent, medications charted at a pre-op clinic appointment, day case. Baseline: A. n = 118, median (IQR) age 64 (47–75), 51% male B. n = 119, median (IQR) age 62 (52–71), 55% male C. n = 118, median (IQR) age 65 (54–75), 49% male	*Intervention*: Groups A&B- pharmacists interviewed patients at the time of admission on day of surgery & documented regular medication list. Group A- the pharmacist prescribed the regular medications on the medication chart via supplementary prescribing. Group C- patients had no interaction with the pharmacist prior to surgery. Medications were charted immediately post-surgery by the medical officer in the normal time frame. *Setting*: • X1 Tertiary Hospital. All surgical units, John Hunter Hospital, Newcastle, NSW, Australia.	*Primary clinical outcome*: The number of medication doses missed inappropriately during the inpatient stay. *Secondary clinical outcome*: Number of medications charted at incorrect dose or frequency. Number of missed medication doses post operatively of significant medications e.g. beta blockers, 3-hydroxy-3-methyl-glutaryl-CoA reductase inhibitors, antiplatelets, anticoagulants.	*Clinical Outcomes*: Significantly reduce number of missed doses per patient during hospital stay for group A ($p = 0.02$) but not group B compared to group C. Significantly less medications charted at an incorrect dose for Groups A ($p<0.001$) &B ($p = 0.004$) compared to group C, with group A having less errors that group B. Significantly less numbers of medications charted at an incorrect frequency by groups A&B compared to group C ($p<0.001$).	Non-medical prescribing qualification/ credential/ accreditation not disclosed. NMP- Pharmacists supplementary prescribing. No power calculations used to calculate sample size.

IP- Independent Prescribing, SP- Supplementary Prescribing, CPG- Chronic pain grade (CPG), HADS- Hospital Anxiety & Depression Score, PSSRU- Personal Social Services Research Unit, QALYs- Quality-adjusted life years, TAU- Treatment as usual, Venous thromboembolism- VTE, PAC- Pre-admission clinic, ROM- Resident Medical Officer

https://doi.org/10.1371/journal.pone.0193286.t001

No comparable secondary outcome measures were used across the three trials. Bruhn et al (2013) assessed pain using the 'Chronic Pain Grade' measure and anxiety and depression with the 'HADS' (Hospital Anxiety and Depression Scale). The other trials focused on the uses of the medicines prescribed, with one trial examining the appropriateness of VTE prophylaxis prescribing [27] and the other examining the number of medications chartered at an incorrect dose or frequency, and the number of missed doses of specific medications post operatively [28].

Outcomes: Cost effectiveness

The PIPPC trial evaluated the costs associated with: intervention, pain related hospitalisation, primary care visits for chronic pain, primary care chronic pain related telephone contacts, and prescribed and non-prescribed OTC pain related medicines [26]. Quality-adjusted life years (QALYs) were calculated [26]. The QALYs in the PIPPC trial were generated from the associated costs and analysis of clinical outcomes from the SF-6D (patient reported outcome measure). As this trial was a pilot, the expected value of sample information was calculated to assess whether a definitive trial would be worthwhile.

Risk of bias

100% inter-reviewer agreement was achieved regarding risk of bias assessment, with no mediation required from the third reviewer. Table 2 provides a summary of the overall risk of bias assessed using the Cochrane Risk of Bias Tool for each included trial. Of the three included trials, one was high risk of bias [27], one unclear [28], and one low risk of bias [26, 29]. Marotti et al (2011) was assessed as unclear risk of bias, as the reviewers were unable to view the registered trial protocol, therefore bias owing to selective outcome reporting remained unclear.

Table 2. Summary assessment of the overall risk of bias for each study.

Study	Domain of risk of bias							Summary within study	Comments on high-risk components
	1	2	3	4	5a	5b	6		
PIPPC Trial [26, 29]	L	L	L	L	L	L	L	**Low** (7)	
Hale et al, 2013 [27]	L	L	H	L	L	L	L	Low (6) **High** (1)	One high risk domain: 3 "RMO's in clinic during the study were aware of the intervention pharmacist's role, which may have led to an increased number and quality of medication charts prescribed in the control arm."
Marotti et al, 2011[28]	L	L	L	L	U	U	L	Low (5) **Unclear** (2)	
Overall risk of bias across studies								**Unclear risk of bias**	

Domain of risk of bias: 1, sequence generation; 2, allocation concealment; 3, blinding of participants; 4, incomplete outcome data; 5a, short-term selective outcome reporting; 5b, long-term selective outcome reporting 6, other sources of bias.

Levels of risk of bias: L, low risk of bias; U, unclear risk of bias; H, high risk of bias

Summary within study: Low, low risk of bias for all key risk criteria; Unclear, unclear risk of bias for all key risk criteria; High, high risk of bias for all key risk criteria.

RMO- Resident Medical Officer

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Hale et al (2013) was assessed as high risk of bias with the domain 'blinding of participants' rated at high risk, whilst all other domains were rated low risk. It was agreed that the weight of this domain to overall risk of bias within the RCT was substantial, as the resident medical officers involved in the trials were aware of the pharmacist prescribing as part of a formal study. Losses to follow-up were reported in all included trials [27, 28]. Across all trials, losses were less than 20% and therefore considered acceptable [30]. The overall risk of bias across trials was evaluated as unclear as 75% of the included studies were rated as low or unclear risk of bias [24].

Summary measures and synthesis of results

Clinical Effectiveness Outcomes. **SF-12v2:** for functional health and wellbeing from the patient's perspective, the PIPPC trial[26, 29] at low risk of bias found no significant difference ($p = 0.75$) between groups.

Chronic Pain Grade (CPG): for overall chronic pain severity (pain intensity and pain-related disability), the trial by Bruhn et al (2013) at low risk of bias found significant improvement on the pain intensity subscale ($p = 0.02$) for the pharmacist experimental prescribing groups when compared to treatment as usual. This improvement was not found for the disability subscale ($p = 0.55$).

Hospital Anxiety and Depression Scale (HADS): for depression, anxiety and emotional distress, the trial by Bruhn et al (2013) at low risk of bias found that both the experimental groups involving prescribing pharmacists were seen to improve significantly more compared to the treatment as usual group (Group A $p = 0.022$, Group B $p = 0.045$).

The frequency of omission and prescribing errors: when compared against a patient's medical history, the trial by Hale et al (2013) which was at high risk of bias found significantly less unintended omissions of medications when prescribed by the pharmacist ($p<0.001$). There were significantly fewer prescribing errors concerning selection of drug, dose or frequency in the non-medical prescribing group ($p<0.001$), and significantly less medication orders from the NMP group with at least one constituent of the prescription missing, incorrect or imprecise compared to that of the control group ($p<0.001$).

Prescription of VTE prophylaxis: the trial by Hale et al (2013) at high risk of bias found no significant difference between the NMP group and the control group ($p = 0.29$) for the appropriateness of prescription of VTE prophylaxis.

The number of medication doses missed inappropriately during an inpatient stay: the trial by Marotti et al (2011) that had an unclear risk of bias, found a significant difference (p = 0.002) between the pharmacist supplementary prescribing group compared to the pharmacist drug history taking group and the control group for the number of medication doses inappropriately missed during an inpatient stay. The number of drugs charted at the wrong dose and/or frequency was significantly reduced in the pharmacy history taking group and the pharmacist-prescribing group ($p<0.001$), compared to that of the control group. The pharmacist-prescribing group were also seen to have fewer dose errors compared to the pharmacy drug history taking group (p = 0.004).

Cost Effectiveness Outcomes. **Associated Costs:** the PIPPC trial [26] which had a low risk of bias, found that both pharmacist prescriber-led intervention groups were less costly than TAU based on raw unadjusted mean total costs. Adjustment for variances in baseline costs and controlling for baseline participant characteristics resulted in a positive incremental mean cost difference for both the experimental groups compared to the TAU group. Following adjustments, both pharmacist prescribing and review groups were significantly (regression coefficient p = 0.00) more expensive than usual care secondary to baseline costs.

Quality-Adjusted Life Years (QALYs): the PIPPC trial [26] at low risk of bias found for unadjusted data, that both experimental groups generated increased QALYs compared to TAU. Following adjustment for baseline costs, pharmacist-led groups were largely unchanged relative to the TAU ('pharmacist prescribing' group, 0.0069 QALYs, <-0.0091 to 0.0229>, 'pharmacist medication review' group, 0.0097QALYs, <-0.0054 to 0.0248>), although the adjusted difference in cost was reduced in the prescribing group (£21, from -£124 to £167) and increased in the review group (£75, from -£72 to £221) relative to the TAU group.

Additional analyses

Meta-analysis was not justified owing to insufficient homogeneity of the outcome measures used across the trials. Although the interventions used across the trials were similar, the low number of trials included compounds the heterogeneity of the outcome measures.

Discussion

Summary of evidence

Owing to the low number of included trials and overall unclear risk of bias, recommendations about NMP in the context of its potential clinical and cost-effectiveness are limited. Adequate patient safety and clinical outcomes are key elements in clinical effectiveness required for the valid and ethical use of any clinical intervention. Evidence with an overall unclear risk of bias across the trials investigating the safe practice of NMP on tertiary care surgical wards, indicates that NMP may lead to a significant reduction in omissions and prescribing errors, with the medications prescribed by medical and non-medical prescribers being equally appropriate[27, 28]. Further, the PIPPC pilot trial low risk of bias evidence[29], suggests that NMP is practical, acceptable and leads to improvement in pain outcomes in primary care. However, it is unclear from the PIPPC trial data whether the participants' improved pain outcomes were due to the changes in medication prescribed by the pharmacists and/or participants' education regarding optimal timing for administration of the medications. The heterogeneity of the included trials did not allow for meta-analysis. This evidence, when combined with the findings from the previous Cochrane review [31], might indicate that non-medical prescribers can independently optimise medication management for chronic pain as effectively as medical prescribers, and therefore have the potential to effectively support over-stretched medical practitioners working in pain management in primary care.

Embedding a new clinical tool or process into practice often requires explicit economic benefit before it is adopted by a health community [3, 11]. For this reason, it was surprising that only one pilot RCT evaluating the cost-effectiveness of NMP exists[26], even though NMP is now widely practised internationally by a range of health professions. It is important that the results of this trial are interpreted in the context of it being a pilot trial, with the aim to estimate optimal sample size for a definitive trial, not to determine effectiveness. The trial's results [26], evaluated as having low risk of bias, suggest at first glance that pharmacist prescribing may be more costly than traditional treatment once baseline costs are accounted for (e.g. education costs required for pharmacist prescribers to become qualified, endorsed and registered as non-medical prescribers). However, these baseline costs relate directly to the development of new services that use NMP, where non-medical prescribers do not currently exist and full support for new non-medical prescribers is required. This may be short sighted, reflecting only initial set-up costs, rather than future long-term patient care. As the development, implementation and utilisation of NMP varies across professions internationally, future economic assessment should ensure that both initial and ongoing costs are analysed, establishing economic benchmarks for future comparisons. The SF-6D outcome measure was used to calculate a QALY effect[26], with results indicating that the use of non-medical prescribers generated increased QALYs. However, incomplete data (one third of questionnaires incomplete), possibly owing to participant understanding and the complexity of the measure [26] may have had significant influence on the outcomes and should be considered further prior to the design of an adequately powered definitive trial.

Comparison of the results from this review with the wider literature is difficult, as no RCTs in addition to those included in the present review have been undertaken, and there are no previous systematic reviews. The majority of research has concentrated on reporting the experiences of stakeholders and has not used validated outcome measures to investigate cause and effect relationships related to the uses of NMP[26]. The potential benefits of NMP in terms of clinical and cost-effectiveness are illustrated by the included trials, however the deficit of low risk of bias RCTs across professions, specialties and settings, highlights the need for adequately powered low risk of bias RCTs to inform both clinical and cost-effectiveness across important outcome measures. In order to enhance the quality and comparability of future RCTs, the development of a minimum data-set of important outcome measures for the assessment of NMP would be beneficial, providing healthcare managers, clinical care quality and safety agencies as well as the general public with the require evidence needed to evaluate the overall value of NMP.

Strengths and limitations of the review

This is the first systematic review to synthesise the existing evidence using rigorous methods to provide clarity of the level and quality of existing evidence. Evaluation of the evidence using GRADE (the Grading of Recommendations Assessment, Development and Evaluation system) assessment revealed moderate quality evidence for both the clinical and cost effectiveness of NMP (Table 3)[32]. However, the limited number of trials available for inclusion and overall unclear risk of bias of the included trials limits the external validity of the review. Each trial used different outcome measures limiting scope for meta-analysis, due to limited homogeneity. Only NMP by pharmacists was investigated limiting generalisability across all professions. Limitations in the diversity of the included nations, specialties, methods of NMP (independent versus supplementary) and the nature of the use of NMP were evident between the included studies, resulting in high heterogeneity, limiting their comparability and ability to make generalisations.

Table 3. GRADE assessment summary.

Clinical effectiveness: NMP V TAU		Sample population size **(n) = 932**
Trials Contributing: Bruhn et al, 2013 [29]; Hale et al, 2013 [27]; Marotti et al, 2011 [28]		
Type of evidence	+4	RCTs
Quality	−1	Problem with 1 element, blinding not utilised in any trial
Consistency	0	Most studies show similar results
Directness	−1	Problem with 1 element, Problem with 1 element, difficulty generalising across all specialties, professions, locations, health-sectors, internationally
Effect size	+1	<0.5 for all studies
Total	**3**	**Moderate Quality**
Cost-effectiveness: NMP V TAU		Sample population size **(n) = 193**
Trials Contributing: Neilson et al, 2015 [26]		
Type of evidence	+4	RCTs
Quality	−1	Problem with 1 element, Other methodological concerns: incomplete inclusion and used of SF12 data
Consistency	0	Only x1 trial included
Directness	−1	Problem with 1 element, Problem with 1 element, difficulty generalising across all specialties, professions, locations, health-sectors, internationally
Effect size	+1	<0.5 for all studies
Total	**3**	**Moderate Quality**

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Conclusions

This systematic review has identified limited evidence with moderate quality and unclear risk of bias evaluating the clinical effectiveness of NMP across all professions and clinical settings. Three trials have shown significant results indicating that NMP is safe and can provide effective clinical outcomes for patients. The benefit to the health economy remains unclear, with the cost-effectiveness of NMP assessed by a single pilot RCT that, although at low risk of bias, by its nature was not powered to evaluate cost-effectiveness. Adequately powered low risk of bias RCTs, evaluating safety, quality, appropriateness of care and economic benefit across a range of clinical professions, specialties and settings is urgently required. Evidence from future RCTs can then be used to inform politicians, policy makers, clinicians and healthcare managers when considering the utilisation of NMP in the planning and provision of future quality and effective healthcare services[3, 4]. The development of a minimum data-set of outcome measures is required to ensure homogeneity/ comparability of data when analysing and assessing non-medical prescribing within and across individual clinical fields, professions, and across international healthcare boundaries.

Supporting information

S1 Fig. PRISMA Checklist.
(DOCX)

Author Contributions

Conceptualization: Timothy Noblet, Debra Shirley, Alison Rushton.

Data curation: Timothy Noblet, Emma Graham-Clarke.

Formal analysis: Timothy Noblet, Emma Graham-Clarke, Alison Rushton.

Funding acquisition: Timothy Noblet.

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Methodology: Timothy Noblet, Alison Rushton.

Project administration: Timothy Noblet.

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Supervision: John Marriott, Alison Rushton.

Validation: Timothy Noblet.

Visualization: Timothy Noblet.

Writing – original draft: Timothy Noblet.

Writing – review & editing: Timothy Noblet, John Marriott, Emma Graham-Clarke, Alison Rushton.

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8.3 Appendix 3: Response to reviewers, PLOS One, Clinical and cost-effectiveness of non-medical prescribing: a systematic review of randomised controlled trials, 11th September 2017

Editors/Reviewers Comments	Changes made or Reason(s) for not making changes
Reviewer 1	
Thank you for the opportunity to review your article entitled, 'Clinical and Cost Effectiveness of NMP: a systematic review of RCTs.' Your article is well-written and uses appropriate existing tools.	Thank you for your comments and feedback.
I was pleased to note you had registered a protocol with CRD which I read prior to preparing this peer review. There are several discrepancies between your protocol and your SR. The protocol was largely based on physiotherapy for the background and UK based (some Australian) for the domain; the search terms were not included; many of the search locations/databases were UK-centric e.g. RPS, RCN, Dept of Health, NHS websites (but I was not clear why you would search these anyway); studies were to have been reported in English but this need not have precluded studies from non-English speaking countries; study design was RCTs for outcome 1 but open for outcome 2 (think this aspect was omitted for your actual SR); inconsistency in applying 'independent' to NMP.	The submitted article addressed objective 1 of the research project registered with PROSPERO. Objective 2 will be submitted for publication independently due to complexity and limited word count. We have edited the manuscript to ensure that this is clear to the reader by adding the sentence *"This article reports objective 1 of the published protocol".* To ensure transparency the authors have contacted CRD to ask for the addition of a note stating that the outcomes of the two registered objectives will be published separately. The overall introduction included in the protocol discusses the need for professions such as physiotherapy who are new to prescribing (focus on UK and Australian physiotherapists as these countries are the two correctly involved in physiotherapist prescribing (NMP)) to learn lessons from other professions around the world that have been involved in non-medical prescribing for some time. Objective 1 focused on the clinical and cost-effectiveness of NMP, an issue that is key to all non-medical prescribing professions and is therefore reflected in the introduction of this article. International search engines/databases were utilised (see Figure 2) and supplemented further by UK recourses to ensure the diversity of professions (largest in the UK) using NMP were captured. Although time consuming, these methods were deemed important by the

	authors to uphold methodological rigor, ensuring all trials available were found and assessed for inclusion. The eligibility criteria ensured that all studies from English and non-English-speaking countries were eligible for inclusion if written in English. Unfortunately, no trials from non-English-speaking countries were found to meet the inclusion criteria following reviews by title and abstract and full text.
However, reviewing your article as a standalone without the protocol, raised the following points. Your review references standard key research methods papers around conducting systematic reviews (please note Bowling has a more up to date edition but was not needed here) but your article lacks references to several key reviews and NMP papers which I feel would likely have helped you define your aims and search terms.	Thank you for your feedback, and yes further key articles were utilised to define our aims and search terms. These references, previously edited out of the introduction owing to word count have been added, alongside a sentence reading: *"A range of robust studies utilising survey designs have concluded that NMP practice is both safe and appropriate, exhibiting good patient satisfaction [15 49-52]"*. The introduction then continues to explain why the systematic review was required.
As NMP exists in several countries worldwide under different terminology and with different interpretations of what constitutes prescribing those should have been explored and explained or at least referenced.	Text has been added to the introduction and referenced to address this point: *"It is utilised by a range of professions, with limited consistency regarding definition and terminology internationally".*
As for search terms, items 15, 16 and 18 are random inclusions not directly related to the stated objective and cost effectiveness has been omitted, as have variations of key search terms including hyphenation.	The example search strategy was used to search for trials investigating the clinical effectiveness of NMP- this has now been clarified in the text…. *"Figure 3 illustrates an example full electronic search strategy for studies investigating clinical effectiveness in Medline OvidSP"*. MeSHs were used to capture variations. Search terms 15 (Treatment outcome*), 16 (Error*) and 18 (medication error*) were utilised following preliminary search outcomes and consultation with library professionals at the University of Birmingham, as clinical effectiveness may also be referred to as 'treatment outcomes' and be assessed using a diversity of positive and/or negative measures.

I was intrigued by your comment that the recent Cochrane review by Weeks et al of which you say 'rigorous systematic methods were not utilised' as Cochrane standards are normally viewed as the gold standard. Unfortunately, I don't think you have a clearly evidenced rationale for your review (which has moved quite some way from your protocol), nor a comprehensive set of search terms consistently developed and applied which leads me to doubt the sensitivity and specificity of this review. That said, we would all welcome a high quality, rigorous review of the title you have proposed.	The review completed by the Cochrane collaboration in this case was a scoping review thus included broad inclusion criteria. The authors have therefore re-written the sentence to read, "*A recent Cochrane review compared resource utilisation and assessed for non-inferiority in clinical outcome measures and patient reported outcomes of NMP to medical prescribing, concluding that non-medical prescribers provide comparable care across a range of clinical specialities [62]. This scoping review included high risk of bias evidence across a broad range of study designs. The future development of NMP across professions internationally is dependent on low risk of bias evidence regarding clinical and cost-effectiveness; without which, it is difficult to demonstrate that NMP offers quality care and patient safety [1]. To date, no systematic review has synthesised this existing evidence".*
Reviewer 2	
Thank you very much for the opportunity to review the manuscript "Clinical and Cost Effectiveness of Non-Medical Prescribing: a systematic review of randomised controlled trials." This is a well written paper in an area whose literature is really scarce and the findings will certainly provide clinicians in particular, third party payers, and patients the valuable evidence for the use of Non-Medical Prescribing. The methods and study data are well described with a clear purpose. The search strategy, inclusion criteria, quality assessment and risk of bias were appropriately described. Authors explained relevant details and potential concerns of three studies included in their review. The results are adequately organized. The discussion is well-written and supported by the data presented, with relevant policy information.	Thank you for your detailed feedback.

Due to small number of studies included in the review, only one was considered low risk bias, many methodological issues were raised by the study. However, authors adequately captured these concerns in a way that would enable readers to put the study findings in right context. Hence, readers should put in perspective and make better and informed use of the study findings. The conclusions adequately summarized the implications of the study findings supported by limited evidence.	
Minor comments Study findings adequately summarize evidence from three RCT of which only one was considered of low risk of bias. Therefore, it is critically important that authors emphasize the limitations (not only difficulties –please, rephrase first statement in the Discussion- of making any inferences based on study findings. There are a couple of instances where authors should tone down and rephrase any causal language. See for example last statement, first paragraph of the Discussion. Authors likely mean that "This evidence, …, might indicate that non-medical prescribers can independently optimize medication management for chronic pain as effectively as medical prescribers …" "The present review demonstrates the potential benefits of NMP in terms of clinical and cost-effectiveness". Authors should rephrase.	All edits requested by reviewer #2 have been completed- please see the revised manuscript with track changes.

Reviewer 3	
1) Introduction seemed a bit short. The authors could have done more in setting the stage.	Thank you for this comment. Addressing comments by reviewers 1 & 2 have increased the introduction length whilst acknowledging word count limitations.
2) The main problem from my point of view is that the authors have not performed meta-analyses, when it appears possible to do so. Heterogeneity is not the end of the world and it can be successfully modelled. On the contrary, when it is identified it is a good sign since it tends to be underestimated. If there is that high a clinical heterogeneity in the interventions, I'm sorry but the authors are asking the wrong question. From what I saw in the paper it does not seem that high to justify not performing a meta-analysis. In terms of the outcomes, yes different ones are reported but there is overlap across some outcomes. Finally, the low number of studies seems like another excuse. True, meta-analysis methods are not at their best (since they work asymptotically) with low study numbers but are routinely used and even with the underlying uncertainty (which can be successfully taken into account through sensitivity analyses e.g. see https://www.ncbi.nlm.nih.gov/pubmed/23922860) are much more informative that a systematic review. Even if high statistical heterogeneity is picked up (which the authors have not tried to quantify), we would like to see the overall effects and visualisations of them (and the heterogeneity levels!). Without meta-analyses the paper is difficult to follow, and the results are unfocused and/or uncertain. I am always unconvinced by papers of this type	The authors agree with reviewer 3; meta-analyses where indicated add rigor to a systematic review. We acknowledge that we were not clear on this issue in the initial draft of the paper. Having discussed at length, unfortunately in this review we were unable to perform a meta-analysis that would represent the data and move our understanding forwards in a robust way. This was specifically due to the heterogeneity of the outcome measures used to measure different clinical effectiveness outcomes across the included trials. In particular, the constructs that measures were assessing where different. We are conscious that in this circumstance, the use of models across few, small data sets, measuring different clinical outcomes may add researcher bias, limiting the validity of the systematic review, and further may serve to confuse the reader. To clarify this we have reworded the additional analyses section to read: *"Additional Analyses* *Meta-analysis was not justified owing to the insufficient homogeneity of the outcome measures used across the trials."* The lack of meta-analysis has been acknowledged in the limitations section: *"the limited number of trials available for inclusion and overall unclear risk of bias of the included trials limits the external validity of the review. Each trial used different outcome measures limiting scope for meta-analysis, due to limited homogeneity. Only NMP by pharmacists was investigated limiting generalisability across all professions. Limitations in the diversity of the included nations, specialities, methods of NMP (independent versus supplementary) and the nature of the use of NMP were evident between the included*

(systematic review without a meta-analysis). If the question is focused, a meta-analysis should be at the end of it. If not, then you are probably asking the wrong question in the first place!	*studies, resulting in high heterogeneity, limiting their comparability and ability to make generalisations"* The authors feel that the inability to complete a meta-analysis due to the heterogeneous nature of the outcome measure used highlights an important point: future studies should attempt to use standardised outcome measures to allow comparison and integration. This is now highlighted in the discussion: *"In order to enhance the quality and comparability of future RCTs, the development of a minimum data-set of important outcome measures for the assessment of NMP would be beneficial, providing healthcare managers, clinical care quality and safety agencies as well as the general public with the require evidence needed to evaluate the overall value of NMP"* This important message has been re-enforced by adding this statement to the conclusion: *"The development of a minimum data-set of outcome measures is required to ensure homogeneity/ comparability of data when analysing and assessing non-medical prescribing within and across individual clinical fields, professions, and across international healthcare boundaries."*

8.4 Appendix 4: PRISMA Checklist, Barriers to and facilitators of independent non-medical prescribing in clinical practice: a mixed-methods systematic review

Section/topic	#	Checklist item	Reported Yes/No
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	Yes
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	N/A
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	Yes
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	Yes
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	Yes
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	Yes
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	Yes

Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Yes
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	Yes
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	Yes
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	Yes
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	Yes
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	Yes
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	Yes
Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	Yes
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	Yes
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	Yes
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow up period) and provide the citations.	Yes

Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	Yes
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	Yes
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	Yes
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	Yes
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	Yes
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	Yes
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	Yes
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	Yes
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	Yes

8.5 Appendix 5: Full electronic search strategy for Medline OvidSP, 25th June 2015

1. independent* prescrib*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
2. supplementary prescrib*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
3. nurs* prescrib*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
4. pharmac* prescrib*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
5. podiatr* prescrib*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
6. chiropad* prescrib*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
7. radiograph* prescrib*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
8. optometr* prescrib*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
9. physiotherap* prescrib*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
10. physio* prescrib*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
11. autonomous prescrib*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
12. prescription/
13. non-medical prescrib*.mp.
14. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13
15. Facilitator*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
16. Success*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
17. Value*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
18. Advantag*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
19. Patient satisfaction.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
20. Patient experience.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
21. Implementation.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
22. patient satisfaction/
23. (Organisation and management).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
24. 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23
25. 14 and 24
26. Barrier*.mp.
27. Safety issue*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
28. Education*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
29. Obstacle*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
30. Failure*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
31. education/
32. medication error/
33. drug safety/
34. patient safety/
35. 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34
36. 14 and 35
37. 25 or 36
38. limit 37 to (human and English language and yr="1994 - 2015")
39. 14 and 15
40. 14 and 26
41. 39 or 40
42. limit 41 to (human and English language and yr="1994 -Current")

8.6 Appendix 6: Phase 1, Included Studies & Characteristics

Ref No	Study	Design	Country	NMP Profession	Healthcare Setting	Healthcare Speciality	Participants
1	Avery et al, 2007[115]	Surveys & Interviews	UK (England)	Nurses, Pharmacists	Community Care, Hospital Care	Range of Specialities	**Total n=110** Surveys n=85: Nurses n=80, Midwives n=3, Pharmacists n=2, Interviewed n=25: Nurses n=16, Doctors n=5, Pharmacist n=1, Managers n=3,
2	Bennett & Jones, 2008[116]	Surveys & Focus Groups	UK	Nurses	Community Care	HIV	**Total n=8** Surveys: Nurses n=8 Focus Groups: Nurses n=8
3	Bradley & Nolan, 2007[117]	Interviews	UK	Nurses	Community Care, Hospital Care	Range of Specialities	**Total n=45** Nurses n=45, Face-to-face interview n=31, Telephone interview n=14
4	Bradley et al, 2008[118]	Focus Groups	UK	Nurses	Community Care, Hospital Care	Mental Health	**Total n=15** Nurses n=15
5	Carey et al, 2009[119]	Interviews	UK	Nurses	Hospital Care	Paediatrics	**Total n= 21** Nurses n=7, Doctors n=11, Managers n=3
6	Carey et al, 2010[52]	Interviews	UK (England)	Nurses	Community Care	Dermatology	**Total n=40** Nurses (prescribers) n=11, Doctors n=12, Admin Staff n=11, Nurses (Non-prescribers) n=6
7	Courtenay & Carey, 2009[120]	Interviews	UK (England)	Nurses	Hospital Care	Paediatrics	**Total n=14** Nurse prescribers n=7, Doctors (consultant level) n=4, Managers n=3
8	Courtenay et al, 2011[121]	Interviews	UK (England)	Community-practitioner prescribers, Pharmacists, Nurses, Physiotherapists, Podiatrists, Optometrists	Community Care, Hospital Care	Range of Specialities	**Total n=28** NMP leads n=28
9	Cousins & Donnell, 2012[122]	Interviews	UK (England)	Nurses	Community Care	General Practice	**Total n=6** Nurses n=6
10	Downer & Shepherd, 2010[123]	Interviews	UK (Scotland)	Nurses	Community Care	District nursing	**Total n=8** District nurses n=8

11	Earle et al, 2011[124]	Interviews	UK (England)	Nurses	Community Care	Mental Health	**Total n=8** Nurse prescribers n=2, Service users n=6
12	Glod & Manchester, 2000[125]	Surveys	USA	Nurses	Community Care Hospital Care	Mental Health	**Total n=1352** Advance practice nurses n=1352
13	Guirguis et al, 2014[126]	Interviews	Canada	Pharmacists	Community Care	Range of Specialities	**Total n=38** Pharmacist prescribers n=13, Non-prescribing pharmacists n=25
14	Hales, 2002[127]	Surveys	USA	Nurses	Community Care Hospital Care	Mental Health	**Total n=32** Advanced Practice Nurses **n=32**
15	Hall et al, 2003[128]	Interviews	UK (England)	Nurses	Community Care	Range of Specialities	**Total n=21** Community Nurses **n=21**
16	Hall et al, 2006[129]	Interviews & Surveys	UK (England)	Nurses	Community Care	Range of Specialities	**Total n= 67** Interviewed n=23: District nurses n=11, Health visitors n=10, Practice nurses n=2 Surveys: NMP Leads n=44
17	Hill et al, 2014[130]	Interviews	UK (Scotland)	Pharmacists	Community Care	Addiction Services	**Total n=97** Service users n=86, Pharmacist prescribers n=5, Doctors n=6
18	Hobson et al, 2010[131]	Interviews	UK (England)	Pharmacists, Nurses	Community Care Hospital Care	Range of Specialities	**Total n=18** Service users n=18
19	Jones et al, 2011[132]	Interviews, non-participant observation & surveys	UK (England)	Nurses	Hospital Care	Range of Specialities	**Total: n=196** Interviewed n=18: prescribers (profession not stated) n=3, mentors/colleagues n=7, Managers n=8 Structured non-participant observation of nurse prescribers n=2, Doctors n=2, consultations n=52 Surveys: Service users n=122
20	Kelly et al, 2010[133]	Surveys	UK (England)	Nurses	Community Care	General Practice	**Total n=151** Community Practice nurses n=151
21	Lewis-Evans & Jester, 2004[134]	Interviews	UK (England)	Nurses	Community Care	Range of Specialities	**Total n=7** Nurses n=7
22	Luker et al, 1997[135]	Interviews	UK (England)	Nurses	Community Care	Range of Specialities	**Total n=256** Service users n=256; pre prescribing n=157, post prescribing n=148 (33.3% interviewed post were also interviewed pre-prescribing).

23	Maclure et al, 2013[51]	Survey	UK (Scotland)	Community-practitioner prescribers, Pharmacists, Nurses, Physiotherapists, Podiatrists, Optometrists	Community Care Hospital Care	Range of Specialities	**Total n=1855** Service users n=1855
24	Makowsky et al, 2013[136]	Interviews	Canada	Pharmacists	Community Care	Range of Specialities	**Total n=38** Pharmacists n=38
25	McCann et al, 2011[137]	Surveys	UK (NI)	Pharmacists	Community Care Hospital Care	Range of Specialities	**Total n=105** Pharmacists n=105
26	McCann et al, 2012[138]	Interviews	UK (NI)	Pharmacists	Community Care Hospital Care	Range of Specialities	**Total n= 35** Pharmacists n=11, Doctors n=11, Other Stakeholders n=13
27	Mulholland, 2014[139]	Surveys	UK	Pharmacists	Hospital Care	Paediatrics	**Total n=45** Pharmacists n=45
28	Nolan et al, 2004[140]	Surveys	UK	Nurses	Community Care Hospital Care	Mental Health	**Total n=51** Nurses n=51
29	Page et al, 2008[141]	Interviews	UK (England)	Nurses	Hospital Care	Dementia	**Total n=20** Service users n=13, Staff (non-prescribers) n=7
30	Ross & Kettles, 2012[142]	Surveys & focus groups	UK (Scotland)	Nurses	Community Care Hospital Care	Mental Health	**Total n=45** Nurses n=33, Focus group, Nurses n=12
31	Ryan-Woolley et al 2008[112]	Survey	UK	Nurses	Community Care Hospital Care	Oncology & Palliative Care	**Total n=2252** Nurses n=2252
32	Ryan-Woolley et al 2007[111]	Survey	UK	Nurses	Community Care Hospital Care	Oncology & Palliative Care	**Total n=2252** Nurses n=2252
33	Scrafton et al, 2012[143]	Interviews	UK (England)	Nurses	Hospital Care	Range of Specialities	**Total n=6** Nurses n=6
34	Shannon & Spence, 2011[144]	Focus groups & Interviews	UK (Scotland)	Nurses	Community Care Hospital Care	Cardiology	**Total n=21** Focus Groups: Doctors n=21 Interviews: Doctors n=21,
35	Stenner et al, 2009[145]	Interviews	UK (England)	Nurses	Community Care Hospital Care	Dermatology	**Total n=18** Doctors n=12, Nurses (non-prescribers) n=6
36	Stenner et al, 2010[146]	Interviews	UK (England)	Nurses	Community Care Hospital Care	Diabetes	**Total n=31** Nurse prescribers n=10, Doctors n=9, Admin staff n=9, Nurses (non-prescribers) n=3

37	Stenner & Courtenay, 2008a[113]	Interviews	UK (England)	Nurses	Community Care Hospital Care	Pain Management	**Total n=26** Nurse prescribers n=26
38	Stenner & Courtenay, 2008b[114]	Interviews	UK (England)	Nurses	Community Care Hospital Care	Pain Management	**Total n=26** Nurse prescribers n=26
39	Stenner et al 2011[50]	Interviews	UK (England)	Nurses	Community Care	Diabetes	**Total n=41** Service Users n=41
40	Travers, 2005[147]	Focus groups & interviews	UK (England)	Nurses	Community Care	Range of Specialities	**Total n=7** Focus Groups: Nurses n=7 Interviews: Nurses n=7,
41	While & Biggs, 2004[148]	Surveys	UK (England)	Nurses	Community Care	Range of Specialities	**Total n=91** Community Nurses n=91
42	Wix, 2007[149]	Surveys	UK (England)	Nurses	Community Care Hospital Care	Mental Health	**Total n=78** Service users n=78
43	Young, 2009[150]	Interviews	UK (Wales)	Nurses	Community Care	Range of Specialities	**Total n=5** Community Nurses n=5

8.7 Appendix 7: Quality assessment using the QATSDD tool, Phase 1

	Avery et al, 2007	Bennett & Jones, 2008	Bradley & Nolan, 2007	Bradley et al, 2008	Carey et al, 2009	Carey et al, 2010	Courtenay & Carey, 2009	Courtenay et al, 2011	Cousins & Donnell, 2012	Downer & Shepherd, 2010	Earle et al, 2011	Glod & Manchester, 2000	Guirguis et al, 2014	Hales, 2002	Hall et al, 2003	Hall et al, 2006	Hill et al, 2014	Hobson et al, 2010	Jones et al, 2011	Kelly et al, 2010	Lewis-Evans & Jester, 2004	Luker et al, 1997
Explicit theoretical framework	0	0	2	0	1	1	2	1	1	3	3	1	3	2	0	0	0	3	3	0	3	0
Statement of aims/objectives in main body of report	2	3	1	2	3	3	3	2	2	3	3	2	2	1	1	2	0	2	3	3	3	0
Clear description of research setting	3	2	2	2	2	1	3	3	3	1	3	3	3	2	2	2	1	3	3	2	3	2
Evidence of sample size considered in terms of analysis	1	1	3	0	2	1	1	1	3	0	1	1	3	0	0	3	0	3	3	1	3	0
Representative sample of target group of a reasonable size	3	3	2	1	2	2	3	3	3	0	2	2	3	1	2	2	2	3	2	3	1	1
Description of procedure for data collection	1	3	3	3	2	2	3	3	2	2	3	2	3	2	2	3	3	2	3	1	2	1
Rationale for choice of data collection tool(s)	2	3	0	0	0	0	3	2	1	3	0	0	3	0	0	0	0	0	2	0	3	0
Detailed recruitment data	3	3	1	1	2	1	3	3	2	1	3	3	3	0	0	2	2	3	3	2	1	1
Statistical assessment of reliability and validity of measurement tool(s) (Quantitative only)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	1	N/A	N/A	N/A	N/A	N/A	N/A	1	N/A	N/A	N/A
Fit between stated research question and method of data collection (Quantitative)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	3	N/A	N/A	N/A	N/A	N/A	N/A	1	N/A	N/A	N/A
Fit between stated research question and format and content of data collection tool e.g. interview schedule (Qualitative)	0	0	0	0	0	0	0	0	0	0	0	3	0	0	0	0	0	0	1	0	0	0
Fit between research question and method of analysis	0	0	0	0	0	0	3	3	3	3	0	3	0	0	0	3	2	3	1	3	0	0
Good justification for analytical method selected	0	1	2	0	1	3	1	0	0	3	2	0	3	0	0	3	0	3	3	0	3	0
Assessment of reliability of analytical process (Qualitative only)	0	0	0	0	3	3	3	2	3	0	3	0	3	0	0	3	1	2	3	0	3	0
Evidence of user involvement in design	0	0	0	0	0	0	0	1	0	0	0	0	0	1	1	1	1	1	0	2	0	0
Strengths and limitations critically discussed	3	0	3	0	2	2	2	1	1	1	3	3	3	0	1	3	2	3	3	0	3	0
Total	**18**	**19**	**19**	**9**	**20**	**19**	**30**	**25**	**24**	**20**	**26**	**27**	**32**	**9**	**9**	**27**	**14**	**31**	**35**	**17**	**28**	**5**

Continued

	Maclure et al, 2013	Makowsky et al, 2013	McCann et al, 2011	McCann et al, 2012	Mulholland, 2014	Nolan et al, 2004	Page et al, 2008	Ross & Kettles, 2012	Ryan-Woolley et al 2008	Ryan-Woolley et al 2007	Scrafton et al, 2012	Shannon & Spence, 2011	Stenner et al, 2009	Stenner et al, 2010	Stenner & Courtenay, 2008a	Stenner & Courtenay, 2008b	Stenner et al 2011	Travers, 2005	While & Biggs, 2004	Wix, 2007	Young, 2009
Explicit theoretical framework	1	3	0	2	0	0	2	1	0	0	3	2	2	1	0	2	2	0	0	0	3
Statement of aims/objectives in main body of report	3	3	3	2	2	1	0	3	2	2	3	3	3	3	3	3	3	1	3	2	1
Clear description of research setting	3	3	2	2	2	2	3	2	1	2	2	2	2	2	2	2	3	2	2	3	2
Evidence of sample size considered in terms of analysis	0	3	2	2	2	1	0	1	1	3	3	0	3	1	2	3	0	0	1	0	0
Representative sample of target group of a reasonable size	2	3	3	3	2	2	2	2	1	3	3	2	1	2	3	2	2	1	3	1	1
Description of procedure for data collection	1	3	2	3	1	2	2	3	2	2	3	3	1	2	2	2	3	1	2	2	2
Rationale for choice of data collection tool(s)	0	2	0	0	0	0	2	3	0	0	2	0	2	0	0	3	0	0	0	0	2
Detailed recruitment data	0	3	3	3	2	3	1	3	2	3	2	2	1	2	1	2	3	2	3	1	2
Statistical assessment of reliability and validity of measurement tool(s) (Quantitative only)	N/A	N/A	1	N/A	0	N/A	N/A	1	N/A	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0	0	N/A
Fit between stated research question and method of data collection (Quantitative)	N/A	N/A	0	N/A	0	N/A	N/A	0	N/A	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0	0	N/A
Fit between stated research question and format and content of data collection tool e.g. interview schedule (Qualitative)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Fit between research question and method of analysis	3	0	0	3	0	0	0	3	2	2	3	3	0	3	3	3	2	0	0	0	0
Good justification for analytical method selected	2	3	1	1	0	0	1	3	0	0	2	2	1	0	1	1	0	1	1	0	1
Assessment of reliability of analytical process (Qualitative only)	0	3	0	3	0	2	3	3	2	0	1	2	3	3	3	3	3	0	0	0	1
Evidence of user involvement in design	2	0	2	0	0	2	0	3	1	0	0	2	0	0	0	0	0	2	2	0	1
Strengths and limitations critically discussed	1	3	1	1	0	2	3	3	1	2	2	1	3	2	2	2	2	0	3	1	3
Total	**18**	**32**	**20**	**25**	**11**	**17**	**19**	**34**	**15**	**19**	**29**	**24**	**22**	**21**	**22**	**28**	**23**	**10**	**20**	**10**	**19**

8.8 Appendix 8: Phase 2, Included Studies & Characteristics

Study	Design	Country	NMP Profession	Healthcare Setting	Healthcare Speciality	Participants
Courtenay & Carey, 2008[153]	Survey: Postal questionnaire 2006	UK	Nurses	Community Care, Hospital Care	Range of Specialities	**Total n=1992** Nurses n=1992
Courtenay et al, 2012[49]	Survey: Online questionnaire 2010-2011	UK	Community-practitioner prescribers, Pharmacists, Nurses, Physiotherapists, Podiatrists, Optometrists	Community Care, Hospital Care	Range of Specialities	**Total n=883** Nurses n=793, Managers n=33, Pharmacists n=36, Allied health & Optometrists n=9, not disclosed n=12
Farrell et al, 2011[154]	Survey: Online or postal questionnaire Collection year NR	UK	Nurses	Community Care, Hospital Care	Oncology	**Total n=103** Nurses n=103
Gumber et al, 2012[157]	Survey: Postal questionnaire 2010	UK	Nurses, Pharmacists	Community Care, Hospital Care	Range of Specialities	Total **n=20** Nurses n=18, Pharmacists n=2
Hutchison et al, 2012[152]	Survey: Online questionnaire 2010	Canada	Pharmacists	Hospital Care	Range of Specialities	**Total n=342** Pharmacists n=342
Kaplan & Brown, 2004[155]	Survey: Postal questionnaire 2001	USA	Nurses	Community Care, Hospital Care	Range of Specialities	**Total n=1241** Nurses n=1241
Larsen, 2004[156]	Survey: Postal questionnaire	UK	Nurses	Community Care, Hospital Care	Emergency/ Urgent care	**Total n=192** Managers n=192

8.9 Appendix 9: Phase 2, Results of Quality Assessment using the QATSDD Tool

Domain	**Study Reference Number**						
	Courtenay & Carey, 2008	Courtenay et al, 2012	Farrell et al, 2011	Gumber et al, 2012	Hutchison et al, 2012	Kaplan & Brown, 2004	Larsen, 2004
Explicit theoretical framework	1	0	0	0	0	0	0
Statement of aims/objectives in main body of report	3	3	2	3	1	3	3
Clear description of research setting	2	3	2	3	3	3	2
Evidence of sample size considered in terms of analysis	3	1	2	1	1	1	0
Representative sample of target group of a reasonable size	3	3	3	2	3	3	1
Description of procedure for data collection	3	3	2	1	3	3	2
Rationale for choice of data collection tool(s)	0	1	1	0	0	1	0
Detailed recruitment data	3	3	3	1	3	3	2
Statistical assessment of reliability and validity of measurement tool(s) (Quantitative only)	0	0	0	0	0	0	0
Fit between stated research question and method of data collection (Quantitative)	0	0	0	0	0	0	0
Fit between stated research question and format and content of data collection tool e.g. interview schedule (Qualitative)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Fit between research question and method of analysis	0	0	0	0	0	0	0
Good justification for analytical method selected	0	2	0	0	0	0	0
Assessment of reliability of analytical process (Qualitative only)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Evidence of user involvement in design	1	1	2	0	2	2	2
Strengths and limitations critically discussed	2	2	0	3	3	1	2
Total	**21**	**22**	**17**	**14**	**19**	**20**	**14**

8.10 Appendix 10: Article, Journal of Physiotherapy, Barriers to and facilitators of independent non-medical prescribing in clinical practice: a mixed-methods systematic review

Noblet T, Marriott J, Graham-Clarke E, Rushton A. Barriers to and facilitators of independent non-medical prescribing in clinical practice: a mixed methods systematic review. Journal of Physiotherapy 2017;63(4):221-34. doi: https://doi.org/10.1016/j.jphys.2017.09.001

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Research

Barriers to and facilitators of independent non-medical prescribing in clinical practice: a mixed-methods systematic review

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KEY WORDS

Barriers
Facilitators
Non-medical prescribing
Independent prescribing

ABSTRACT

Question: What are the factors that affect the implementation or utilisation of independent non-medical prescribing (iNMP)? **Design**: Mixed-methods systematic review. Two reviewers independently completed searches, eligibility and quality assessments. **Data sources**: Pre-defined search terms were utilised to search electronic databases. Reference lists, key journals and grey literature were searched alongside consultation with authors/experts. **Eligibility criteria for included studies**: Qualitative and quantitative studies investigating independent prescribing by any non-medical professional group. Study participants included any stakeholders involved in actual or proposed iNMP. Measurements reported on data describing stakeholders' perceptions and experiences of the barriers to/facilitators of iNMP. **Results**: A total of 43 qualitative and seven quantitative studies from three countries (n = 12, 117 participants) were included. Quality scores varied from 9 to 35 (Quality Assessment Tool for Studies with Diverse Designs, 0 to 48). Qualitative data were synthesised into four themes (and subthemes): systems (government and political, organisational, formulary); education and support (non-medical prescribing (NMP) courses/continuous professional development (CPD)); personal and professional (medical profession, NMP professions, service users); and financial factors. Quantitative data corroborated the qualitative themes. Integration of the qualitative themes and quantitative data enabled the development of a NMP implementation framework. **Conclusion**: Barriers to and facilitators of the implementation and utilisation of iNMP are evident, demonstrating multifactorial and context-specific variables within four explicit themes. Professional bodies, politicians, policy and healthcare managers and clinicians could use the resulting NMP implementation framework to ensure the safe and successful implementation and utilisation of NMP. Clinical physiotherapists and other clinicians should consider whether these variables have been adequately addressed prior to adopting NMP into their clinical practice. **Registration**: PROSPERO CRD42015017212. **[Noblet T, Marriott J, Graham-Clarke E, Rushton A (2017) Barriers to and facilitators of independent non-medical prescribing in clinical practice: a mixed-methods systematic review. *Journal of Physiotherapy* 63: 221–234]**

Introduction

Non-medical prescribing (NMP) is utilised in a diversity of ways by a variety of health professions internationally.[1] In the UK the two types of NMP that are used by prescribers are supplementary non-medical prescribing (sNMP) and independent non-medical prescribing (iNMP).[2,3] Clinicians prescribing via sNMP use a clinical management plan in partnership with a medical or dental practitioner, whereas iNMP requires the clinician to be entirely autonomous, prescribing medicines based on their individual clinical reasoning and judgments.[2] Independent physiotherapy prescribing was introduced in the UK in 2012, with the first physiotherapists qualifying as independent prescribers in 2013.[4] Physiotherapists in Australia have now expressed an interest in NMP and commenced national processes to evaluate potential clinical need, quality and safety issues.[5] The implementation and legal utilisation of NMP will require healthcare policy modification and legislative reform. Organisational objectives, professional issues and societal influence must be reflected in national and local policy if change is to occur.[6] However, robust research is required to guide the implementation of evidence-based NMP practice and the necessary changes in policy.

Pharmacist prescribing has demonstrated clinical effectiveness for the management of chronic pain in primary care and postoperative pain in a tertiary surgical unit, with statistically significant improvements in pain intensity ($p = 0.02$), anxiety and depression ($p = 0.022$),[7] and reduced prescribing errors ($p < 0.001$)[8] compared to traditional practices.[7–9] The effectiveness of prescribing in physiotherapy-specific settings has not yet been examined because the instigation of independent physiotherapy prescribing is recent. Physiotherapists must ensure that they learn from the evidence from other professions and their application of strategies to implement and utilise NMP.[10] The analysis and synthesis of this evidence is paramount to understand the factors

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acting to enable or block iNMP[10,11] because successful implementation of innovations (such as iNMP) depend on exploiting facilitators and planning for potential barriers.[6,12]

Therefore, the specific research question for this systematic review was:

> What are the factors that affect the implementation or utilisation of independent non-medical prescribing (iNMP)?

Method

A mixed-methods systematic review was conducted according to a pre-defined protocol that followed the Cochrane Handbook and was reported in accordance with the PRISMA statement.[13–15] The protocol was registered with PROSPERO (CRD42015017212).[16,17] A sequential exploratory approach harmonised the qualitative and quantitative literature.[18]

Identification and selection of studies

A comprehensive pre-determined search strategy of the databases outlined in Box 1 was developed in MEDLINE as shown in Appendix 1 (see eAddenda for Appendix 1), and customised for the other databases.[19] The other information sources outlined in Box 1 were also searched. Where eligible pilot studies were identified, the reviewers searched for the full studies. Authors were contacted if full studies were not retrieved, to confirm the existence of a full study and/or any other related (un)published literature. Reference lists of included studies were searched,[20,21] and subject experts were consulted to detect any further studies.[13,20–22]

Eligibility criteria were defined a priori. The inclusion criteria are presented in (Box 2). Studies not written in English were excluded once identified, in order to provide information on potential bias.[19] Descriptive papers, editorials and opinion papers were excluded due to their potential internal bias.[23] All studies satisfying the eligibility criteria were included.

Two investigators completed the literature searches (TN/EGC); each independently evaluated titles and abstracts for inclusion. A third reviewer (AR) mediated in cases of disagreement. Where exclusion was not possible based on title and abstract, the investigators independently reviewed the full text. All studies fulfilling eligibility criteria were included.

Data extraction

Qualitative data

One reviewer (TN) used commercial software[a] to extract data assessing stakeholders' experiences of the barriers to and facilitators of iNMP.[20] A second reviewer (EGC) independently reviewed data extraction by ensuring that all relevant data were extracted. Differences in opinion were resolved at a consensus meeting.[22]

Quantitative data

Data pertaining to barriers and facilitators were extracted from the quantitative studies independently by the two reviewers (TN, EGC) using data extraction sheets specific to the study objectives.[20] The third reviewer (AR) checked for consistency, clarity and aided resolution throughout the process.

Assessment of study quality

The comprehensiveness of reporting and transparency was evaluated using the Quality Assessment Tool for Studies with Diverse Designs (QATSDD).[23] producing a quality rating score for each study. Good validity, inter-rater reliability and test-retest reliability have been established for the QATSSD across a diversity of study designs, demonstrating its value for consistent quality assessment in mixed-methods designs.[23,24] Two researchers (TN and EGC) independently assessed each study, with disagreements discussed and resolved.[22]

Box 1. Information sources.

Databases
- CINAHL, EMBASE, MEDLINE, AMED, NICE, Medicines Complete, HMIC, ASSIA, Web of Science, Health and Safety Science Abstracts

Internet sites
- PUBMED, Turning Research into Practice, Google Scholar, Royal College of Nursing, Royal Pharmaceutical Society, King's Fund, National Institute of Clinical Excellence, Department of Health, National Prescribing Centre, Chartered Society of Physiotherapy, Society of Chiropodists and Podiatrists, American Association of Nurse Practitioners, Australian College of Nurse Practitioners, Canadian Pharmacists Association, Optometry Australia, British Optometry Association

National Research Register
Hand searching of key journals
System for Information on Grey Literature, unpublished research
Expert opinion
Reference lists of all included papers

Box 2. Inclusion criteria.

Population
- Independent non-medical prescribers from any professional group with legal authorisation to prescribe medicines independently,[82] or stakeholders engaged with non-medical prescribers/NMP services.

Intervention
- NMP provided by a professional group with legal authorisation to prescribe medicines independently.[82]

Comparator(s)/control
- Not applicable

Qualitative study designs
- Any empirical qualitative study that describes the sampling strategy, data collection procedures, and type of data analysis.[83]

Qualitative outcomes
- Consumers', carers' and/or healthcare professionals' perceptions and experiences of the barriers to and/or facilitators of iNMP.[13]

Quantitative study designs
- Any design reporting quantitative data.[13]

Quantitative outcomes
- Quantitative survey questions assessing: the barriers to and/or facilitators of iNMP; economic comparisons; patient, staff and/or educational satisfaction/expectation; location comparisons; and health sector/specialty comparisons.[13]

iNMP = independent non-medical prescribing, NMP = non-medical prescribing.

Data analysis and synthesis of results

A three-step process of analysis synthesised the qualitative and quantitative data.

Qualitative component

Qualitative data were synthesised using a thematic analytical approach.[25] One reviewer (TN) undertook line-by-line coding of data relating to barriers and facilitators of iNMP. Data were grouped into descriptive themes and then developed into analytical themes/sub-themes.[25] Two reviewers reviewed preliminary themes/sub-themes; they re-read all included studies to ensure that the identification of all relevant data was complete.[25] The themes/sub-themes were then scrutinised by a panel of experts to agree upon the findings. Characteristics and outcomes of the included studies were tabulated.

Quantitative component

Data from quantitative survey questions assessing barriers and facilitators were extracted from the quantitative studies. Studies' characteristics and outcome data were tabulated. A narrative analysis of the quantitative evidence was undertaken independent of the qualitative literature analysis.[21]

Integration

The qualitative and quantitative data were compared through an integration process to determine agreement or disagreement within identified themes/sub-themes.[18,26] Data were tabulated into an integration matrix.[25–27] Whether qualitative and quantitative data corroborated and confirmed findings was observed and reported. To demonstrate the key factors that affect the implementation and utilisation of iNMP, the integrated data were used to develop an implementation framework.[25]

Results

Flow of studies through the review

As shown in Figure 1, 3247 (3244 from database searches, three from reference lists) potentially relevant studies were identified. No unpublished studies were identified. Following removal of duplicates (n = 247), 3000 citations remained. Screening by title and abstract excluded 2876 studies, with full texts of the remaining 124 studies examined in detail. This resulted in 43 qualitative studies and seven quantitative studies, totalling 50 included studies.

Characteristics of qualitative studies

Study characteristics

Characteristics of the qualitative studies are summarised in the first three columns of Table 1. More detailed characteristics are available in Table 2 (see the eAddenda for Table 2). Studies were undertaken in three countries: 39 (91%) in the UK, two (5%) in Canada and two (5%) in the USA.

Study methods

Of the 43 included studies, 24 (56%) used interviews, 11 (26%) used surveys, and one (2%) used focus groups as the primary research method. The remaining seven (16%) studies used a mixed-methods approach including surveys/interviews/focus groups/non-participant observation.

Participants

Across the 43 studies, 7344 participants were recruited. In two instances, data from one sample were reported across two studies. Where sample populations were duplicated across multiple studies reporting different data, participants were counted once.[28–31] Table 3 summarises the stakeholder groups engaged

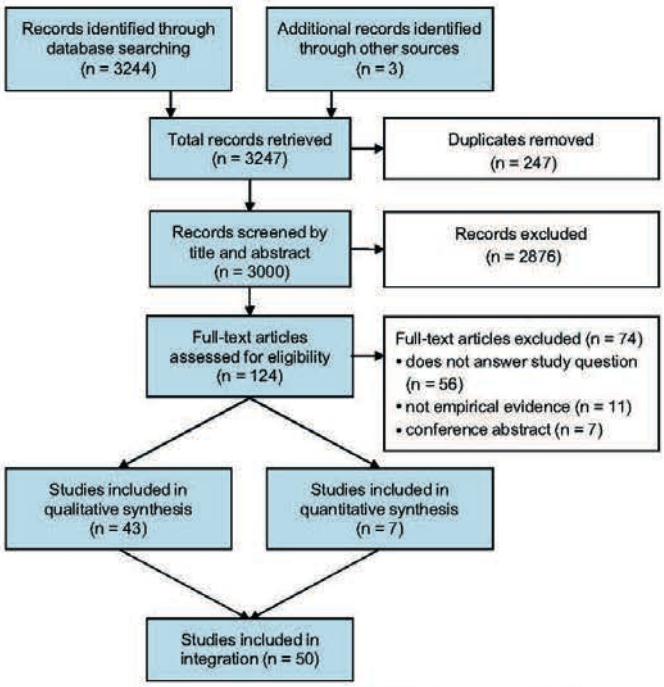

Figure 1. Flow of studies through the review (adapted from Moher et al).[19]

Table 1
Characteristics and quality of the included qualitative studies (n = 43).

Study	Setting	Specialty	Total (n)	Mode of data collection: number of participants from each profession	Quality[a] (0 to 48)
Avery[32]	Community/Hospital	Various	110	Survey: 80 nurses, 3 midwives, 2 pharmacists. Interview: 16 nurses, 5 doctors, 1 pharmacist, 3 managers	18
Bennett[45]	Community	HIV	8	Survey: 8 nurses. Interview: 8 nurses	19
Bradley[81]	Community/Hospital	Various	45	Face-to-face interview: 31 nurses. Telephone interview: 14 nurses	19
Bradley[86]	Community/Hospital	Mental Health	15	15 nurses	9
Carey[87]	Hospital	Paediatrics	21	7 nurses, 11 doctors, 3 managers	20
Carey[88]	Community	Dermatology	40	11 prescribing nurses, 12 doctors, 11 admin staff, 6 non-prescribing nurses	19
Courtenay[89]	Hospital	Paediatrics	14	7 nurse prescribers, 4 consultant doctors, 3 managers	30
Courtenay[33]	Community/Hospital	Various	28	28 NMP leads	25
Cousins[82]	Community	General Practice	6	6 nurses	24
Downer[55]	Community	District nursing	8	8 district nurses	20
Earle[57]	Community	Mental Health	8	2 prescribing nurses, 6 service users	26
Glod[48]	Community/Hospital	Mental Health	1352	1352 advance practice nurses	27
Guirguis[74]	Community	Various	38	13 prescribing pharmacists, 25 non-prescribing pharmacists	32
Hales[90]	Community/Hospital	Mental Health	32	32 advanced practice nurses	9
Hall[75]	Community	Various	21	21 community nurses	9
Hall[40]	Community	Various	67	Interview: 11 district nurses, 10 health visitors, 2 practice nurses. Survey: 44 NMP leads	27
Hill[78]	Community	Addiction Services	97	86 service users, 5 prescribing pharmacists, 6 doctors	14
Hobson[49]	Community/Hospital	Various	18	18 service users	31
Jones[50]	Hospital	Various	196	Interview: 3 prescribers (profession n/s), 7 mentors/colleagues, 8 managers. Structured non-participant observation: 2 nurse prescribers, 2 doctors, 52 consultations. Survey: 122 service users	35
Kelly[54]	Community	General Practice	151	151 community practice nurses	17
Lewis-Evans[58]	Community	Various	7	7 nurses	28
Luker[77]	Community	Various	256	256 service users (157 pre-prescribing, 148 post prescribing)	5
Maclure[41]	Community/Hospital	Various	1855	1855 service users	18
Makowsky[59]	Community	Various	38	38 pharmacists	32
McCann[42]	Community/Hospital	Various	105	105 pharmacists	20
McCann[43]	Community/Hospital	Various	35	11 pharmacists, 11 doctors, 13 other stakeholders	25
Mulholland[85]	Hospital	Paediatrics	45	45 pharmacists	11
Nolan[53]	Community/Hospital	Mental Health	51	51 nurses	17
Page[84]	Hospital	Dementia	20	13 service users, 7 non-prescribing staff	19
Ross[34]	Community/Hospital	Mental Health	45	33 nurses. Focus group: 12 nurses	34
Ryan-Woolley[29]	Community/Hospital	Oncology/Palliation	2252	2252 nurses	15
Ryan-Woolley[30]	Community/Hospital	Oncology/Palliation	2252	2252 nurses	19
Scrafton[35]	Hospital	Various	6	6 nurses	29
Shannon[76]	Community/Hospital	Cardiology	21	Focus group: 21 doctors. Interview: 21 doctors	24
Stenner[83]	Community/Hospital	Dermatology	18	12 doctors, 6 non-prescribing nurses	22
Stenner[46]	Community/Hospital	Diabetes	31	10 prescribing nurses, 9 doctors, 9 admin staff, 3 non-prescribing nurses	21
Stenner[30]	Community/Hospital	Pain Management	26	26 prescribing nurses	22
Stenner[31]	Community/Hospital	Pain Management	26	26 prescribing nurses	28
Stenner[60]	Community	Diabetes	41	41 service users	23
Travers[44]	Community	Various	7	Focus group: 7 nurses. Interview: 7 nurses	10
While[52]	Community	Various	91	91 community nurses	20
Wix[79]	Community/Hospital	Mental Health	78	78 service users	10
Young[80]	Community	Various	5	5 community nurses	19

Admin = administrative, HIV = human immunodeficiency virus, NMP = non-medical prescribing, n/s = not stated.
[a] Quality Assessment Tool for Studies with Diverse Designs.[23]

with each data collection method. A few participants (0.4%) had no defined role, being described as general stakeholders.

Intervention

Most of the included studies investigated nurse iNMP (n = 33, 77%), with pharmacists being the only other professional group that was specifically investigated (n = 6, 14%). Two studies investigated both nurse and pharmacist iNMP together (5%), with a further two studies investigating iNMP from all potential professional groups (5%).

Setting

Study settings included both community healthcare (40%) and hospital settings (14%), with most studies conducted across both healthcare settings (47%). A total of 42% of included studies encompassed all healthcare specialties (n = 18). The remaining studies examined: mental health (16%), paediatrics (7%), dermatology (5%), general practice (5%), oncology and palliative care (5%), diabetes (5%), pain management (5%), human immunodeficiency virus (2%), district nursing (2%), addiction (2%), dementia (2%) and cardiology (2%).

Table 3
The number of stakeholders engaged with each data collection method.

Stakeholder	Surveys (n)	Interviews (n)	Focus groups (n)	Observation (n)	Total n (%)
Nurses	4053	222	42	2	4319 (59)
Service users	2055	420	0	52	2527 (34)
Pharmacists	152	93	0	0	245 (3)
Medical doctors	0	91	21	2	114 (2)
NMP leads	44	28	0	0	72 (1)
General	0	30	0	0	30 (<1)
Admin staff	0	20	0	0	20 (<1)
Managers	0	17	0	0	17 (<1)
Total	6304	921	63	56	7344 (100)

Admin = administrative, NMP = non-medical prescribing.

Quality assessment

Quality scores of the qualitative studies are summarised in Table 1 and ranged from 9 to 35. Detailed quality criteria information is provided in Table 4 (see eAddenda for Table 4).

Results and synthesis of qualitative studies

Identified factors were categorised into four major themes: systems factors; education and support factors; personal and professional factors; and financial factors. The major themes and their subthemes are described below. Each theme can be both a barrier and facilitator, depending on context. Table 5 lists the studies that reported or discussed each theme, providing illustrative quotations from participants or study authors for each subtheme. It is acknowledged that the themes interact with each other.

Systems factors

Participants in 32 (74%) of the included studies highlighted a range of system factors that may act as either barriers or facilitators to implementing NMP, including government and political factors, organisational factors and practices, and delivery in terms of formulary.

Government and political factors: Participants perceived that factors such as political motive, government funding availability for education, adequate and appropriate political drive, and strategic/cohesive planning at all government levels could facilitate or impede NMP use.[32–35] Specifically, participants recognised facilitators such as the importance of access to funding and the need for implementation pressure on health services from government.[32,35] Potential barriers were identified as the absence of political leadership, and politically driven promotion of NMP as a cheap alternative to medical prescribing, rather than promotion of non-medical prescribers with the knowledge and skills to enhance patient access to care.[33,34]

Organisational factors: Participants highlighted the importance of robust local clinical governance policies, pathways and procedures in place prior to training non-medical prescribers,[28,31–44] with standardised local policy to ensure quality of care and patient safety, and lines of authority and responsibility clearly defined.[32,34] Scope, parameters, boundaries and guidelines should be clearly documented and readily accessible to all stakeholders.[34] Adequate support mechanisms with time and funding for continuing professional development (CPD) activities should also be documented.[30,38] Further, participants deemed it essential that institutions ensure access to patients' medical records where required, with clear guidelines regarding clinical documentation, incident reporting and communication.[40,41,43] Clinicians must prescribe within their individual competency, with transparent policies to alleviate concerns from pressure to prescribe outside of scope from senior colleagues and managers.[35,42–44] Participants recommended that databases should be developed locally to: enable prescribing practice audit; ensure evidence-based clinical practice, transparency and accountability;[33] and showcase potential economic savings.[36]

Participants noted that financial processes enabling infrastructure, administration and logistics must be in place prior to implementation.[33,45] Excessive delays in access to prescription pads or electronic prescribing were a fundamental issue that prevented clinicians from utilising their prescribing skills.[33,34,40,46] Both local and national administrative processes required for prescriber authorisation and to start prescribing were seen as barriers.[40,42,47,48] Processes were described as long and arduous, resulting in many potential prescribers feeling that the outcome was not worth the stress and effort,[47,48] or loss of confidence by qualified prescribers by the time they were given the authority and facilities to prescribe.[47] The availability of appropriate clinical facilities was considered important.[49] Absence of a consultation room in some facilities may compromise assessment of patients' needs.[49]

Facilitation of NMP was recognised when a strategic, collaborative and consultative approach to develop and implement it into a service was adopted.[32,33,50] This reduced the risk of professional territorialism, and ensured that the focus remained on patient-centred care rather than a specific profession's interests.[51] A lack of vision regarding the benefits of commissioning innovative areas of practice was reported as a barrier.[33] It was recognised that for NMP to become embedded in practice, service development and implementation should reflect the needs of the local community and address issues such as workforce planning, CPD requirements and clinical frameworks development.[34,36,37,51] Long-term viability of NMP services was highlighted as a historical area of weakness. One study[36] recommended that if NMP were to develop in a health service, four or five non-medical prescribers should be trained to ensure support and succession planning. Participants recognised that well-defined selection criteria aimed at selecting the best candidates for NMP training was beneficial.[37,39] Conversely, others warned that overly restrictive criteria might be a barrier to NMP expansion into new areas of practice.[33] Another key barrier was a fragmented health service caused by the division of funding for service provision and prescription drugs, plus geographical restrictions due to law, regulation or organisational jurisdiction.[33,36,40] To counteract this, innovative service design alongside utilising an individual profession's skills, talents and mastery were recommended. Simply replacing medical staff in conventional clinical environments with non-medical prescribers, where budgets, or medical staff availability dictate practice, was perceived as short sighted.[33,38]

Formulary: Most participants identified a 'limited formulary' as a potential barrier. Due to the dynamic nature of drug availability, and constantly evolving evidence-based practice, frustrations were frequently felt because of practice limitations secondary to formulary restrictions.[31,44,52,53] Participants reported situations when they could not prescribe appropriate medication because it was outside an out-dated formulary governing their practice.[44,53] Some UK clinicians had waited to become non-medical prescribers until national prescribing restrictions had been removed, as prior to this their practice would have been too limited to be worthwhile.[54] Conversely, one study[31] acknowledged that a 'limited formulary' might facilitate NMP, as defined limits of practice enable new prescribers to resist pressure from patients, managers and clinical colleagues to prescribe outside scope.[31] Open formularies were reported to actively facilitate successful NMP implementation, allowing competent clinicians to prescribe within their professional code of conduct; reducing patient waiting times and further easing the workloads of medical prescribers, who would previously have had to prescribe if the required drug was absent from the NMP restricted formulary.

Education and support factors

Participants in 27 (63%) of the included studies reported that the educational processes related to the application of NMP, and the level and type of support offered to non-medical prescribers by stakeholders can act as either barriers to or facilitators of successful implementation of iNMP.

Education: Participants reported that NMP course attendance was often influenced by their employers' willingness to provide financial support for tuition and relief from duties.[54] Many clinicians were unwilling to undertake NMP courses because of limited incentives, with no financial gain following qualification, and pre-existing busy clinical caseloads.[54] The cost and time related to completing course prerequisites such as numeracy, pharmacology and assessment/diagnostic training were also barriers.[33] Nevertheless, other participants recognised the prerequisites as imperative to maintaining quality standards and ensuring academic ability.[33] Many participants felt that the generic, interdisciplinary nature of NMP courses did not adequately prepare them to prescribe, with pharmacology content frequently described as lacking.[34,35,44,55] Despite this, courses were perceived to facilitate NMP by providing access to all

Table 5
Themes and sub-themes from the included studies, with illustrative quotations from the studies' participants or authors.

Theme Sub-theme	Example quotations from included studies	*n* (*N*)	Key elements	Studies
Systems Factors		32 (74)		
Government and political factors		4 (9)		
	The introduction of this initiative was accompanied by a lot of pressure from the Department of Health on the trusts to push through as many nurses as quickly as possible.[32] p3	1 (2)	Drivers	32
	The Government had given these free places for training and there was this sort of scrabble for all of us to be put into doing it whether or not we needed it.[35] p2046	1 (2)	Funding sources	35
	... a lack of leadership at both a national and strategic health authority level.[32] p8	1 (2)	Cohesive thinking and strategy	32
	Participants believed that patient benefit rather than doctor shortage should be the motivation behind nurses prescribing.[35] p2049	2 (5)	Motives	34,35
Organisational factors	... an institutional strategy is required if non-medical prescribing is to be successful in these settings.[32] p3	31 (72)		
	Ensuring that clinical governance systems were in place and up-to-date was felt to be a critical part ...[33] p5 It is particularly important that pharmacists develop a culture of safety, do not prescribe outside their areas of competency and are supported in their prescribing role. Rigorous and robust governance procedures should be in place where pharmacist prescribers operate ...[43] p830	15 (35)	Clinical governance policy and audit	28,31 33,37 44,53
	Logistical barriers to implementation identified such as information technology issues (lack of access to patient notes in primary care).[42] p830	16 (37)	Practicalities and logistics	28 30,33 35,40 42, 43,46,48,49,52,74
	A colleague completed a course 12 months ago and still no policy is in place to enable her to prescribe. This discourages others from making the effort and attending the course.[29] p175	26 (60)	Policy development and implementation	28,29,31 46,49 51, 52,54,58,59,61
Formulary	I wanted to do the nurse prescribing course for 2 years – until the BNF was opened fully, it was not worth my while.[54] p23 Local formulary restrictions and formal agreements (such as an 'intent to prescribe') were helpful in defining the limits of practice and assisting nurses to resist pressure from patients or professionals to prescribe outside of their area of competence ...[31] p28 The participants were very positive about prescribing and the improvements it had brought to their roles in providing holistic care. However, they all stated that the limitations of the formulary severely restricted its usefulness.[44] p165 It really does frustrate me, especially when I know exactly what I'm looking at and I know exactly what I need to prescribe, but I have to ask the patient to come back later because I can't prescribe off the [formulary] ...[44] p165	10 (23)		31 33,35,44,45,53 54,58
Education and support factors		27 (63)		
Education	... created a feeling of dissatisfaction with my work, as I feel underpaid for the responsibility I have now undertaken in practice. This does not encourage me to undertake an onerous course for little financial recompense.[54] p2	18 (42)		
	... access to CPD and formal feedback are areas that need to be developed by education providers and more formally embraced by managers within each organisation.[28] p505 ... haphazard approach and lack of a formal national infrastructure to guide CPD activity was viewed negatively and appeared to be the cause of some frustration.[35] p2047	11 (26)	Continuous professional development	31,33 35,39,44,54 58
	Undertaking any course can be stressful and can generate anxiety. There is anecdotal evidence that the prescribing course, including a mathematics test that requires a 100% mark to pass, has generated a lot of anxiety among participants.[54] p23 GP employers are often unwilling to support courses when they are expected to absorb the cost of locum practice nurse cover.[54] p23 As nurses are unable to undertake the prescribing course without the support of a medical supervisor, they are dependent on a doctor agreeing to supervise.[28] p930 ... the majority of prescribers ... thought that the prescribing course did not adequately prepare them to prescribe.[28] p927	11 (26)	NMP course	28,30,34,39,37,44, 52 55,65
Support	Participants accessed support from clinicians and peers, non-medical prescribing groups, specialist networks ...[28] p504 Team processes and communication between the different disciplines within the team impacted on the success of a pharmacist prescriber.[43] p130 A number of respondents perceived a lack of medical support as their main reason for not wishing to undertake nurse prescribing training.[29] p175 There is a lack of understanding by medical staff. I know nurses who have undertaken the course and are unable to use their skills. It seems pointless to do nurse prescribing training unless it can be used effectively.[29] p175 Lack of support included lack of supervision, lack of support in the prescribing role, and lack of support from all professionals involved. The lack of support from management in permitting the implementation of nurse prescribing when the prescriber has qualified.[54] p927 The significant contribution that NMP leads play in embedding NMP within organisations should be acknowledged by clearer national guidance for the role, its responsibilities and workload.[32] p9	23 (53)		28 33,37 43,43,49, 54 59,63,81

Table 5 (*Continued*)

Theme Sub-theme	Example quotations from included studies	*n* (%)	Key elements	Studies
Personal and professional factors[a]		34 (79)		
Medical profession	I think it's useful because a lot of the junior doctors obviously rotate through every 3 to 6 months and actually if anything someone who's a permanent team member is probably more familiar with the drugs and protocols and the dose ranges.[35] p2672 When I have a patient that I know can be followed up by a nurse practitioner I am thrilled because I have got no room in my follow-up clinics . . . What I have actually done is become dependent. I mean if the nurse practitioner in this department was withdrawn I would not be able to look after the patients under my care.[28] p502 Junior doctors . . . they said that I was taking over their role . . . they were saying, 'Oh yeah and you're taking over our role and they won't need us.'[61] p125 I am the doctor; I am supposed to be in charge.[29] p2673 Nurses described a lack of support from GP colleagues and in some cases this extended to GPs specifically instructing nurses not to prescribe for their patients.[42] p407	26 (60)		28,32,34, 40-44,48, 50, 55-59,61,70, 82
NMP professions	I get more job satisfaction now because I can instigate treatment or first pills. If the patient is coming for the pill, I can prescribe it and see them again. It has given me more autonomy.[62] p225 I'm not sure that the qualification would improve my level of patient care. [Doctors] sign scripts as required.[34] p83 There is absolutely no financial incentive for taking on the huge responsibility of prescribing . . .[34] p927 In the area that I work I have pockets of deprivation. I know if I am going into those areas I tend not to take my prescription pad with me. I keep it locked up in the office and if they need prescriptions I either ask somebody to come to clinic to collect it or I ask them to get it from the GP just because I'd feel vulnerable carrying a pad about with me at that time.[42] p407	15 (35)		28,34,40,42,53 55, 62,34,70
Service users	I would be very happy for pharmacist to prescribe medicines which I take on a regular basis, for example, my inhalers or tablets for reflux . . .[48] p706 Service users felt that the nurse prescriber knew what she was talking about and had a good understanding of their circumstances and their illness . . .[64] p146 As far as I'm concerned, I am extremely worried about anyone other than a doctor prescribing any medicines . . .[42] p705 . . . also I think there is no privacy in a pharmacy is there? I don't think there is anyway . . . You kind of chat over the counter for all and sundry to hear.[53] p116	4 (9)		48,49,60,64
Financial factors		11 (26)		
Education and support	Nurse prescribing education was offered by line managers to the nurses . . . The reason behind this, some suggested, was that there was no direct cost incurred by the employer at that time. The availability of centrally funded prescribing education therefore appears to have been a significant factor in the uptake of training.[35] p2046 The Trust will not allow me to undertake nurse prescribing training. There is no management support – no time or funding[29] p174	4 (9)		29,35,42,55
Infrastructure, practicalities and logistics	. . . barriers such as cost and access to patient records are preventing benefits from occurring for outpatients in chronic pain[32] p33 . . . financial pressures, both organisational and personal (eg, cost of indemnity insurance) as barriers to expanding the services offered by prescribing pharmacists.[42] p830	3 (7)		29,32,42
Remuneration	Recognition in terms of status and pay for the increased responsibility of prescribing aroused the most emotion and sense of unfairness, and was found to be a major barrier in the study. Many believed the prescribing role would not be taken seriously until it was remunerated.[34] p930	3 (7)		34,35,52
Time and backfill Drugs	I believe it is impossible to carry a large caseload with no one covering it to go on this course (nurse prescribing training) . . .[29] p174 Reducing prescribing costs in secondary care meant that only onsite treatment and emergency medication are financed, and all other prescribing has to go through primary care via the General Practitioner.[35] p2048 Another frustration was their inability to prescribe for patients attending their clinic if the patient's GP was located in another Trust.[42] p407	3 (7) 4 (9)		29,40,42 32,35,40,73

CPD = continuing professional development, GP = general practitioner, NMP = non-medical prescribing.
[a] Includes thoughts and perceptions regarding the acceptability and value of NMP.

associated professions, whereas small uni-professional cohorts would limit a university's capacity to offer and deliver.[34,35] Accessing a medical mentor to complete the course was perceived as a barrier, with variability of medical professionals' willingness to undertake this role, and a perception that medical mentorship was frequently inadequate.[28,34,53]

Participants reported that a formal national infrastructure to guide CPD would be beneficial, as support from managers, availability of specialty courses, funding and time were highlighted as barriers to appropriate CPD activities and courses.[33,35,38,54] This in turn limited a prescriber's ability to maintain awareness of the current evidence base, directly influencing NMP utilisation in practice.[33,35,38,56] The introduction of 'buddy systems' alongside regular in-house multidisciplinary CPD were positive and economical in maintaining evidence-based medicines use.[44,57]

Support: Type and level of support to implement, maintain and develop NMP were reported to depend on the participant's reasons for commencing NMP and their role within the health service.[29,33,34,58] Engagement and support from all parties, especially medical staff and health managers, were essential for planning and successful implementation.[34,55,59] Support from medical professionals as mentors during training and post-qualification was strongly emphasised as important, and an NMP facilitator. However, time to undertake mentored activities was recognised as a potential barrier.[34,37] Support from healthcare managers and government were reported as key to ensuring provision of policy and funding, overcoming barriers presented by other groups, and facilitating organisational pressure to enable implementation of NMP.[29,32,35,55,59] Support from within the NMP professions was reported as fundamental to: advocate for colleagues to be trained to prescribe; act as buddies to reduce feelings of isolation; and develop services.[34,37,56,57] The adoption of NMP lead roles was reported as crucial for coordination and promoting the benefits of NMP, ensuring that organisations provide safe practice environments and liaison with higher education providers.[33,39] Service users' poor knowledge and understanding of the level of education and experience required by non-medical prescribers were acknowledged as potential barriers.[49,60] Participants accepted that support from service users was vital,[49,60] with service user consultation recognised as fundamental when contemplating health service redesign.[41,49,60]

Personal and professional factors

Participants in 34 (79%) studies reported that the thoughts and perceptions relating to acceptability and value of NMP had significant impact on its implementation and utilisation.

Medical profession: Negative thoughts and perceptions held by medical professionals were widely perceived to result from a lack of understanding of NMP roles and responsibilities, causing fear of deskilling or loss of power and/or control.[29,32,39] Medical practitioners reported confusion about autonomy, responsibility and insurance, which in turn led to a lack of support for NMP.[32] Practitioners working in private practice acknowledged the threat of NMP competing for business with medical colleagues,[56] and junior doctors felt that NMP threatened their roles.[51] Some general practitioners wanted to maintain ownership of patients in health systems in which general practices have responsibility for direct funding of medicines.[32,35]

Conversely, medical professionals with positive feelings towards NMP acknowledged the benefits to service users, healthcare staff and the health economy.[36,38] They reported enhancement in service provision, efficiency and patient care.[38] Doctors acknowledged that non-medical prescribers who had a strong and established relationship with the medical team had the experience and knowledge to prescribe successfully.[39,44,61] NMP was reported to be extremely helpful in reducing and avoiding waiting lists, especially in specialties where long-term drug monitoring is prevalent.[32,36,38] When doctors were unable to see patients in a timely manner, a non-medical prescribers' ability to initiate, titrate and modify treatments had a positive effect on patients' access to medicines.[32,36–39] It was also highlighted that non-medical prescribers, unlike junior doctors, are permanent team members, and therefore become more familiar with drugs, protocols and dose ranges.[39] Recognition of these benefits was reported to drive medical professionals to advocate for the inclusion of NMP into local healthcare systems.[32,36–39]

NMP professions: The main facilitator observed by participants was job satisfaction.[54,55,62] Some participants reported that the inclusion of NMP into their roles gave them more autonomy, improving the level of patient care they offered.[54,55,62] In contrast, some participants reported that the risk and responsibilities associated with NMP increased stress and anxiety, restricting time spent on traditional areas of practice.[29,54] Many participants, although supportive, recognised that NMP would not enhance their individual roles within interdisciplinary teams, as medical prescribers are readily available to prescribe.[29,53,54,63]

The phase of an individual's career was perceived to affect the uptake of NMP into practice. Many clinicians with the high level of experience required prior to NMP training might prioritise non-clinical job roles, pursue other areas of study or be nearing retirement, and not motivated to undertake NMP.[54,56] Participants acknowledged the lack of additional remuneration offered to non-medical prescribers as a barrier.[34,56,62] Specifically, the enhanced responsibility and associated safety risks, with no reward (financial or otherwise), was reported to deter many.[40,53,54]

Service users: Most participants were happy with NMP services, citing closer relationships with non-medical prescribers than doctors, due to the time limitations within medical clinics. NMP services were often more convenient, providing faster access to required treatment compared to traditional medical care.[60,64] Conversely, participants in two studies reported that they felt prescribing responsibilities belong to medical professionals and were unsure about the qualifications possessed by non-medical prescribers.[41,49] A final subgroup reported that they were happy for non-medical prescribers to monitor long-term medication use; however, assessment of a new medical condition was felt to be the job of the medical practitioner.[41] To avoid poor uptake of NMP services, participants recommended that service users be consulted at all levels and phases of service planning, with education of service users essential if these key stakeholders were not to be a barrier to successful implementation.[41,49,60,64]

Financial factors

Participants in 11 (26%) studies reported financial factors to be key facilitators or barriers to NMP. Financial factors underpinned all themes/sub-themes, with inadequate funding creating and reinforcing significant barriers to successful implementation.[32,35,62,65] Funding for time and education should include financial support for both completion of the NMP course and CPD.[29,35,42,65] Further, appropriate financial resources were required to backfill roles previously undertaken by non-medical prescribers whilst training and post implementation of NMP into their roles.[29,35,40,42] Participants advised when planning, implementing and developing any NMP services, organisations must ensure they have sufficient financial resources for the necessary infrastructure, logistics, remuneration of staff and other practical implications of NMP such as administrative support and insurance.[30,34,42,56] Participants also highlighted the funding of drugs themselves as a possible barrier. Issues related to equity and equality of patient care, especially where patient care crosses borders, organisational boundaries and/or funding pools, were considered immoral, frustrating, and a barrier to good practice and successful implementation.[32,35,40]

Characteristics of quantitative studies

Study characteristics

Seven quantitative studies were included in the systematic review;[63,66–71] their characteristics are summarised in

Table 6
Characteristics and quality of the included qualitative studies (n = 7).

Study	Survey method	Year of data collection	Specialty	Total (n)	Number of participants from each profession	Quality[a] (0 to 48)
Courtenay[66]	Postal questionnaire	2006	Various	1992	1992 nurses	21
Courtenay[71]	Online questionnaire	2010 to 2011	Various	883	793 nurses, 33 managers, 36 pharmacist, 9 allied health and optometrists, 12 n/s	22
Farrell[67]	Online or postal questionnaire	n/s	Oncology	103	103 nurses	17
Gumber[70]	Postal questionnaire	2010	Various	20	18 nurses, 2 pharmacists	14
Hutchison[63]	Online questionnaire	2010	Various	342	342 pharmacists	19
Kaplan[68]	Postal questionnaire	2001	Various	1241	1241 nurses	20
Larsen[69]	Postal questionnaire	2003	Emergency/urgent care	192	192 managers	14

n/s = not stated.
[a] Quality Assessment Tool for Studies with Diverse Designs.[23]

Table 6. More detailed characteristics are available in Table 7 (see eAddenda for Table 7).

Study methods

All seven included studies used survey methodology.[63,66–71] Distribution of questionnaires was varied, with four (57%) studies using postal questionnaires,[66,68–70] two (29%) using online questionnaires,[63,71] and one (14%) providing participants with a choice of both methods.[67] The studies were undertaken in three countries from 2001 to 2011, with five (71%) in the UK, one (14%) in Canada and one (14%) in USA.

Participants

A total of 4773 participants were recruited across the seven studies.[63,66–71] The key stakeholders that were recruited were nurses (87%), pharmacists (8%), health service managers (5%) and allied health/optometrists (<1%). A small percentage of participants (<1%) did not disclose their job roles or profession.

Intervention

Most of the included studies investigated nurse iNMP (n = 4, 57%).[66–69] Pharmacists were the only other profession individually investigated (n = 1, 14%).[63] One study investigated both nurse and pharmacist iNMP (14%),[70] with one further study investigating iNMP as a whole, including all potential professionals (14%).[71] Six (86%) studies included participants working across community and hospital settings,[66–70] with one (16%) focusing on hospital care.[63] Five (71%) studies encompassed all healthcare specialties;[63,66,68,70,71] the remaining studies focused on individual specialties including oncology (14%) and emergency/urgent care (14%).[67,69]

Outcomes

All seven studies contained at least one quantitative survey question relating to barriers or facilitators of NMP.[63,66–71] Data supported three (75%) of the four themes synthesised from the qualitative studies. Four (57%) studies contained data relating to 'systems factors',[66–68,71] five (71%) studies 'education and support',[66,68–71] and five (71%) studies 'personal and professional factors'.[63,66–68,70] No studies contained data directly relating to 'financial factors'.

Quality assessment

Quality scores of the quantitative studies are summarised in Table 6 and ranged from 14 to 22 (mean 18). The individual quality criteria met by the studies are presented in Table 8 (see eAddenda for Table 8).

Results and synthesis of quantitative studies

Table 9 summarises the results of individual studies.

Systems factors

Four studies investigated systems factors.[66–68,71] Results highlighted local policy and lack of access to computer-generated prescriptions as key barriers.[66,68] One study[67] assessed barriers due to time, capacity and resources, finding that whole health organisations, rather than individual directorates, were responsible for limiting use of iNMP due to these factors.[67] One study[71] reported that 86% of employers had up-to-date policies in place, facilitating quality and safe use of NMP. Key elements of these policies were: agreed and documented scope of practice; regular clinical services audit; and standardised procedures for communicating updates regarding safety warning and drug alerts.[66]

Education and support factors

Two studies investigated education and support factors.[68,71] Results revealed that NMP course content, support following qualification, and adequate access to CPD were key factors.[71] Barriers were examined across three studies.[66,68,70] Results identified a lack of support from medical professionals and peers, and deficiency of adequate supervision when training to prescribe.[66,68,70] One study investigated factors influencing healthcare managers' decisions to send clinicians on the NMP course.[69] Facilitating factors that were identified were: increasing autonomy; improvements in patient care; improvements in clinicians' pharmacology knowledge; and improved accountability. Barriers were: time; factors related to the backfill of course candidates; medical supervisor requirements; and a limited formulary being too restrictive to be beneficial.[69]

Personal and professional factors

Three studies[66,68,70] investigated personal and professional factors. Objections and concerns by medical professionals and pharmacists regarding competency, liability and competition were found to be important external factors.[68] Internal factors such as a professional's caseload and fear of litigation were also demonstrated.[70] One study[67] found that time, capacity and resources were barriers, which were reported in some cases as being induced by nursing and medical directorates, with further reasoning not reported. One study[63] investigated the level of influence of factors affecting an individual's decision to seek or not seek NMP authorisation. Those that had chosen to seek authorisation reported a high relevance to practice and increased efficiency/job satisfaction as key motivators. Clinicians who decided not to seek authorisation reported concerns regarding increased liability and poor relevance to their practice as key factors not to prescribe.[63]

Integration of qualitative and quantitative data

Data from 12 117 participants (combined from the qualitative and quantitative studies) were integrated. Table 10 shows the total number of participants from each stakeholder group involved in iNMP included in the integration.

Data from the qualitative and quantitative components of the systematic review were brought together in the integration matrix (Table 11) and used to construct the resultant 'NMP Implementation Framework' (Figure 2). Data extracted from the quantitative studies corroborated the existence and importance of the subthemes identified in three themes developed from the qualitative studies. Integration was undertaken for six (75%)

Table 9
Findings from quantitative studies categorised under the themes generated by the analysis of the qualitative studies.

Theme Study	General focus of the study	Specific findings of the study, reported by n (%) participants	Quality[a] *(0 to 48)*
Systems Factors			Mean 20
Courtenay[66]	Barriers to iNMP:	local policy, 619 (66%)	21
		national policy, 87 (9%)	
		unable to use computer-generated prescriptions, 575 (61%)	
		access to medical records, 26 (3%)	
Kaplan[68]	Barriers to iNMP:	restricted formularies, 183 (24%)	20
Farrell[67]	Time, capacity and resources were reported to be barriers induced by:	the health organisation, 41 (41%)	17
		nursing directorate, 14 (14%)	
		medical directorate, 22 (22%)	
Courtenay[71]	89% of employers had up-to-date NMP policies in place. Policies dictated:	regular audit and review of clinical services, 561 (74%)	22
		regular feedback data re prescribing practice, 328 (44%)	
		access own prescribing practice data, 281 (37%)	
		agreed scope of practice with employers, 642 (85%)	
		supplied with safety warnings, drug alerts, etc, 678 (90%)	
		NMPs involved in the development of local formularies/guidelines, 357 (48%)	
Education and support factors			Mean 18
Courtenay[71]	Facilitators of iNMP:	adequate support following qualification to undertake iNMP, 304 (47%)	22
		adequate access to support prescribing role, 561 (74%)	
Courtenay[66]	Barriers to iNMP:	lack of peer support, 126 (13%)	21
Kaplan[68]	Barriers to iNMP:	medical professional availability to support, 33 (4%)	20
Gumber[70]	Barriers to iNMP:	adequate supervision: strongly agree, 4 (20%); agree, 10 (50%); undecided, 4 (20%); disagree 2 (10%)	14
	Facilitators of iNMP:	prescribing course content: strongly agree, 4 (20%); agree, 12 (60%); undecided, 2 (10%); disagree 2 (10%)	
		support and guidance from medical professional: strongly agree, 11 (55%); agree, 9 (45%)	
Larsen[69]	Facilitators of manager's decision to send clinicians to a NMP course:	autonomy, (44%); patient care, (37%); improve clinicians' pharmacology, (38%); improve knowledge of accountability, (34%); requested by staff, (18%); recruitment/retention, (11%); organisational drivers, (14%)	14
	Barriers to manager's decision to send clinicians to a NMP course:	time, (11%); backfill, (17%); formulary too limited to be beneficial, (29%); finding medical supervisor, (11%); poor medical support, (2%); funding of drugs, (<1%); poor intra-professional support, (2%)	
Personal and professional factors			Mean 18
Courtenay[66]	Barriers to iNMP:	objections by medical professionals/pharmacists, 153 (16%)	21
Kaplan[68]	Barriers to iNMP:	medical professionals' concerns regarding liability, 183 (24%)	20
		competition between medical and non-medical prescribers, 33 (4%)	
Gumber[70]	Barriers to iNMP:	conflicts with medical staff: agree, 9 (45%); undecided, n (5%); disagree, 4 (20%); strongly disagree, 6 (30%)	14
		significant increases in caseload: strongly agree, 2 (10%); agree, 11 (55%); undecided, 5 (25%); disagree, 1 (5%); strongly disagree, 1 (5%)	
		fear of litigation; agree, 7 (35%); undecided, 7 (35%); disagree, 5 (25%); strongly disagree, 1 (5%)	
Farrell[67]	Time, capacity and resources were reported to be barriers induced by:	nursing directorate, 14 (14%)	17
		medical directorate, 22 (22%)	
Hutchison[63]	Level of influence on individual's decision to seek NMP authorisation, as rated by clinicians who had applied for authorisation to prescribe:[b]	relevance to practice: strongly (70%); moderately (22%); somewhat (5%); slightly (3%); not at all (0%)	19
		increased efficiency: strongly (62%); moderately (22%); somewhat (3%); slightly (11%); not at all (3%)	
		importance to the profession: strongly (56%); moderately (22%); somewhat (11%); slightly (3%); not at all (8%)	
		time: strongly (8%); moderately (19%); somewhat (6%); slightly (11%); not at all (56%)	
		job satisfaction: strongly (37%); moderately (29%); somewhat (11%); slightly (9%); not at all (14%)	
		concerns, increased liability: strongly (17%); moderately (17%); somewhat (17%); slightly (34%); not at all (14%)	
	Level of influence on individual's decision to seek NMP authorisation, as rated by clinicians who decided not to apply for authorisation to prescribe:[b]	relevance to practice: strongly (37%); moderately (26%); somewhat (17%); slightly (6%); not at all (15%)	
		increased efficiency: strongly (16%); moderately (16%); somewhat (17%); slightly (14%); not at all (36%)	
		importance to the profession: strongly (14%); moderately (13%); somewhat (21%); slightly (11%); not at all (41%)	
		time: strongly (18%); moderately (18%); somewhat (17%); slightly (9%); not at all (39%)	
		job satisfaction: strongly (7%); moderately (15%); somewhat (16%); slightly (18%); not at all (45%)	
		concerns, increased liability: strongly (23%); moderately (23%); somewhat (23%); slightly (16%); not at all (15%)	

CPD = continuing professional development, GP = general practitioner, NMP = non-medical prescribing.
[a] Includes thoughts and perceptions regarding the acceptability and value of NMP.
[b] Scale: not at all, slightly, somewhat, moderately, strongly.

Table 10
Total number of participants included in the systematic review.

Stakeholder group	Total n (%)
Nurses	8466 (70)
Service users	2527 (21)
Pharmacists	625 (5)
Managers	242 (2)
Medical doctors	114 (<1)
NMP leads	72 (<1)
Others	42 (<1)
Administrative staff	20 (<1)
Allied health professionals	9 (<1)
Total	12 117 (100)

NMP = non-medical prescribing.

subthemes within these themes. No data from the quantitative studies disagreed with the thematic synthesis. Integration was not possible for financial factors, government and political factors and service users sub-themes, as no data relating to these themes/sub-themes were retrieved from the quantitative studies.

Discussion

The evidence from this systematic review suggests that successful implementation of iNMP requires a coordinated, transparent and inclusive approach at all systems levels.[32,33,50] From governments to local clinical departments or businesses, the development of laws, regulations, guidelines, policies and procedures must be created with consistency, and involve consultation with all key stakeholders. A strategic, collaborative and consultative implementation process is fundamental to manage potential barriers, including personal and professional self-interest, professional territorialism, fear of change, and poor quality or unsafe clinical practice.[51,56] These findings confirm results from a large study evaluating nurse and pharmacist prescribing in the UK,[72] which highlighted that a lack of local planning and strategic vision had previously been a key barrier to NMP.[72] With economic savings driving implementation, it is paramount that robust local clinical governance policy exists to protect both those using NMP services and non-medical prescribers themselves.[32,33,66,71] Policy should be locally defined within a national framework, as different clinical settings will require unique procedures and safeguards, depending on locality, availability of immediate clinical support and professional specialty.[34] NMP should be integrated as an additional clinical skill, complementing traditional expertise and scope of practice, to enhance patient care.[33,34] It is essential to clearly define scope, parameters, boundaries, accountability and lines of responsibility, in order to avoid risks associated with potential confusion and ambiguity,[34] alongside communication and documentation policies, incident reporting processes, and CPD requirements to embed a culture of quality and safety.[34,35,42,43] Health organisations should work together to ensure that bureaucracy does not limit clinicians' abilities to provide quality patient-centred care by adopting innovative service designs.[33,36,40] To ensure the longevity and future expansion of NMP, health organisations should aim to

Table 11
Integration matrix. The rows of the matrix represent the subthemes developed from synthesis of the qualitative studies, and the columns contain citations of the quantitative studies.

Theme	Quantitative studies (n = 7)						
Sub-theme	Courtenay[66]	Courtenay[71]	Farrell[67]	Gumber[70]	Hutchison[63]	Kaplan[68]	Larsen[69]
Systems factors							
Government and political factors	N	N	N	N	N	N	N
Organisational factors	Y	Y	Y	N	N	N	N
Restricted formulary	N	N	N	N	N	Y	N
Education and support							
Education	N	Y	N	Y	N	N	Y
Support	Y	Y	N	Y	N	Y	Y
Personal and professional factors							
Members of the medical profession	Y	N	Y	Y	N	Y	N
Members of the NMP professions	Y	N	Y	Y	Y	N	N
Service users	N	N	N	N	N	N	N
Financial factors[a]	–	–	–	–	–	–	–

N = not identified as a relevant factor in the quantitative studies, Y = identified as a relevant factor in the quantitative studies.
NMP = non-medical prescribing.
[a] Financial factors were not assessed in any of the quantitative studies.

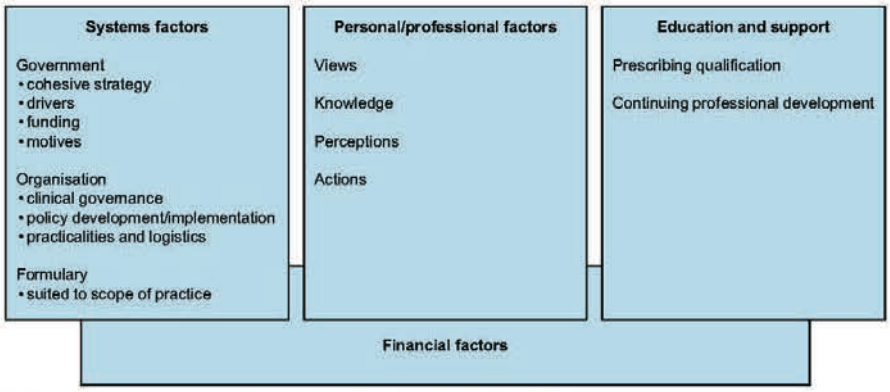

Figure 2. NMP Implementation Framework. Factors to consider when implementing independent NMP.
CPD = continual professional development

future-proof services through workforce and succession planning, alongside clinical outcome and cost-effectiveness audits to ensure ongoing quality, effectiveness and funding.

Owing to innovations in medical science, clinicians, health organisations and authorities have recognised that legally restricted formularies may quickly become outdated.[31,44,52,53] Restrictions within scope of practice are thought to deter potential non-medical prescribers from training, and lead to professional frustration and low levels of engagement for those who are qualified.[54] Risk may be managed via local formulary defined in organisational policy. This method has the benefit of flexibility without restrictions in law, whilst protecting the local prescribers and service users.[32,54] Selection criteria alongside academic and professional prerequisites are currently utilised by health organisations and higher education institutions to ensure academic ability, safeguard quality and select suitable NMP training course candidates.[33] Although courses fulfil nationally agreed standards, the evidence suggests that a lack of profession-specific content may lead to candidates feeling underprepared.[34,35,55] Further, lack of access to a medical mentor may impede qualification, with inconsistencies in mentorship quality affecting a clinician's confidence to prescribe.[28,34,68] It has been suggested that national frameworks be developed that govern CPD activity and facilitate access time and funding.[33,35,38,54] These factors therefore require further investigation to ensure high-quality education and resource optimisation.

The positive or negative thoughts and perceptions of both individual stakeholders and their wider professions appear intimately related to the level of support offered to non-medical prescribers, their educational activities and NMP services. Improved job satisfaction due to increased autonomy and the ability to provide improved patient care are key drivers for clinicians undertaking NMP roles.[54,55,62] Conversely, increased job stress and anxiety, associated safety risks and restricted time to complete traditional roles, with no increase in remuneration for the increased responsibility, are key barriers.[29,54] The engagement of medical professionals in consultative, planning and governance roles, and as clinical mentors[34,55,59,68] may minimise barriers associated with the medical profession, due to fears of: deskilling, loss of power and job roles, competition to earnings and confusion regarding autonomy, responsibility, liability and insurance.[29,32,39] Consistent with the findings of previous research,[73] this review emphasises the benefits of adopting NMP lead roles within health organisations to aid in overcoming systems, personal and professional barriers,[33,39] and reducing feelings of professional isolation, where the number of prescribers are limited.

To promote NMP implementation and practice, health organisations should undertake a thorough economic evaluation as part of planning and development, securing the appropriate finances required for success.[30,34,42] To ensure no detrimental effects to patient care or clinician job satisfaction it is recommended that complexities related to funding streams crossing organisational boundaries or fragmented health systems should be resolved prior to offering NMP services.[32,35,40] Whilst the potential economic savings act to engage many individuals or professions with the benefits of utilising NMP, some financial factors act to resist NMP through difficulties in modernising funding streams and increased clinical responsibility with potentially no increase in remuneration. If NMP is to further grow and develop, these barriers must be acknowledged, planned for and resolved across all aspects of the health economy.

This review used rigorous systematic methods with a synthesis strengthened by the engagement of a multidisciplinary research team, including both registered non-medical prescribers and non-prescribers. This combination ensured specialist knowledge of iNMP alongside specific disciplinary perspectives, facilitating a rigorous analytical process. Most included studies were limited to nursing and a small range of Western countries, potentially limiting transferability of the results across all clinical and professional specialties internationally. No temporal or spatial analysis was undertaken within the review; therefore, caution is recommended when interpreting the contemporary nature of the barriers or facilitators into individualised contexts.

This is the first mixed-methods systematic review to investigate the barriers to and facilitators of iNMP. Integration of the quantitative and qualitative data demonstrates, with strong agreement, multifactorial and context-specific variables existing within four explicit themes. The evidence supports that when factors are acknowledged and accommodated, they become facilitators, but may become barriers when they are not. Clinical physiotherapists and other clinicians should consider whether these factors have been adequately addressed before training to become non-medical prescribers. Politicians, policy and healthcare managers and clinicians should use the resulting NMP implementation framework to ensure the safe and successful adoption, implementation and utilisation of physiotherapist prescribing. Where physiotherapist prescribing is currently outside the legal scope of practice, the resulting NMP Implementation Framework, and this review's evidence, should be core to the implementation strategy of physiotherapy professional bodies wishing to adopt NMP practice. There is a clear need for future research to evaluate the personal and professional motivations for physiotherapy prescribing internationally, implementation strategies, and the efficacy in terms of clinical and cost-effectiveness of services employing iNMP. To fully understand the long-term uses of NMP it is paramount that variables such as profession, specialty, geographic location, clinical indications and funding models are assessed alongside the needs of service users, communities and the impact on all stakeholders.

What is already known on this topic: Non-medical prescribing is undertaken by various professions internationally. Non-medical prescribing may be supplementary (ie, via a clinical management plan in partnership with a medical practitioner) or independent (ie, the non-medical professional prescribes autonomously).

What this study adds: Qualitative studies have identified barriers and facilitators to non-medical prescribing in: political/organisational factors; whether a formulary is used; education and support; personal and professional factors among the medical profession, other professions, and service users; and financial factors. Quantitative studies confirm these factors. Based on this evidence, an implementation framework is proposed to assist professional bodies, politicians, policy-makers, healthcare managers and clinicians to ensure that a non-medical prescribing system would be introduced safely and successfully.

Footnotes: [a] NVivo 11, QSR International, Melbourne, Australia.

eAddenda: Tables 2, 4, 7 and 8 and Appendix 1 can be found online at: http://dx.doi.org/10.1016/j.jphys.2017.09.001

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Competing interests: Nil.

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Provenance: Not invited. Peer reviewed.

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8.11 Appendix 11: Response to reviewers, Journal of Physiotherapy, Barriers to and facilitators of independent non-medical prescribing in clinical practice: a mixed-methods systematic review, 1st September 2017

Editors/Reviewers Comments	Changes made or Reason(s) for not making changes
Editor	
[1] You must format the abstract according to JoP guidelines. That means the Abstract starts with a question, not an aim. Please use something like "Question: What are the factors that affect the implementation or utliisation of independent non-medical prescribing (NMP)?" The question also gets repeated, word for word, at the end of the Introduction section, with the following lead-in: "Therefore, the specific research question for this systematic review was:".	This has been completed as per request.
[2] In the last sentence of the Abstract, you need to change "should" to "could" so that you are not overstating what your review has shown, i.e., you have generated a framework that relevant stakeholders think will work - you haven't measured what happens when the framework is implemented.	This has been completed as per request.
[3] I'm happy with the title but hyphenate 'mixed methods' and don't capitalise any words after the first word.	This has been completed as per request in the title and within the manuscript.
[4] In the Phase 2 section, under the subheadings "Study Methods" and "Participants", you still state that there were seven studies, but then only cite six studies, i.e., 60,63-67. You need to add in 68, presumably.	Thank you for spotting this omission. Citation 68 has been added to both sections.

Reviewer 1	
1. This paper will be of interest to readers of Journal of Physiotherapy. For the most part, it is an impressive and much-needed piece of work.	Thank you for your comments. The authors hope that the article will be used to advocate for the physiotherapy profession.
2. I don't find the Phase terminology helpful. It implies a chronology that I think barely exists in the methods. The searching and assessment of eligibility surely wasn't done in two phases. (The researchers didn't seriously hand trawl through 3000 search results for qualitative studies and then go back to the start and hand trawl for quantitative studies, did they?) I admit that the topics for data extraction from the quantitative studies were dictated by the themes that arose from the qualitative studies, but apart from that, the two phases seem simultaneous. It would be clearer to just delete the words Phase 1 and Phase 2 everywhere and then insert 'qualitative data' and 'quantitative data' as headings where needed. For example, at the end of the first paragraph of the Results, the researchers could just put 'This resulted in 43 qualitative studies and 7 quantitative studies, totalling 50 included studies.' Then simply the heading 'Qualitative studies' and then the subheading study characteristics. Then continue with the text 'Characteristics of the qualitative studies are summarised in ...'	Thank you for this comment. We have happily edited the manuscript using your suggestion. Phases 1 and 2 have been replaced with Qualitative and Quantitative Components. Phase 3 is now “Integration”.
3. The system of categorisation explained in Box.3 and Box.4 introduces a disappointing, pseudo-science ending to an otherwise robust and convincing systematic review. I can see what the researchers are attempting to achieve but significance	The authors thank you for your comment. We have addressed this point as suggested by reviewer 2. In the integration sections we have tabulated the relevant factors from the qualitative studies and note whether they are also identified as relevant factors in the quantitative studies, simplifying Figure 2 to just the blue and yellow

testing is irrelevant to identifying barriers/facilitators in surveys. Even if statistically significant studies were found, it would lead the researchers to something akin to vote counting, which the Cochrane handbook eschews. More importantly the system leads the researchers to make some odd conclusions, such as that medical doctors can only be a potential barrier, not a potential facilitator. This conclusion is inconsistent with the quotes highlighted in the manuscript such the paragraph that starts 'Conversely, medical professionals with positive feelings towards NMP acknowledged the benefits to service users, healthcare staff and the health economy'. That paragraph's supportive quotes arise from 6 studies, which suggests that doctors can be a facilitator. The conclusion that doctors can only be a barrier is also unhelpful because doctors who are onside - i.e., those have seen how NMPs are typically long-standing colleagues who can improve efficiency -- are NMP's greatest asset in this situation. Don't put them off. More importantly, don't reinforce the views of doctors who see themselves as the last line of defence against NMP. Let them see that other doctors have tried working with NMP and found it helpful. (Think 'Green Eggs and Ham' if that means anything to the researchers!) Since the review is already quite long, I suggest cutting Box.3 and Box.4 and not using their system of categorisation to generate Fig.2.	columns, and the yellow columns would be populated with Y for "also identified as a relevant factor in the quantitative studies " and N for "not identified as a relevant factor in the quantitative studies". The methods/results sections related to the integration of the qualitative and quantitative data has been changed to: Methods: *"Integration* *The qualitative and quantitative data were compared through an integration process, to determine agreement or disagreement within identified themes/subthemes[94 95]. Data were tabulated into an integration matrix [95 108 110]. Whether qualitative and quantitative data corroborated, and confirmed findings was observed and reported. To demonstrate the key factors that affect the implementation and utilisation of iNMP, the integrated data were used to develop an implementation framework[108]."* Results: ***"Integration of Qualitative and Quantitative Data*** *Data from the qualitative and quantitative components of the systematic review were brought together in the integration matrix (Figure 2) and used to construct the resultant 'NMP Implementation Framework' (Figure 3). Data extracted from the quantitative studies corroborated the existence and importance of the subthemes identified in 3 themes developed from the qualitative studies. Integration was undertaken for 6 (75%) subthemes within these themes. No data from the quantitative studies disagreed with the thematic synthesis. Integration was not possible for financial factors, government and political factors and service users' sub-themes, as no data relating to these theme/ sub-themes was retrieved from the quantitative studies."*

	This will hopefully avoid any confusion by the readers and remedy the inconsistencies noted.
MINOR COMMENTS Abstract, Lines 8-10: The grammar here is wrong. I suggest 'Eligibility criteria: Included studies must be qualitative and quantitative studies investigating independent prescribing by any non-medical professional group. Study participants can be any stakeholders in actual or proposed independent non-medical prescribing.' 4. Abstract, Results, Line 6: The abbreviation CPD is used but it has not been defined earlier. It is not re-used in the Abstract so write it in full. 5. Introduction, Paragraph 2, Line 1: Do the abbreviations NMP and iNMP need to be used so often in the paper? The sentence 'Pharmacist NMP has demonstrated clinical effectiveness...' sounds odd when the abbreviation is read in full 'Pharmacist non-medical prescribing has demonstrated...'. If a pharmacist is doing the prescribing, it is redundant to then specify 'non-medical'. What's wrong with "Pharmacist prescribing has demonstrated clinical effectiveness..."? 6. Introduction, Paragraph 2, Lines 1-2: I suggest 'for the management of chronic pain in primary care and post-operative pain in a tertiary surgical unit'.	Thank you for these minor comments. Comments 1-7 have been completed as per request. Comment 8: This has been addressed by introducing 'non-medical prescribing' as 'NMP' and writing non-medical prescriber(s) in full throughout the manuscript. Comment 9: Thank you for highlighting the possible confusion between the umbrella term non-medical prescribing (NMP) and the different methods of NMP such as independent (iNMP) and supplementary (sNMP) prescribing. Abbreviations are used correctly throughout the manuscript dependent on whether addressing NMP as a whole or a specific method of NMP such as iNMP or sNMP. Following discussions with the editor, this issue has been addressed by adding a section to the introduction to clarify the umbrella term and specific methods of prescribing that lie within: *"Non-medical prescribing (NMP) is utilised in a diversity of ways by a variety of health professions internationally [3]. In the UK the two types of NMP that are used by prescribers are supplementary (sNMP) and independent (iNMP) non-medical prescribing [201 202]. Clinicians prescribing via sNMP use a clinical management plan in partnership with a medical or dental practitioner, whereas iNMP requires the clinician to be entirely autonomous, prescribing medicines based on their individual clinical reasoning and judgments [201]."*

7. Method, Paragraph 2, Line 3: I suggest 'across other databases'. 8. Results, Education and Support Factors, Line 2: The abbreviation NMP is introduced as 'non-medical prescribing' but it is later used to mean 'non-medical prescribers'. It should only have one meaning. The prescrib-er meaning is far less common, so those instances could be written in full. 9. Results, Education and Support Factors, Line 3: The abbreviations iNMP and NMP seem to be being used interchangeably. Is the 'independent' redundant anyway? I have tried unsuccessfully to see a distinction in how the two are used in the paper. If there is a distinct difference in meaning, it needs to be clearer and perhaps the two terms used more carefully to portray this. If there is no fundamental difference in meaning, it would be less confusing to just define the abbreviation NMP as something like 'prescribing undertaken by non-medical professionals, independent of medical supervision' and then to use the abbreviation consistently throughout the paper. 10. Results, Education and Support Factors, Education, Paragraph 1, Line 11: I suggest 'mono-professional' to avoid any confusion with 'university'.	Comment 10: The word uni-professional has been left as the oxford medical dictionary recognises this word but not mono-professional. An example of its use/ definition is: *"Most healthcare education (particularly in the pre-registration university or classroom setting) is **uni-professional**, in which students learn together as a single group, e.g. nurses, doctors, dentists, midwives, allied health professionals or social workers, and do not learn with or alongside other **professional** groups."* Definitions — E-Learning Modules www.faculty.londondeanery.ac.uk/e-learning/interprofessional-education/definitions
Reviewer 2	
The review has many strengths. The question is topical, and the data have not been adequately and systematically summarised elsewhere. The protocol was prospectively registered. A	Thank you for your comments. The authors strived to achieve rigor and transparency.

reporting checklist has been used. Duplicate processes (completed searchers, eligibility and quality assessment) further strengthen the review. The conclusions are appropriately based on the data identified by the review.	
[47] The system used to categorise the quantitative study results into (i) statistically significant or not and (ii) facilitator or barrier uses inappropriate categorisations on which to summarise the evidence: (i) It is completely unsurprising that none of the quantitative papers tested for statistical significance, because they are merely reporting the proportion of respondents who perceived a given barrier or facilitator (or something similar). Statistical tests would not be expected in such studies. The only imaginable study where you could "show a barrier with statistical significance" would be a trial in which a barrier was either applied or not applied at random and NMP was the outcome, but this is so unfeasible no such studies would exist. (ii) The included studies in this review identify factors that can be either facilitators or barriers depending on whether the factor is present or absent. This is the case in most qualitative research into facilitators and barriers. The authors acknowledge this repeatedly in the paper (e.g., "Each theme can be both a barrier and facilitator depending on context"). An elegant solution would be to simply tabulate the relevant factors (i.e., regardless of whether they are discussed in the text	Thank you for this comment. We have utilised the reviewer's suggestion tabulating the relevant factors from the qualitative studies and noting whether they are also identified as relevant factors in the quantitative studies. Figure 2 has been simplified to just the blue and yellow columns and populated with Y for "identified as a relevant factor in the quantitative studies " and N for "not identified as a relevant factor in the quantitative studies".

as barriers and/or facilitators) from the qualitative studies and note whether they are also identified as relevant factors in the quantitative studies. This would simplify Figure 2 to just the blue and yellow columns, and the yellow columns would be populated with Y for "also identified as a relevant factor in the quantitative studies " and N for "not identified as a relevant factor in the quantitative studies".	
A weakness of the review is that the data extracted from the quantitative papers only related to themes identified in the qualitative papers. If some quantitative researchers had thought of an interesting and relevant topic to survey, why not include it? But the review is done, and this is a minor point, so it is not worth revising. However, if all the topics in the quantitative papers were already uncovered by the qualitative papers (i.e., no relevant data in any of the quantitative papers were ignored because they hadn't been identified in qualitative papers), then the authors could change "Data pertaining to themes identified in phase 1 were extracted from the quantitative studies independently by the two reviewers" to "Data pertaining to barriers and facilitators were also extracted from the quantitative studies by two reviewers".	The sentence has been changed to *"Data pertaining to barriers and facilitators were also extracted from the quantitative studies by two reviewers"* as suggested, for the reasons highlighted by the reviewer.
MINOR COMMENTS The term "mixed methods systematic review" is inconsistent with previous papers in this journal, which have described this methodology as "a systematic review of quantitative and qualitative studies". A quick look at the literature indicates that	Thank you for your minor comments. These have all been actioned as per request. The editor has confirmed the use of “mixed-methods systematic review”- this has been changed throughout the manuscript.

"mixed-methods systematic review" is more common in titles. The editor should provide guidance. Introduction - paragraph 2; Change "Physiotherapy must ensure" to "Physiotherapists must ensure" or "Members of the physiotherapy profession must ensure". Method - parag 1; Cite Reference 15 only once in this sentence. Method - parag 2; Do the authors mean "All pilot studies" or merely "All eligible pilot studies"? Method - parag 10; Omit "textual" because any narrative analysis in a published paper is text-based. Method - parag 11; Change "disagreement to" to "disagreement within". Results - parag 1; The sentence about the number of exclusions based on title and abstract is mathematically incorrect. The same problem arises in the flow diagram. Results - Systems Factors - paragraph 3; Change the last sentence to "Participants recommended that databases should be developed locally to: enable prescribing practice audit; ensure evidence-based clinical practice, transparency and accountability; and showcase potential economic savings." Results - Systems Factors - paragraph 5; Change "beneficial" to "beneficial".	We have deleted the column in table 9 as suggested to support the changes to the integration section of the paper.

8.12 Appendix 12: Modified SPIRIT Checklist, views and perceptions of Australian physiotherapists and physiotherapy students about the potential implementation of physiotherapist prescribing in Australia

Section/item	Item No	Description	Page
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	128
Protocol version	3	Date and version identifier	N/A
Funding	4	Sources and types of financial, material, and other support	194
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	130
Objectives	7	Specific objectives or hypotheses	133
Design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (e.g., superiority, equivalence, noninferiority, exploratory)	134
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	134
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	135

Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	135
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (e.g., systolic blood pressure), analysis metric (e.g., change from baseline, final value, time to event), method of aggregation (e.g., median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	137
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	136
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	136
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (e.g., duplicate measurements, training of assessors) and a description of study instruments (e.g., questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	137
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	140
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	140
Ethics and dissemination			
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8.13 Appendix 13: Article, BMC Health Service Research, views and perceptions of Australian physiotherapists and physiotherapy students about the potential implementation of physiotherapist prescribing in Australia: a survey protocol

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BMC Health Services Research

STUDY PROTOCOL Open Access

Views and perceptions of Australian physiotherapists and physiotherapy students about the potential implementation of physiotherapist prescribing in Australia: a survey protocol

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Abstract

Background: Non-medical prescribing (NMP) is acknowledged as an expanding area of clinical practice across the world. The physiotherapy profession is currently investigating the introduction of physiotherapist prescribing in Australia, with the case for reform centred around meeting the healthcare needs of the current and future Australian population. Conflict within a profession has been identified as a barrier to implementation of new clinical innovations. An online survey has been developed with the aim to collect and synthesise the views and perceptions of Australian physiotherapists and physiotherapy students about the potential use of NMP by physiotherapists in Australia.

Methods: A cross-sectional descriptive survey design, using a pre-tested online questionnaire, including quantitative and qualitative components, will be utilised to explore the views and perceptions of Australian physiotherapists and physiotherapy students regarding NMP by physiotherapists in Australia. Quantitative data will be analysed descriptively and regression analysis will be utilised to identify associations between the specific question outcomes and demographic data. A thematic analytical approach will be utilised to synthesise qualitative data from open-questions.

Discussion: The results from this survey will serve to inform decision-makers about the current views of the Australian physiotherapy profession with regards to the potential implementation of physiotherapist prescribing in Australia. Data will be used in conjunction with cost-benefit analyses, risk analysis as well as assessment of the health-requirements and consultation with key stakeholders including the Australian health consumer when contemplating change.

Keywords: Non-medical prescribing, Physiotherapy, Australia, Views, Survey, Questionnaire

Background

Australian physiotherapists have expressed an interest in non-medical prescribing (NMP) following the introduction of independent physiotherapist prescribing in the United Kingdom (UK) in 2012. Recently, the Australian Physiotherapy Association (APA) in collaboration with the Australia Physiotherapy Council (APC) and Council of Physiotherapy Deans Australia and New Zealand (CPDANZ) have commenced national processes to evaluate potential clinical need, quality and safety issues [1]. The anticipated future implementation in Australia will require physiotherapists, alongside politicians, policy makers and healthcare managers, to welcome change within national and local healthcare systems [1–4]. In July 2015, the APA submitted a proposal for the endorsement of registered physiotherapists for autonomous prescribing to the Physiotherapy Board of Australia [1]. The case for reform centred around meeting the healthcare needs of the modern Australian population. Inequity in access to medicines for people living in rural and remote Australia was recognised as a key driver for the introduction of physiotherapy prescribing. Further, it was suggested that physiotherapy prescribing may also help

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resolve health equities between Aboriginal and Torres Strait Islander peoples and other minority groups by increased access to medicines via non-medical prescribers (NMPs) in the local communities [1].

A recent mixed methods systematic review of the NMP literature evaluating the facilitators and barriers to NMP, across all professions internationally, identified four main themes affecting the implementation and utilisation of NMP: systems, education and support, personal and professional, and financial factors [5]. Analysis of the 'Personal and Professional' theme highlighted that the views and perceptions of individual clinicians' may or may not agree and/or be synergistic in nature with the overall view of the profession as a whole. This is important as potential conflict within a profession has been identified as a barrier to implementation of new clinical innervations [6]. Anecdotal evidence suggests that physiotherapists prescribing may retain Australian physiotherapists within the profession, as they would be able to optimally utilise their knowledge and skills, providing seamless patient care regardless of geographical location or health sector [1, 7]. However, survey literature investigating the views of NMP professions in the UK and USA suggests that views about NMP by the individual professional may vary depending on the individual's job specification, access to medical support, geographical location, health sector, level of experience and the timespan of the individual's career [8–12].

To date no evidence exists evaluating the Australian physiotherapy professions' views and perceptions about the potential use of NMP by physiotherapists in Australia. If the profession's views are left unknown, a potential divided opinion within the physiotherapy profession may serve as a barrier to implementation of NMP in the future. For this reason, an online survey has been developed with the aim to collect and synthesise the views of Australian physiotherapists and physiotherapy students about the potential use of NMP by physiotherapists in Australia in order to address the following research question:

What are the views of Australian physiotherapists and physiotherapy students regarding non-medical prescribing (NMP) by physiotherapists in Australia?

More specifically, this study has the following objectives:

1. To explore the views of Australian physiotherapists and physiotherapy students about the potential implementation and use of NMP by physiotherapists in Australia.

2. To explore how the geographical location and health sector that a clinician works/studies in may influence the views of Australian physiotherapists and physiotherapy students about the potential implementation and application of NMP by physiotherapists in Australia.

3. To explore similarities or differences in the views of student physiotherapists and registered physiotherapists of differing years' experience, about the potential implementation and application of NMP by physiotherapists in Australia.

4. To explore the views of Australian physiotherapists and physiotherapy students about how physiotherapy prescribing might impact the care that the physiotherapy profession can provide.

Methods/design

To ensure transparency and reproducibility this study protocol follows an adapted version of the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement [13], in line with the SUrvey Reporting GuidelinE (SURGE) guidance [14]. Unfortunately, no register currently exists for survey research. For this reason, the authors have chosen to publish the study protocol to ensure quality, rigor and transparency [15, 16].

Survey design

A cross-sectional descriptive survey design, using an online questionnaire will be utilised as this method enables the collection of a broad range of empirical data across a large geographical area in a finite time span [16, 17]. An online questionnaire will be adopted as this can be conducted remotely, enabling participants to complete the survey at a time and place convenient to them, without relying on availability of interviewers, therefore wide spread distribution of the questionnaire to physiotherapists located in all metropolitan, regional and remote areas, across all states and territories of Australia is possible [16, 18].

Participants

Participant inclusion criteria is outlined in Table 1. Data published by the Physiotherapy Board of Australia reports that 28,855 physiotherapists are currently registered with the Australian Health Professionals Registration Authority (AHPRA) [19]. Currently in Australia there are 20 Universities offering entry level physiotherapy programs with a total of approximately 7000 physiotherapy students enrolled.

Table 1 Participant inclusion criteria

- Physiotherapist registered with AHPRA or a student enrolled in an accredited, entry level physiotherapy course in Australia leading to AHPRA registration as a physiotherapist.
- Able to read and understand written English.
- Able to legally consent to participate in the survey independently.

Data collection, management and analysis

Procedure

An advertisement containing a link to the online survey will be emailed to all members of the APA on newsletters and associated clinical and professional network's electronic-communications to encourage participation in the survey. A reminder advert will be sent via email 4 weeks later to facilitate recruitment [16, 18]. Use of the APA membership as a platform for recruitment to this study has been selected as current APA membership is 20,972, representing the majority of physiotherapists and physiotherapy students in Australia [20]. Power calculations have shown a sample of n= > 1037 (95%CI) is required to be representative of the total population [15, 21]. The APA membership is representative of all physiotherapy specialties across all localities in Australia, representing physiotherapists throughout all years of post-qualification practice as well as all student physiotherapists in Australia [20]. It is anticipated that referrals through professional networks will also occur, with participants or professionals who have gained knowledge of the survey communicating the survey's existence to other registered physiotherapists and/or physiotherapy students [16, 18]. The email link will also be sent to the 20 Universities offering Australian physiotherapy programs via the Council of Physiotherapy Deans Australia and New Zealand for distribution to physiotherapy students. Data collection will take place 1st March - 30th April 2017. Data will be collected automatically by the online survey software, Qualtrics (Qualtrics, Provo, UT) to avoid human data inputting errors [22].

The questionnaire

The questionnaire was designed using evidence from a thematic synthesis of data from a mixed methods systematic review examining the barriers to and facilitator of NMP [5]. The review identified that the personal views of members of a profession utilising NMP were key to the implementation of NMP by that profession. To ensure the inclusion of the optimal questions the views, knowledge and perceptions of non-medical prescribers (NMPs) from a variety of professions internationally highlighted in the systematic review were prioritised through consultation with experts in the fields of physiotherapy, non-medical prescribing and Australian state/federal law and health policy [16, 17, 23]. The included questions were designed to specifically answer the research objectives [16, 17, 23].

The online survey was built using Qualtrics Research Suite survey software (Qualtrics, Provo, UT). This software was selected as it enables online questionnaires to be completed on a range of electronic devices, including both desktop, laptop and mobile based devices, whilst storing data in real-time [24]. Context specific questioning is utilised to limit acquiescence bias [25]. To minimise the difficulty of the survey for participants and combat potential satisficing, we have aimed to minimise duration and distractions via fluidity of design and inbuilt survey logic [26]. A short survey (5–10 min completion time) has been designed containing one question per page to maximise recruitment [22].

Questions/measures

The full questionnaire can be found in Additional file 1. In summary, the questionnaire comprises of four sections of questions consisting specifically of:

Section 1: Demographics.

This section contains 11 closed demographic questions regarding the participants age, gender, level of experience, clinical specialty and locality (reported using the Rural, Remote and Metropolitan Areas (RRMA) classification [27].

Section 2: Views about the physiotherapy profession.

The second section contains four closed-answer questions regarding the participants views about NMP by physiotherapists, giving opportunity to express opinions regarding benefits and/or concerns [5].

Section 3: Views about the individual physiotherapist.

The third section contains three closed-answer questions designed to collect data regarding the likelihood of the individual participants to train as a prescriber and their motivations/ barriers to do this should physiotherapist prescribing become a legal reality in Australia [5]. Inbuilt survey logic ensures participants are shown only those questions that are pertinent to them based on their previous answers provided.

Section 4: Wider impacts.

Section 4 contains two open-ended questions designed to gather qualitative data regarding the participants' views and perceptions about how physiotherapist prescribing might positively or negatively impact on the care that the profession can provide to all patient groups. Open questions are utilised to allow the participants to express individualised answers to complex questions without limitation [16]. The final question also allows participants to share any additional information that they deem applicable and relevant to the survey, aiming to capturing useful insight not considered elsewhere within the questionnaire [16, 17].

Pre-testing

The questionnaire was piloted by a sample of the target population ($n = 10$) to test for internal consistency [17]. The pilot participants are not excluded from completing the full questionnaire. Ten participants were purposely sampled representing the physiotherapy professional population in Australia, including key specialties and

student physiotherapists [16, 17]. The pre-testing followed the procedure for the main survey to enable the identification of potential problems with interpretation of the instructions and questions, and identification of any potential reasons for poor responses [16, 17]. Following the pre-testing, small changes were made to the survey logic to optimise the user experience, and Anglo-Australian terminology was clarified to minimise confusion due to linguistics.

Data storage

All data will be electronic and stored in password protected computer files that can be accessed only by study investigators at Macquarie University and the University of Birmingham. Participants who choose to disclose personal details will be additionally protected via coding on data files. This coding will be kept in a password protected computer file on the University of Birmingham and Macquarie University servers, only accessible to the research team ensuring confidentiality [16, 17]. The password-protected files will be retained for 10 years, satisfying policies at both the University of Birmingham and Macquarie University.

Data analysis

Only data from completed questions from fully completed questionnaires will be included in the data analysis. Demographic data will be tabulated and primary descriptive analysis of the data will be completed [16]. For the data collected from questions in sections 2 and 3, we will utilise multinomial regression for questions with a single option response and poisson regression for multiple-option questions, to determine the likelihood that health sector, geographical location, or years qualified as a physiotherapist, are associated with specific views. To ensure the transparent synthesis of data from the questions in section 4, we will use thematic analysis to identify key themes in the data [28]. Answers will be coded line-by-line using NVivo 11 software (QSR International, Melbourne, Australia) by one researcher (TN) and be verified by a second researcher (TJ). Independently generated themes/sub-themes will then be discussed with a panel of experts for confirmation and agreement [28].

Ethics and dissemination

Ethical considerations

To ensure that the survey is conducted in an ethical manner within best research practice, ethical approval was sort [16, 17]. Approval was granted on 5th December 2016, by the Medical Sciences Human Research Ethics Committee (HREC), Macquarie University, Australia (Reference No: 5201600846), and verified by the Research Governance Officer at the University of Birmingham, UK, on the 12th December 2016 (Reference No: ERN_16–1576).

Consent to participate

Completion of the survey via the link will be entirely voluntary, with no incentives offered to participants to minimise bias [16, 23]. Participant consent will be gained using an online consent form following the provision of information explaining the rationale, content and research dissemination plans to ensure ethical recruitment of participants (the online information and consent for can be found in Additional file 2) [16, 17]. This information and consent section is situated at the start of the online questionnaire. A response to the online consent question will be required before participants can progress to the study questions. Any participants who select the 'no consent' option will automatically exit the questionnaire. Contact details for the research team will be provided to give the participants the opportunity to have any questions they have answered [16, 23]. Participants will be able to stop completing the survey at any point [16, 17]. All surveys will be anonymous unless personal information is disclosed by the participants [17].

Dissemination of findings

The study's findings will be disseminated via study reports, publication in academic peer-reviewed journals and conference presentations [16]. The results will be communicated to participants on request as a summary report written in lay language including key findings and plans for future research.

Discussion

The results from this survey will serve to inform decision-makers about the current views of the Australian physiotherapy profession with regards to the potential implementation of physiotherapist prescribing in Australia. Evidence is required by the physiotherapy professional association, health departments and political leaders to inform clinically safe and economically sound decisions about redefining the scope of physiotherapy in Australia to include NMP. Innovation in professional scope requiring the amendment of legislation and regulation is costly and time consuming [1–4]. Change is seen to be facilitated by a benefit to the health economy and improvements in health care to service users [1, 4]. Resistance to change within the profession is reported as a barrier to implementation of new clinical innovations [5]. The results of this study should be used in conjunction with cost-benefit analyses, risk analysis as well as assessment of the health-requirements and consultation with key stakeholders including the Australian health consumer when contemplating change. It is anticipated that observations identified from the data may inform

further research. Future focus groups and interviews with physiotherapist and other stakeholders may be utilised to investigate specific observations of interest in detail, enhancing data richness [16, 29].

Additional files

Additional file 1: Online Questionnaire. (DOCX 19 kb)
Additional file 2: Online Information and Consent Form. (DOCX 16 kb)

Abbreviations

AHPRA: Australian Health Professionals Registration Authority; APA: Australian Physiotherapy Association; APC: Australia Physiotherapy Council; CPDANZ: Council of Physiotherapy Deans Australia and New Zealand; HREC: Human Research Ethics Committee; NMP: Non-medical prescribing; NMPs: Non-medical prescribers; RRMA: Rural, Remote and Metropolitan Areas classification; UK: United Kingdom

Authors' contributions

TN is a clinical consultant/advanced practice physiotherapist and PhD candidate at the University of Birmingham (UK). AR is a senior lecturer in physiotherapy with a professional focus to musculoskeletal physiotherapy and lead supervisor. JM is a professor of clinical pharmacy and co-supervisor. Both supervisors ensured the rigour of methods and analyses. CD is a professor of physiotherapy and TJ is a lecturer in physiotherapy at Macquarie University (Aus). All authors have contributed to the content of this article. TN wrote the first draft of this article and has worked with all authors to develop subsequent drafts. All authors prior to publication gave final approval.

Ethics approval and consent to participate

This survey is approved by the Medical Sciences Human Research Ethics Committee (HREC), Macquarie University, Australia (Reference Nos 5201600846), and University of Birmingham, UK (Reference No: ERN_16–1576). Completion of the survey via the link will be entirely voluntary, with no incentives offered to participants to minimise bias. Participant consent will be gained using an online consent form following the provision of information explaining the rationale, content and research dissemination plans to ensure ethical recruitment of participants.

Consent for publication

Not applicable.

Competing interests

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare that they have no competing interests: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Publisher's Note

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8.14 Appendix 14: Online Questionnaire

Q1 What is your gender?

- ❍ Male (1)
- ❍ Female (2)
- ❍ Other (3)

Q2 What is your age?

- ❍ 17-29 (1)
- ❍ 30-39 (2)
- ❍ 40-49 (3)
- ❍ 50-59 (4)
- ❍ 60 or older (5)

Q3 Which of the following are you?

- ❍ AHPRA registered physiotherapist (1)
- ❍ Student physiotherapist enrolled in an Australian university (2)

If Student physiotherapist enr... Is Selected, Then Skip To Which state or territory do you curre...

Q4 How many years have you been a qualified physiotherapist?

- ❍ 0-4 (1)
- ❍ 5-9 (2)
- ❍ 10-14 (3)
- ❍ 15-19 (4)
- ❍ 20 or more (5)

Q5 Where did you obtain your primary physiotherapy qualification?

- ❍ Australia (1)
- ❍ Overseas (please specify) (2) _____

Q6 Which state or territory do you currently work? If multiple, select the state or territory that you spent the most time working in over the past 14 days.

- ❍ Australian Capital Territory (1)
- ❍ New South Wales (2)
- ❍ Northern Territory (3)
- ❍ Queensland (4)
- ❍ South Australia (5)
- ❍ Tasmania (6)
- ❍ Victoria (7)
- ❍ Western Australia (8)

Q7 Do you work in a metropolitan or rural area? Please choose the most appropriate option. If you work in multiple areas, select the area in which you spent the most hours working in the past 14 days. If you are unsure, you can check your areas classification using the following website: http://www.doctorconnect.gov.au/internet/otd/publishing.nsf/Content/locator

- ❍ RA1 - Major Cities of Australia (1)
- ❍ RA2 - Inner Regional Australia (2)
- ❍ RA3 - Outer Regional Australia (3)
- ❍ RA4 - Remote Australia (4)
- ❍ RA5 - Very Remote (5)

Q8 In which health sector do you spend most of your time working as a physiotherapist?

- ❍ Public sector (1)
- ❍ Private sector (2)
- ❍ Educational/research institute or university (3)
- ❍ Not-for-profit organisation (4)
- ❍ Other (please specify) (5) _____

Q9 What area/s of physiotherapy do you predominantly work in or identify with? Please select up to a maximum of three (3) areas.

- ❑ Amputees (1)
- ❑ Burns/plastics (2)
- ❑ Cardiorespiratory/acute medicine/surgery (3)
- ❑ Chronic disease management (4)
- ❑ Education (5)
- ❑ Emergency department (6)
- ❑ Gerontology/Aged care (7)
- ❑ Health promotion/Public health (8)
- ❑ Lymphoedema (9)
- ❑ Mental health (10)
- ❑ Musculoskeletal/orthopaedics (11)
- ❑ Neurology (12)
- ❑ Occupational health (13)
- ❑ Paediatrics (14)
- ❑ Pain (15)
- ❑ Palliative care (16)
- ❑ Rehabilitation (mixed) (22)
- ❑ Rheumatology (17)
- ❑ Rural generalist (18)
- ❑ Sports (21)
- ❑ Women's health/continence (19)
- ❑ Veterinary (20)

Display This Question:

If Which of the following are you? Student physiotherapist enrolled in an Australian university Is Selected

Q10 Which state or territory do you currently attend university?

- ❍ Australian Capital Territory (1)
- ❍ New South Wales (2)
- ❍ Northern Territory (3)
- ❍ Queensland (4)
- ❍ South Australia (5)
- ❍ Tasmania (6)
- ❍ Victoria (7)
- ❍ Western Australia (8)

Q11 Autonomous prescribing: "Prescribing occurs where a prescriber undertakes prescribing within their scope of practice without the approval or supervision of another health professional. The prescriber has been educated and authorised to autonomously prescribe in a specific area of clinical practice. Although the prescriber may prescribe autonomously, they recognise the role of all members of the health care team and ensure appropriate communication occurs between

team members and the person taking medicine". The Health Professionals Prescribing Pathway (HPPP), p16 (2013) To what extent do you agree with the following statement: "I believe that autonomous prescribing responsibilities should be introduced for physiotherapists in Australia."

- ❍ Strongly agree (1)
- ❍ Agree (2)
- ❍ Neither agree nor disagree (3)
- ❍ Disagree (4)
- ❍ Strongly disagree (5)

Q12 What do you see the benefits of physiotherapists prescribing medicines to be? Select as many options as are appropriate to you.

- ❑ Improved efficiency of service delivery (1)
- ❑ Reduced costs of health care delivery to the consumer (2)
- ❑ Improved consumer experience (3)
- ❑ Reduction in the overall costs of healthcare to the Australian economy (4)
- ❑ Improved retention of clinicians within the physiotherapy profession (5)
- ❑ Potential for enhanced remuneration (6)
- ❑ Reduced safety risks to consumers (7)
- ❑ Improved access for consumers to prescription medications (8)
- ❑ Future proofing the Australian healthcare system with a flexible workforce (9)
- ❑ Other (please specify) (10) _____
- ❑ I do not believe there would be any benefits (11)

Q13 What are your concerns about the prescription of medicines by physiotherapists? Select as many options as are appropriate to you.

- ❑ Prescribing of medicines is not a physiotherapists' role (1)
- ❑ Physiotherapists do not have adequate pre-requisite knowledge to undertake a prescribing course (2)
- ❑ There is no need for physiotherapists to prescribe medicines (3)
- ❑ Physiotherapist prescribing will create a two (2) tier profession (4)
- ❑ Physiotherapist prescribing will increase safety risks to consumers (5)
- ❑ Remuneration does not match the responsibility associated with the prescribing of medicines (6)
- ❑ Other (please specify) (7) _____
- ❑ I do not have any concerns (8)

Q14 How many years experience do you think a physiotherapist should have prior to being able to train as a physiotherapist prescriber?

- ❍ 0 - Should be included in pre-registration physiotherapy qualification (1)
- ❍ 1-2 years (2)
- ❍ 3-5 years (3)
- ❍ 6-9 years (4)
- ❍ 10 or more years (5)
- ❍ Physiotherapists should not be able to train as prescribers (6)

Q15 If physiotherapists became able to autonomously prescribe medicines, how likely are you to want to train to become a prescriber?

- ❍ Extremely likely (1)
- ❍ Somewhat likely (2)
- ❍ Neither likely nor unlikely (3)
- ❍ Somewhat unlikely (4)
- ❍ Extremely unlikely (5)

Display This Question:

If If physiotherapists became able to autonomously prescribe medicines, how likely are you to want t... Extremely likely Is Selected

Or If physiotherapists became able to autonomously prescribe medicines, how likely are you to want t... Somewhat likely Is Selected

Or If physiotherapists became able to autonomously prescribe medicines, how likely are you to want t... Neither likely nor unlikely Is Selected

Q16 What are your key motivations to becoming a prescriber?Select as many options as are appropriate to you.

- ❑ Improving the care I am able to provide (1)
- ❑ Improved job satisfaction (2)
- ❑ Increased remuneration (3)
- ❑ Improved professional reputation (4)
- ❑ Other (please specify) (5) _____

Display This Question:

If If physiotherapists became able to autonomously prescribe medicines, how likely are you to want t... Extremely unlikely Is Selected

Or If physiotherapists became able to autonomously prescribe medicines, how likely are you to want t... Somewhat unlikely Is Selected

Or If physiotherapists became able to autonomously prescribe medicines, how likely are you to want t... Neither likely nor unlikely Is Selected

Q17 What makes you unlikely to want to train as a prescriber? Select as many options as are appropriate to you.

- ❑ I do not believe that physiotherapists should prescribe medicines (1)
- ❑ I do not think that I have the knowledge required to train as a prescriber (2)
- ❑ I do not wish to complete additional training (3)
- ❑ I am not prepared to take on the additional responsibility associated with prescribing medicines (4)
- ❑ In my current role, being able to prescribe would not change the care provided (5)
- ❑ A prescriber is readily available to the clients that I provide care for (6)
- ❑ I work in a non-clinical role (7)
- ❑ Other (please specify) (8) _____

Q18 Do you have any additional thoughts about how physiotherapist prescribing may impact the care that the profession is able to provide? For example, a positive or negative impact on a specific group e.g. minority groups, immigrants, students, travellers.....

Q19 Is there any additional information you would like to share at this time?

8.15 Appendix 15: Ethics approval

MQ Health Research
Unit 75 Talavera Road
Level 1
Macquarie University
NSW 2109 Australia
T:
http://www.research.mq.edu.au/research_ethics ABN 90 952 801 237
CRICOS Provider No 00002J

5 December 2016

Dear Tim

Reference No: 5201600846

Title: Physiotherapy NMP survey

Thank you for your recent correspondence. Your response has addressed the issues raised by the Faculty of Medicine and Health Sciences Low-risk Ethics Subcommittee. Approval of the above titled application has been granted, **effective 5 December 2016** you may now commence your research.
This research meets the requirements set out in the *National Statement on Ethical Conduct in Human Research*
(2007 – Updated May 2015) (the *National Statement*).

Standard Conditions of Approval:

Continuing compliance with the requirements of the *National Statement,* which is available at the following website: http://www.nhmrc.gov.au/book/national-statement-ethical-conduct-human-research

This approval is valid for five (5) years, subject to the submission of annual reports. Please submit your reports on the anniversary of the approval for this protocol.
Progress Report 1 Due: 5 December 2017
Progress Report 2 Due: 5 December 2018
Progress Report 3 Due: 5 December 2019
Progress Report 4 Due: 5 December 2020
Final Report Due: 5 December 2021

Progress reports and Final Reports are available at the following website:
http://www.research.mq.edu.au/current_research_staff/human_research_ethics/application_resources
NB. If you complete the work earlier than planned, you must submit a Final Report as soon as the work is completed. If the project has been discontinued or has not commenced for any reason, you are also required to submit a Final Report for the project.

All adverse events, including unforeseen events, which might affect the continued ethical and scientific acceptability of the project, must be reported to the subcommittee within 72 hours.

All proposed changes to the project and associated documents must be submitted to the subcommittee for review and approval before implementation. Please complete and submit a Request for Amendment Form available at the following website:

http://www.research.mq.edu.au/current_research_staff/human_research_ethics/application_resources

At all times you are responsible for the ethical conduct of your research in accordance with the guidelines established by the University. This information is available at the following websites:

http://www.mq.edu.au/policy/

http://www.research.mq.edu.au/for/researchers/how_to_obtain_ethics_approval/human_research_ethics/policy

The HREC Terms of Reference and Standard Operating Procedures are available from the Research Office website:

http://www.research.mq.edu.au/for/researchers/how_to_obtain_ethics_approval/human_research_ethics

It is the responsibility of the Chief investigator to retain a copy of all documentation related to this project and to forward a copy of this approval letter to all personnel listed on the project.

Should you have any queries regarding your project, please contact Health Sciences Centre Ethics Support by phone: or email:

The FMHS Low-risk Ethics Subcommittee wishes you every success in your research. Yours sincerely

Dr Mark Butlin

Deputy Chair, Faculty of Medicine and Health Sciences Low-risk Ethics Subcommittee
Lecturer, Department of Biomedical Sciences

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research* (2007) and the *CPMP/ICH Note for Guidance on Good Clinical Practice*.

Approval Date: 5 December 2016
The following documentation has been reviewed and approved by the FMHS Low-risk Ethics Subcommittee

Documents reviewed	Version no.	Date
Macquarie University Ethics Application Form	*[Version no 1] [07/11/16]*	07.11.16
Correspondence responding to the issues raised by the FMHS Low-risk Ethics Subcommittee	*[Version no 1] [28/11/16]*	01.12.16
MQ Participant Information and Consent Form (PICF), Information Sheet, Participant Survey (Qualtrics)	*[Version no 2] [01/12/16]*	01.12.16
Participant recruitment advertisement	*[Version no 2] [01/12/16]*	01.12.16

***If the document has no version date listed one will be created for you. Please ensure the footer of these documents are updated to include this version date to ensure ongoing version control.**

From: Jane Mitchell
Sent: 12 December 2016 12:11
To: Alison Rushton
Subject: Ethics Self-Assessment Confirmation

Dear Alison Rushton,

Thank you for submitting a University Ethics Self-Assessment Form (SAF) for your project entitled:

Physiotherapy Non-Medical Prescribing survey

This was received and logged by the Research Support Group and has been assigned reference number **ERN_16-1576**. On the basis of the SAF you have submitted **no further ethical review is required.**

If you disagree with the assessment above (e.g. you have already submitted the required ethics applications, or your project falls under an existing ethical approval), or if the nature of your project changes during its course, please contact the Research Ethics Officer, Mrs Susan Cottam, at

Please quote this reference number in any subsequent correspondence regarding any ethical review of this project, or to the Research Governance Officer in the event that the project is subject to review by the NHS National Research Ethics Service. You should also quote this reference number on a Request for Contract Services form if you require RSG to prepare or review any contracts arising from this project.

You may also quote this reference number to Research Finance staff as proof of ethical submission in respect of any grant or contract relating to this project.

Please note that the reference number relates to **this project ONLY**, and should not be transferred to any other project, nor should any further SAF be submitted for this project.

RSG Research Ethics Team

8.16 Appendix 16: Online Information and Consent Form

Non-medical prescribing by physiotherapists in Australia

Thank you for taking the time to visit this site. This page provides detailed information about this survey. Please take the time to read this information carefully.

What does the survey aim to do?

We are interested in the thoughts and beliefs of Australian physiotherapists and physiotherapy students regarding about the potential use of non-medical prescribing by physiotherapists in Australia.

(NB, non-medical prescribing is the prescribing of medicines by professionals other than medical doctors)

What is involved?

If you decide to participate, you will be asked to complete a brief survey that will involve answering questions regarding your thoughts and beliefs regarding non-medical prescribing by physiotherapists in Australia. We estimate that this survey will take approximately 5-10 minutes.

Who can participate in this survey?

Anyone who is 17 years and over, and who is a registered physiotherapist with the Australian Health Practitioner Regulation Agency (AHPRA), or is a student studying physiotherapy at an Australian university is eligible to participate in this survey.

Are there any risks?

There are no anticipated risks associated with undertaking this survey. Participation in this study is entirely voluntary. You are not obliged to participate in or to complete this survey.

What about privacy and confidentiality?

Participants will remain anonymous at all times during this survey. Basic demographic details will be collected but this will not be of a nature as to allow for identification. All data will be stored in password protected computer files that can be accessed only by study

investigators at Macquarie University. Any data generated from this survey used in future research studies will only be done so in non-identifiable form.

Who is conducting this survey?

This study is being carried out by physiotherapist, Tim Noblet, as part of a larger body of research being conducted to meet the requirements of Doctor of Philosophy in Physiotherapy. Tim is working with Dr Taryn Jones and Professor Catherine Dean from Macquarie University, as well as Dr Alison Rushton and Professor John Marriott from the University of Birmingham, UK.

The ethical aspects of this study have been approved by the Macquarie University Human Research Ethics Committee. If you have any complaints or reservations about any ethical aspect of your participation in this research, you may contact the Committee through the Director, Research Ethics (Ph: ; email:).

Can I contact the researchers?

The researchers can be contacted by email on or by phone on .

Am I able to obtain a summary of the study results?

Yes, a short summary of the overall study results will be available once the study has been completed. Should you be interested in obtaining a copy of this summary please email Tim Noblet on

What do I do now?

If you have read and understood the above information and would like to participate in the survey, please select "yes" below knowing you can withdraw from the survey at any stage. Should you not wish to participate further, you can select "no" and we thank you for your time.

- ❍ Yes, I have read and understood the information provided to me and would like to participate in the survey. (1)
- ❍ No, I would prefer to not participate in this survey. (2)

If No, I would prefer to not p... Is Selected, Then Skip To End of Survey

8.17 Appendix 17: Article, BMJ Open, perceptions about the implementation of physiotherapist prescribing in Australia: a national survey of Australian physiotherapists

Noblet T, Marriott J, Jones T, Dean C, Rushton A. Perceptions about the implementation of physiotherapist prescribing in Australia: a national survey of Australian physiotherapists. BMJ open 2019;9(5): e024991

BMJ Open

Perceptions about the implementation of physiotherapist prescribing in Australia: a national survey of Australian physiotherapists

Timothy David Noblet,[1,2] John F Marriott,[1] Taryn Jones,[3] Catherine Dean,[4] Alison B Rushton[5]

To cite: Noblet TD, Marriott JF, Jones T, *et al*. Perceptions about the implementation of physiotherapist prescribing in Australia: a national survey of Australian physiotherapists. *BMJ Open* 2019;**9**:e024991. doi:10.1136/bmjopen-2018-024991

► Prepublication history and additional material for this paper are available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2018-024991).

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ABSTRACT

Objectives To explore: (1) the views of Australian physiotherapists regarding potential implementation of non-medical prescribing in Australia, (2) how the geographical location and health sector in which a clinician works may influence their perceptions and (3) the perceptions of Australian physiotherapists about how physiotherapist prescribing might impact the care that the profession can provide.

Design A cross-sectional descriptive survey using open and closed questions.

Setting Participants completed an online questionnaire.

Participants 883 Australian Health Professionals Registration Authority (AHPRA)-registered physiotherapists, working across all states and territories.

Outcome measures An online questionnaire was developed by a panel of subject experts and pretested (n=10) for internal consistency. A hyperlink to the questionnaire was emailed to all members of the Australian Physiotherapy Association. A reminder email was sent 4 weeks later. Quantitative data were analysed descriptively, with use of absolute risk reductions (ARRs) and 95% CIs to determine the likelihood that health sector or geographical location were associated with specific views. Thematic analysis enabled synthesis of the qualitative data.

Results 79.0% participants felt that physiotherapist prescribing should be introduced in Australia, with 71.2% wanting to train as prescribers. Clinical governance, risk management, regulation of clinicians and the development of an education framework were identified as priorities for implementation. Participants working in the private sector were significantly more likely to train as prescribers than those in the public sector (ARR 9.9%; 95% CI 3.5 to 16.4) or educational/research institutions (ARR 23.3%; 95% CI 12.8 to 33.8), with city dwellers significantly more likely to train compared with physiotherapists in remote regions (ARR 19.8%; 95% CI 0.8 to 39.2). Physiotherapist prescribing was predicted to improve efficiency of healthcare delivery, access to medicines and reductions in healthcare costs.

Conclusions AHPRA-registered physiotherapists perceive that the introduction of autonomous physiotherapist prescribing would be beneficial for the Australian population and should be introduced. Decision makers should consider the results of this survey in conjunction with cost–benefit and risk analysis when planning the introduction of physiotherapist prescribing.

Strengths and limitations of this study

- First rigorous survey investigating the perceptions of Australian physiotherapists about the potential implementation of physiotherapist prescribing in Australia.
- Results provide the evidence required by the physiotherapy professional association, health departments and political leaders to inform clinically safe and economically sound decisions about redefining the scope of physiotherapy in Australia to include non-medical prescribing.
- Limitations are inherent with all survey-based research due to selection and response bias.
- It was not possible to determine why non-responders did not participate.

BACKGROUND AND RATIONALE

Non-medical prescribing (NMP) has been used in clinical practice by a variety of professions for over 20 years.[1] However, it was not until 2012 that in the UK, physiotherapists were first granted independent prescribing responsibilities. In July 2015, the Australian Physiotherapy Association (APA) in collaboration with the Australia Physiotherapy Council and Council of Physiotherapy Deans Australia and New Zealand submitted a proposal for the endorsement of registered physiotherapists for autonomous prescribing to the Physiotherapy Board of Australia.[2] To prescribe medicines autonomously, a practitioner must be responsible for the assessment and diagnosis of the patient, prescribing drugs from a specified formulary within their individual scope of practice. The clinician manages ongoing therapy without the requirement of protocols or supervision.[3] Difficulties in accessing medicines for Australians living in

rural and remote areas alongside recognised health inequities between minority groups such as Aboriginal and Torres Strait Islander peoples were cited as key drivers for reform. Benefits of the implementation of prescribing by physiotherapists in Australia, such as the potential to increase access to medicines for health service users across all communities,[2] are therefore anticipated.

The clinical and cost-effectiveness of NMP remains unclear, with a recent systematic review finding only minimal empirical evidence with unknown risk of bias[4]; nonetheless, its popularity in clinical practice continues to grow.[5] A contemporary and robust mixed-methods systematic review of 50 moderate to good quality studies, investigating the barriers to and facilitators of independent NMP, identified conflict within a profession as a key barrier to successful implementation.[5] A united professional position regarding the adoption of innovative clinical practice was highlighted as essential to ensure the development of safe and high-quality practice. Divided opinion between individual clinicians, academics and professional managers/leaders may lead to confusion across the healthcare community, resulting in unwarranted negative thoughts and perceptions about NMP roles and responsibilities. Diverse perceptions regarding the implementation of physiotherapist prescribing and current physiotherapeutic pharmacological knowledge and practices have been reported in national evaluations in Nigeria, South Africa and the UK.[6–9] Data from these evaluations have been used to influence national policy and the political drive towards or against the adoption of NMP within the physiotherapy profession in these countries.[8 9] Acceptance and support for prescribing by the Australian physiotherapy profession will be required for successful implementation into local and national health systems.[2 10–12] It is therefore important that the views of Australian physiotherapists are understood in order to inform key stakeholders and decision makers about redefining the scope of physiotherapy to include NMP in Australia. To date, no evidence exists evaluating the Australian physiotherapy professions' views and perceptions about the potential use of NMP by physiotherapists in Australia.

OBJECTIVES

1. To explore the views of Australian physiotherapists about the potential implementation and use of NMP by physiotherapists in Australia.
2. To explore how the geographical location and health sector in which a clinician's works may influence the perceptions of Australian physiotherapists about the potential implementation and application of NMP by physiotherapists in Australia.
3. To explore the perceptions of Australian physiotherapists about how physiotherapist prescribing might impact the care that the physiotherapy profession can provide.

Box 1 Participant inclusion criteria

- Physiotherapists registered with Australian Health Professionals Registration Authority.
- Ability to read and understand written English.
- Provision of consent to participate in the survey independently.

METHODS

A detailed study protocol was published to ensure transparency and reproducibility.[13] The study is reported in line with an adapted version of the Standard Protocol Items: Recommendations for Interventional Trials statement,[14] recommended by the SUrvey Reporting GuidelinE.[15] This article reports the data collected from registered physiotherapists from a larger study evaluating both registered and student physiotherapists in Australia.[13] The data collected evaluating the views and perceptions of student physiotherapists about the implementation of physiotherapist prescribing in Australia are presented in the related article published independently.[16]

Survey design

A cross-sectional online descriptive survey design enabled the collection of empirical data across Australia.[17–19] An online questionnaire was developed using Qualtrics (Qualtrics, Provo, Utah, USA), thus enabling Australian-wide participation with no geographical or time zone constraints.[17 20]

Participants

Participant inclusion criteria are described in box 1. According to data published by the Physiotherapy Board of Australia, 30 004 physiotherapists were registered with the Australian Health Professionals Registration Authority (AHPRA) at the time of the survey.[21]

Procedure

AHPRA privacy policy[22] prohibits approaching AHPRA-registered physiotherapists directly. Therefore, an advertisement containing a link to the online survey was emailed to all members of the APA, including all clinical and professional networks. A reminder advertisement was sent via email 4 weeks after the initial email to promote participation in the survey.[17 19 20] IP addresses were not saved to ensure participant anonymity. The APA membership was selected as the recruitment platform as it is representative of all physiotherapy specialties and levels of experience (qualified and student physiotherapists) across Australia, with 23 153 members at the time of survey.[23] Word-of-mouth referrals to the survey through professional networks were promoted in the email to facilitate capturing the views of non-APA members.[17 19 20] Data collection took place 1 March–30 April 2017. Participants accessed the questionnaire via the online link. Completion of the survey was anonymous and entirely voluntary.[17 19 20] Participant consent was gained using an online information and consent form.[17–19] Researcher contact details were supplied to enable any questions or

concerns to be answered prior to completing the online questionnaire.[17–19]

Questionnaire development

Data from a mixed methods systematic review examining the barriers to and facilitators of NMP internationally informed the questionnaire design and specific question inclusion.[5] Questions were optimised through consultation with experts in the fields of physiotherapy, NMP and Australian state/federal law and health policy.[17–19]

The questionnaire consisted of four sections:

1. Demographic information including participants' age/gender/number of years qualified/specialty/location.
2. Participants' perceptions of the positive and/or negative aspects of physiotherapist prescribing to the profession as a whole.
3. Participants' perceptions of the impact of physiotherapist prescribing to them as an individual.
4. Participants' perceptions regarding the potential wider impacts of physiotherapist prescribing.

Sections 1–3 used closed questions to collect quantitative data. Section 4 contained two open-ended questions to allow the participants to answer without limitation.[17 19] In-built survey logic ensured that participants were shown questions that were pertinent to them based on their previous answers. Before completion, participants were encouraged to share any additional information that they deemed relevant, capturing useful insights not addressed elsewhere in the questionnaire.[17–19]

The questionnaire was piloted to test for internal consistency and optimise user experience.[18] Ten participants (n=7 registered physiotherapists, n=3 student physiotherapists) were purposely sampled to represent the physiotherapy profession in Australia.[17–19] Following the pilot, Anglo-Australian terminology was clarified, and small changes were made to the linguistics and survey logic. Pilot participants were not excluded from completing the final questionnaire. The final questionnaire can be found in online supplementary file 1.

Data storage

All electronic data were stored in password-protected computer files only accessible by study investigators. Participants who disclosed personal details were additionally protected via coding on data files.[17–19] The password-protected files will be retained for 10 years, satisfying ethical and university policies.

Data analysis

Demographic data (section 1) were tabulated, and primary descriptive analysis of the data was completed using IBM SPSS Statistics for Macintosh, V.22.0. Comparisons of proportions from questions in sections 2 and 3, addressing objectives 1 and 2, were conducted using the PEDro CI calculator (http://www.pedro.org.au).[24 25] Calculations of absolute risk reductions (ARRs) with 95% CIs were used to determine the likelihood that health sector or geographical location were associated with specific views.[25] Thematic analysis was used to ensure the transparent synthesis of data addressing objective 3, collected in section 4 of the online questionnaire. This analysis enabled the identification of key themes within a structured analytical framework.[26] Answers were coded line-by-line using NVivo 11 software (QSR International, Melbourne, Australia) by one researcher (TDN) and were verified by a second researcher (TJ). Independently generated themes/subthemes were then examined by a panel of experts for confirmation and agreement.[26]

Patient and public involvement

The development of this study was informed by the experiences of patients and the general public acknowledged in the literature. Due to the study's objectives, patients and the general public were not used in design of the study or in participant recruitment. The results will be disseminated to all interested parties through publication and presentation at professional conferences.

RESULTS

Demographics

A total of 883 participants (3% of all AHPRA-registered physiotherapists) completed the questionnaire. Demographic data are presented in table 1. Fifty-eight per cent of participants had been qualified for more than 10 years, with the majority of participants (88.4%) gaining their primary professional qualification in Australia. The largest proportion of participants (n=536, 61%) identified musculoskeletal physiotherapy as their specialty area of practice. Of those working clinically, 52% of participants worked in the private health sector. There were participants from every state and territory, with the majority practising in New South Wales (n=299, 34%), Victoria (n=234, 27%), Western Australia (n=130, 15%) or Queensland (n=115, 13%). Seventy-eight per cent of participants worked in a major city.

Participants' perceptions about the impact of physiotherapist prescribing on the physiotherapy profession

Six hundred and eighty participants (79%) reported that they strongly agreed or agreed that autonomous prescribing responsibilities should be introduced for physiotherapists in Australia, with 144 participants (12%) against the introduction (figure 1). Potential benefits and concerns were identified.

The participants reported that physiotherapist prescribing could have a range of benefits in the Australian healthcare system (figure 1). The most commonly identified benefit was an improvement in the delivery of health services (80.1%; n=707). Reduced costs of healthcare delivery to the consumer, as well as a reduction in the overall cost of healthcare and an improved consumer experience were also identified as potential benefits of NMP in Australia. Participants' concerns about the prescription of medicines by physiotherapists centred on quality and safety

Table 1 Demographic data

	AHPRA-registered physiotherapists n (%)
Total participants	883 (100)
Gender (n=883 answered)	
Male	366 (41.4)
Female	517 (58.6)
Age (n=883 answered) (years)	
17–29	258 (29.2)
30–39	260 (29.4)
40–49	173 (19.6)
50–59	124 (14.0)
60+	68 (7.7)
Number of years qualified as a physiotherapist (n=883 answered)	
0–4	192 (21.7)
5–9	178 (20.1)
10–14	109 (12.4)
15–19	101 (11.5)
20+	303 (34.3)
Country of primary qualification (n=883 answered)	
Australia	781 (88.4)
Overseas (Belgium, Canada, Germany, Hong Kong, India, Ireland, Italy, Mexico, Netherlands, New Zealand, Philippines, Portugal, Serbia, Singapore, South Africa, Taiwan, UK and USA)	102 (11.6)
Predominant physiotherapy practice specialties: (max of 3 specialties identified per participant, n=865 answered)	
Amputees	10 (1.1)
Burns/plastics	9 (1.0)
Cardiorespiratory	132 (14.9)
Chronic disease management	100 (11.3)
Education	58 (6.6)
Emergency department	65 (7.4)
Gerontology/aged care	115 (13.0)
Health promotion/public health	10 (1.1)
Lymphoedema	11 (1.2)
Mental health	4 (0.5)
Musculoskeletal/orthopaedics	536 (60.7)
Neurology	81 (9.2)
Occupational health	21 (2.4)
Paediatrics	37 (4.2)
Pain	105 (11.9)
Palliative care	6 (0.7)
Rheumatology	10 (1.1)
Rural generalist	39 (4.4)
Women's health/continence	53 (6.0)
Veterinary	2 (0.2)
Health sector (n=872 answered)	
Public sector	325 (37.3)
Private sector	449 (51.5)
Educational/research institute or university	49 (5.6)
Not-for-profit organisation	36 (4.1)
Other	13 (1.5)
Rural, Remote and Metropolitan Areas classification[39] (n=783 answered)	
Major cities of Australia	679 (77.8)
Inner regional Australia	113 (12.9)
Regional Australia	58 (6.6)
Remote Australia	20 (2.3)
Very remote Australia	3 (0.3)
State or territory (n=879 answered)	
Australian Capital Territory	19 (2.2)
New South Wales	299 (34.0)
Northern Territory	7 (0.8)
Queensland	115 (13.1)
South Australia	64 (7.3)
Tasmania	11 (1.3)
Victoria	234 (26.6)
Western Australia	130 (14.8)

issues. In particular, concerns about whether physiotherapists have the knowledge required to train as a prescriber (34.8%) and a potential increased safety risk to consumers (34.1%) were raised. One-third of participants (33.1%) were concerned that the expected remuneration for this service would not reflect the increased professional risk.

Figure 2 illustrates participants' opinions about the number of years of experience a physiotherapist should have prior to being permitted to train as a prescriber. The majority of participants felt that physiotherapists should have 3 years or more of experience (68.4%), with 34.6% believing this should be at least 6 years.

Participants' perceptions about the impact of physiotherapist prescribing to them as an individual

Six hundred and eight participants (71.2%) would be extremely likely (n=397, 47%) or somewhat likely (n=211,

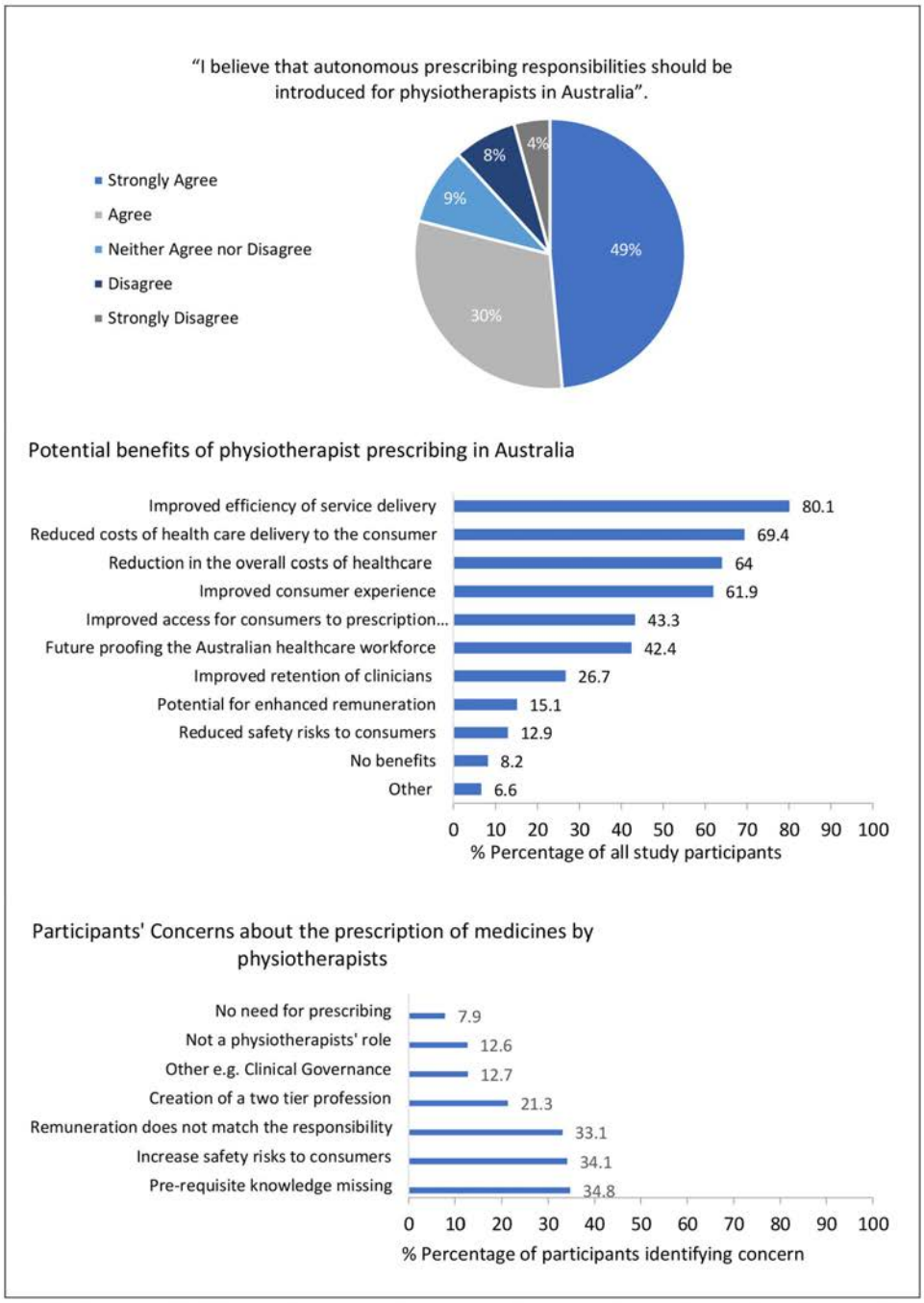

Figure 1 Physiotherapists' belief as to whether physiotherapist prescribing should be introduced in Australia; potential benefits and participants' concerns.

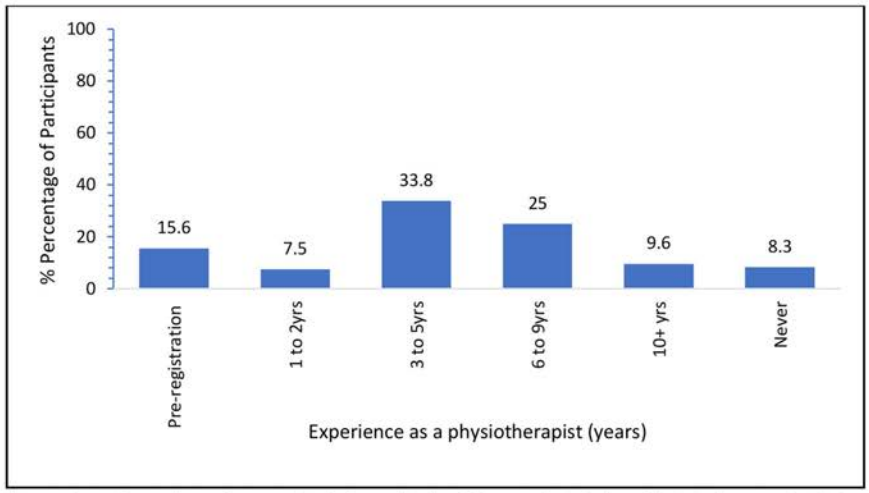

Figure 2 The number of years' experience a physiotherapist should have prior to being able to train as a physiotherapist prescriber.

25%) to train as a prescriber if this were permitted, while 174 participants (20.3%) would not. Figure 3 outlines the key motivators and deterrents among participants to train as a prescriber.

Key motivators cited included the ability to provide improved quality of care (n=646, 96.0%) and the improved professional reputation associated with NMP (n=416, 61.8%). Some participants included increased job satisfaction (n=303, 45.0%) and remuneration (n=125, 18.6%) as motivating factors. Additionally, some participants (n=72, 10.7%) reported being motivated by potential clinical and cost efficiencies for both for the consumer and healthcare provider through enhanced clinical pathways, improved access to medicines and optimisation of clinical knowledge.

The most common deterrent for training to be a prescriber was the belief that this will not change the care that the individual physiotherapist would provide to their patients (n=152, 61.8%). Concerns around an increased level of clinical responsibility were also highlighted as potential deterrents (n=108, 43.9%). Some participants felt that they did not have sufficient background knowledge to undertake the prescribing course (n=76, 30.9%). Additionally, participants reported that the cost of training or distance to travel to universities would be too great or that they were nearing retirement and did not want the additional stress of training to become a prescriber. Furthermore, it is noted that a small number of participants reported that they would not train as prescribers as they are employed in non-clinical roles (n=35, 14.2%).

Influence of health sector and geographical location

The percentage of participants from different health sectors and geographical locations, who agreed or strongly agreed with autonomous prescribing responsibilities being introduced for Australian physiotherapists and those who stated that they were extremely likely or somewhat likely to want to train as a prescriber are summarised in table 2.

Participants working in the private sector were significantly more likely to agree that autonomous prescribing responsibilities should be introduced for physiotherapist in Australia than those who work in education, not-for-profit organisations and the military (ARR 9.8%, 95% CI 0.8 to 20.2). No significant difference (ARR 1.7%; 95% CI −4.0 to 7.6) was seen between participants who worked in the private or public healthcare sectors. Participants working in the private sector were significantly more likely to train as prescribers than those working in the public sector (ARR 9.9%; 95% CI 3.5 to 16.4) or other areas, such as within educational or research institutions (ARR 23.3%; 95% CI 12.8 to 33.8). A significantly higher proportion of participants in city regions expressed a wish to train as a prescriber compared with those in remote regions (ARR 19.8%; 95% CI 0.8 to 39.2). Those practising in cities (ARR 24.0%, 95% CI 5.8 to 43.9) and regional areas (ARR 19.5%, 95% CI 0.4 to 40.1) were significantly more likely to agree with the introduction of physiotherapist prescribing than those from remote regions. However, there was no significant difference (ARR 4.4%, 95% CI −2.2 to 12.0) between participants who practise in major cities compared with regional areas.

Wider impacts of physiotherapist prescribing

Participants were asked to provide additional comments about how NMP may impact the overall level of care that the profession is able to provide. In total, 230 participants provided comments.

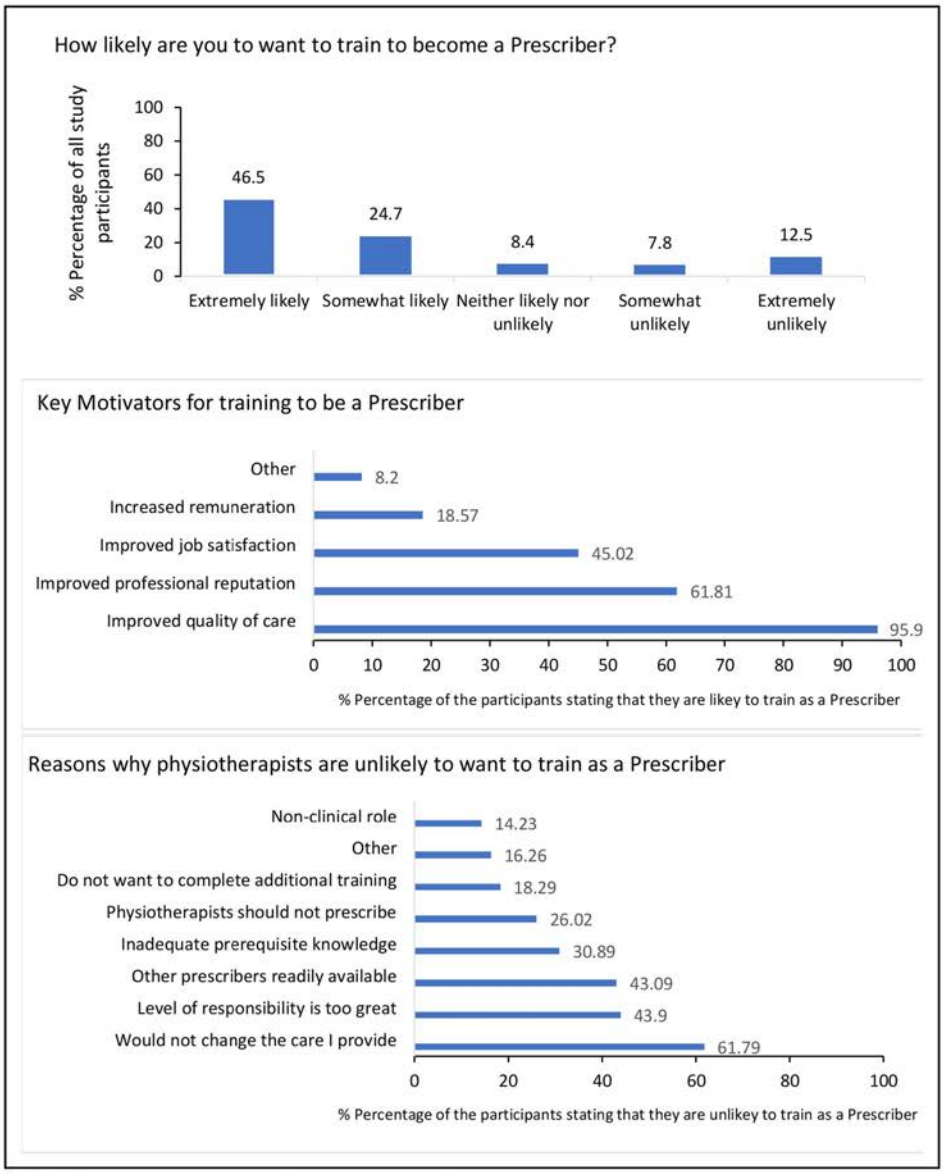

Figure 3 Likeliness to train as a prescriber: motivators and deterrents.

Four major themes were identified:
1. Clinical and cost-efficiency.
2. Access to prescription medicines.
3. Optimal therapeutics and clinical effectiveness.
4. Time management.

Table 3 lists the number of participants that reported or discussed each theme and provides illustrative quotations.

Clinical and cost-efficiency

One hundred and eighteen participants commented that the introduction of autonomous physiotherapist prescribing would have positive effects on both clinical and cost-efficiencies for patients, clinicians and the health economy. Participants identified the positive impact on the overall patient journey as a potential benefit of NMP

Table 2 Percentage of participants from different health sectors and geographical locations, who agreed with the introduction of physiotherapist prescribing and are likely to train

Survey item	Location RRMA % (95% CI)			Subgroup comparisons ARR % (95% CI)		
	City	Regional	Remote	City: regional	City: remote	Regional: remote
Agreed or strongly agreed with autonomous prescribing	80.1 (77.3 to 83.3)	76.1 (69.0 to 81.9)	56.5 (36.8 to 74.4)	4.4 (−2.2, 12.0)	24.0 (5.8 to 43.9)*	19.5 (0.4 to 40.1)*
Likely to train as prescriber	71.9 (68.4 to 75.2)	70.9 (63.4 to 77.3)	52.2 (33.0 to −70.8)	1.0 (−6.3 to 9.1)	19.8 (0.8 to 39.2)*	18.7 (−1.3 to 39)

Survey item	Health sector % (95% CI)			Subgroup comparisons ARR % (95% CI)		
	Private	Public	Other	Private: public	Private: other	Public: other
Agreed or strongly agreed with autonomous prescribing	80.7 (76.8 to 84.1)	79.0 (74.2 to 83.1)	70.8 (61.1 to 79.0)	1.7 (−4.0 to 7.6)	9.8 (0.8 to 20.2)*	8.2 (−1.3 to 18.8)
Likely to train	77.4 (73.3 to 81.1)	67.5 (62.2 to 72.5)	54.2 (44.2 to 63.8)	9.9 (3.5 to 16.4)*	23.3 (12.8 to 33.8)*	13.4 (2.3 to 24.5)*

*Significant at p<0.05.
ARR, absolute risk reductions; RRMA, Rural, Remote and Metropolitan Areas.

by reducing unnecessary appointments with general practitioners (GPs), specialists and surgeons. Specifically, participants recognised the current frequency of referrals from physiotherapists to GPs for analgesic review, access to oxygen therapy, bronchodilators and antibiotics and ongoing pharmacological spasticity management. A common sentiment was that if physiotherapists could provide these services themselves, patients could have more timely access to appropriate medicines, which in turn would complement physiotherapeutic interventions and accelerate patient improvement/recovery. Participants also anticipated that NMP could reduce acute injury recovery times and minimise the risk of chronicity, which in turn could reduce pressures on medical services and end costs to the consumer, Medicare and private health insurers. Furthermore, the presence of physiotherapist prescribers in emergency departments and specialist multidisciplinary clinics was anticipated to reduce waiting times for patients, thus helping to meet performance measures set by governing bodies.

Access to prescription medicines

Seventy-one participants provided comments concerning potential improvements in accessing prescription medicines for all Australians regardless of geographic or other socioeconomic factors. Specifically, it was suggested that physiotherapist prescribers in rural and remote regions could issue prescription medications to patients who might otherwise have limited access to medical professionals. However, no participants from rural/remote regions identified this theme within their responses. Participants from metropolitan and regional areas expressed concerns that patients in rural and remote regions may struggle to navigate an overburdened and expensive healthcare system, frequently waiting for weeks and travelling great distances to see their GP for medications such as analgesics to supplement treatment from their physiotherapists. Participants from all locations identified potential benefits of NMP to healthcare consumers (regardless of location) whose principal healthcare practitioner is a physiotherapist, including persons with physical disabilities and those involved in sports where acute injuries are managed pitch-side by the team physiotherapist.

Optimal therapeutics and clinical effectiveness

Fifteen participants reported the potential for improved optimisation of medicines in line with physical and psychosocial interventions and therefore enhanced clinical effectiveness. Participants stressed optimal and appropriate use of analgesics across all specialties, especially where adjustments (escalation or de-escalation) to prescriptions are required in line with physiotherapeutic intervention. It was felt that that the multimodal skills and techniques used by physiotherapists would promote a more integrated use of medicines into the overall patient management, with medicines forming just one part of a more comprehensive and coordinated approach. Participants specialising in women's health echoed this

Table 3 Comments that reported or discussed each theme and illustrative quotations from participants (quotations have been copied verbatim)

Theme	Number of comments (n)	Illustrative quotations
Clinical and cost efficiency	118	'… [W]ould benefit people financially if they do not have to go back to their GP for medication' (participant 41). 'Time and cost savings for busy workers, that is, not having to go to 2 appointments' (participant 127). '…[I]mprove patient flow and decrease reliance on medical staff' (participant 490). 'Working in an Emergency Dept where access and flow is critical, enabling advanced musc [musculoskeletal] physios to prescribe would improve efficiency in the workplace and the patient experience' (participant 7). 'The ability to prescribe would enable more efficient service delivery to patients. A lot of time is wasted back and forth trying to get appropriate pain medication, antibiotics etc in a timely fashion' (participant 32).
Access to prescription medicines	71	'Working in a rural area where it is difficult for a patient to be able to make a GP appointment (typical 2–3 week wait) I can see the benefit of streamlining the system by giving prescribing rights to physios who are also primary care professionals' (participant 630). 'Will reduce burden on overbooked GP's and ED's for people with pain problems, that is, Severe Acute Low back (pain) or those with inflammatory injuries' (participant 873). 'Physiotherapists working in public health help people from different minority groups every day - indigenous, recent immigrants, people relying on disability pensions, etc. Greater access to simple medications would improve their quality of life and reduce unnecessary attendances at over- worked GP clinics' (participant 12). 'I work in a country setting where travel times are significant and it can be difficult to get a doctor's appointment and, when injured or without a licence, patients rely on friends, relatives or public transport to reach appointments. This means that a physiotherapy appointment with prescription would become a more efficient use of time and people are more likely to comply' (participant 654).
Optimal therapeutics and clinical effectiveness	15	'Will allow physiotherapist to adjust medications particularly in management of chronic pain and LBP…' (participant 333). 'There is considerable potential for this to significantly improve adherence to medication regimes and to problem solve in a time appropriate manner' (participant 45). 'Physios tend to spend more time with patients and often are better skilled to recommend medications than even the registrars, especially in my urogynae advanced practice clinics, being able to prescribe anticholinergics and vaginal oestrogens would significantly increase the efficiency of the clinics as currently [patients] need two appointment times for this' (participant 276). …'[D]e-prescribing' could potentially be a very important role for Physios' (participant 790).
Time management	9	'The time required to keep up to date with medications and well as physiotherapy skills to be safe and effective I feel would impact the time available to treat patients…' (participant 246). 'Puts extra pressure on appointment time when we already have to deal with full assessment and treatment of the patient's physical and psycho-social needs' (participant 693).

statement highlighting the appropriate use of anticholinergics and vaginal oestrogens necessary to holistically treat many of their patients.

Participants agreed that the close working relationships between physiotherapists and their patients, due to the comprehensive time spent completing physiotherapeutic interventions may be used to promote patients' compliance to their prescribed medicines. Physiotherapist prescribers with the appropriate knowledge and skills could legally reinforce the appropriate use of medicines, better recognising poor adherence, dependency, abuse or adverse side effects masquerading as conditions treated by physiotherapists.

Time management

Nine participants suggested that the time requirements needed to train as a physiotherapist prescriber and ongoing time required for continuous professional development (CPD) may be prohibitive to introducing NMP in Australia.

Likely, time away from clinical work for education and development and NMP duties were seen to potentially interfere with tasks currently performed by clinicians. Furthermore, participants felt that although greater efficiency and access to medicines may benefit heath consumers, time presently spent treating patients in the current scope of practice would be lost to procedures related to prescribing medicines. In other words, although NMP may decrease medical practitioners' workload, this would instead increase pressures on already understaffed physiotherapy departments and possibly even threaten clinical outcomes.

Further insights

The final question allowed participants to express any additional thoughts and views about physiotherapist prescribing that they deemed important and had not already been captured. Two hundred and sixty-six participants provided comments. Three major themes were identified:

1. Quality and safety: clinical governance, policies and procedures and education.
2. Professional issues.
3. Physiotherapy professional priorities.

Table 4 lists the number of comments that discussed each theme and subtheme, providing Illustrative quotations from participants.

Quality and safety

Two hundred and seventeen comments were received regarding quality and safety concerns around NMP. These focused on clinical governance, policies and procedures and educational requirements for prescribers.

One hundred and forty-four participants proposed that adequate clinical governance, policies and procedures should be in place for physiotherapist NMP to be successful. Participants identified the need for a clear scope of practice linked to a physiotherapy-centric formulary that is endorsed and regulated promoting transparency and safety. Participants raised concerns that statutory processes and procedures defining a limited formulary could quickly become outdated due to medical advances. Meanwhile, other participants identified that a limited formulary based around the profession's specialist areas of practice would be safest, protecting clinicians from pressures to prescribe out of scope. Participants were concerned that unless communication channels were maintained between physiotherapist prescribers and GPs, there is a risk that patients could shop around for prescriptions, potentially aiding the abuse of prescription medication and causing clinical incidents. Participants were also concerned that the increase in professional risk due to physiotherapist prescribing would lead to an increase in indemnity insurance premiums.

Seventy-three comments were received with regards to education. Participants recognised that the scope of practice must be absolutely clear, endorsed and underpinned by a robust clinical education framework. They felt that thought must be given to the process of assessment and selection of appropriately qualified assessors from outside the profession including medical doctors and pharmacists to ensure quality and safe practice among prescribers.

Access to prescribing courses for physiotherapists living in regional and remote areas was highlighted as a potential issue due to the distance to the nearest university. Participants recommended that the regulatory body should dictate compulsory annual CPD hours, and periodic reassessment of competency should be mandatory. Participants had varying opinions with regards to when physiotherapists should be able to train and qualify as prescribers; however, the participants agreed that current preregistration physiotherapy programmes should be updated to include pharmacology and therapeutics on their syllabi in preparation for the future.

Professional issues

Thirty-nine participants provided comments on important professional issues. Participants noted that the introduction of physiotherapist prescribing could change the 'physiotherapy brand', weakening the public's perception of physiotherapists as experts in manual therapy and exercise, leading to potential loss of patients to other emerging healthcare professions. It was suggested that a marketing campaign may be necessary to manage public expectation and minimise consumer confusion.

Interprofessional relationships between physiotherapists, medical practitioners and pharmacists were highlighted as being fragile. Participants warned that members of the Australian Medical Association would not support the introduction of physiotherapist prescribing, alluding to the possibility that medical doctors might see the introduction as a direct challenge to their authority and private businesses, leading them to reduce referrals to physiotherapy. Participants specifically identified the impact this may have on practice revenues in the musculoskeletal and sport specialties. That said, other participants

Table 4 Additional comments reported or discussed by participants and illustrative quotations from participants

Theme/subtheme	Number of comments (n)	Illustrative quotations (quotations have been copied verbatim)
Quality and safety Clinical governance, policy and procedure Education	217	'Prescribing medicines is a risk to the physiotherapy profession as there can be a lot of risks to the patient with medications. Prescribing and its scope needs to be carefully planned and managed with introduction to the physiotherapy profession' (participant 379). 'The physio who is going be a prescriber needs to undergo a certain number of hours of training… going through an examination process. Continuous on-going training is also important as medications change fairly rapidly' (participant 14). '…[P]rofessional indemnity is required to protect them in case of errors or mishaps' (participant 89). 'Risks of 'doctor shopping' of physiotherapists for opioid based drugs without centralised control' (participant 651). 'The challenge in prescribing is ensuring consumer safety through adequate training of the physiotherapists involved and improved communication across health professions' (participant 56).
Professional issues	39	'I believe that it would create confusion for the public if some physiotherapists could prescribe, while others could not' (participant 227). 'A cultural change is needed, namely adjusting the public's perception of what allied health professionals can do, in order to effectively use non-medical prescribing rights' (participant 380). '… the medical doctors may have their issues with this as it may be seen as a direct challenge to their authority and therefore reduce their use of referral pathways already established' (participant 4). 'I would be concerned that there may be a conflict that forms between doctors and physiotherapists if physios were given prescribing authority. I think there would have to be some very strict guidelines about managing a patient who may be seeking prescriptions from both a doctor and physiotherapist at the same time' (participant 879). 'I think the medical and pharmaceutical professions would have a negative view of physios prescribing and be less willing to work with us/refer patients to us' (participant 447).
Physiotherapy professional priorities	40	'Physio profession needs to become more progressive with enhanced scope roles, career pathways are currently limited' (participant 412). 'I think that the physiotherapy profession should spend their resources and energies trying to improve the ability for Physiotherapists to order radiological investigations (scans etc) and referrals to specialists which would be far more beneficial in a cost and time saving way then being able to prescribe medications' (participant 78). 'Potential for increased reliance on pharmaceutical treatments of MSK conditions over traditional physiotherapy management strategies (i.e. manual therapy, exercise prescription)' (participant 701). 'May potentially de-value other interventions in the management plan (ie, committing to taking medication as prescribed, but not to exercises prescribed in same session)' (participant 219).

reported great support from medical colleagues and the greater multidisciplinary team, citing the streamlining of current clinical services and patient pathways, alongside improved access medicines as key reasons for positive interprofessional support. Participants warned that although these efficiencies would reduce service costs, establishing physiotherapist prescribing would require an initial coordinated investment to ensure appropriate governance, clinical education and safe/quality implementation across Australia.

Physiotherapy professional priorities

Forty participants commented on the profession's professional priorities. Participants described the risks of junior physiotherapists underdeveloping their traditional physiotherapy skills used to treat impairments and instead depending on medicines. To mitigate these risks, a robust career progression framework would need to be introduced to ensure ongoing high-level professional development across all specialties. To safeguard the good reputation of the profession, participants focused on maintenance of quality and safety for patients and clinicians. Physiotherapist prescribing should be introduced in a structured and organised manner with all physiotherapists supporting each other, even if they do not wish to prescribe themselves. Furthermore, participants also commented that the ability for physiotherapists to directly refer to specialist medical or surgical practitioners and ensuring appropriate patient rebates for imaging would have a positive clinical impact.

DISCUSSION

This is the first study to explore the perceptions of Australian physiotherapists regarding NMP by physiotherapists in Australia. The majority of physiotherapists agreed that autonomous prescribing responsibilities should be introduced for physiotherapists in Australia. Improvements in the efficiency of healthcare delivery, access to medicines and reductions in costs across the health economy were suggested as potential benefits. These findings concur with those reported by student physiotherapists in Australia as detailed in a related article,[16] as well as reflecting an evaluation of physiotherapist and podiatrist independent prescribers in the UK,[27] strengthening the external validity and transferability of the results. Concerns regarding clinical safety and management of clinical risk were clearly identified throughout the quantitative and qualitative sections of the survey, supporting the results of an international multiprofession mixed-methods systematic review investigating the barriers and facilitators of the implementation and utilisation of NMP.[5] The systematic review identified the need to address governance, safety, educational and financial factors prior to training prescribers to protect both patients and clinicians from poor practice, process and clinical pathways.[5] To safely and effectively introduce physiotherapist prescribing, politicians, regulatory bodies, healthcare managers, clinicians and the APA, in consultation with experts and health consumers, must develop robust legislation, regulation, clinical governance and safety policies as well as well-defined education and career frameworks.

To ensure that physiotherapists are equipped to prescribe safely within a multimodal physiotherapeutic context, participants perceived that a contemporary, innovative and robust educational framework should be developed prior to the introduction of physiotherapist prescribing. This perception reflects contemporary educational literature that urges educators to carefully consider the ever-evolving healthcare system when designing curricula for physiotherapists.[28] Transforming healthcare needs will require the next generation of physiotherapists to be ready to adapt to changes in consumer complexity and expectation, working within new models of care that are organised, funded and delivered in innovative ways. It has been postulated in the literature that a more flexible, broader and deeper clinical expertise will be required by physiotherapists if the Australian physiotherapy profession wishes to succeed as evidence-based and viable health providers in the integrated, value-driven health industry of the future.[29]

To guarantee quality development of physiotherapists across the profession, participants called for the creation of a contemporary career development framework into which prescribing would be integrated to safeguard mastery of traditional skills, govern quality practice and maintain the 'physiotherapy brand'. This appeal concurs with literature reporting that career frameworks within healthcare help the public understand different clinicians' knowledge, skills and roles within one profession, as well as providing purpose and direction for professionals, promoting engagement and job satisfaction.[30 31] Further, academic qualifications and increased clinical responsibility should lead to enhanced remuneration if physiotherapists are to adopt prescribing into their clinical practice, as a lack of remuneration has been recognised as a barrier to NMP across other professions.[32–34] Improvements in recruitment and retention within the profession were anticipated due to improvements in job satisfaction for clinicians and greater recognition and professional reputation, echoing the findings of other NMP professions reported in the literature.[32 35 36]

Physiotherapists working in cities and regional areas were consistent in observing that physiotherapist prescribing would improve access to medicines across all regions but would be specifically helpful in rural/remote areas where access to medical prescribers may be limited. However, physiotherapists from rural/remote areas, although positive about the introduction of physiotherapist prescribing, were less likely to wish to train as prescribers, identifying potential increased risks when working in geographical isolation owing to a lack of clinical support. Due to a perceived lack of need in the present healthcare environment, participants felt that not all physiotherapists would benefit from undertaking a NMP course. Those working in close multidisciplinary

teams with colocated prescribers, or those employed in non-clinical roles such as healthcare managers or academic physiotherapists were found to be less likely to wish to become prescribers than clinicians working in the public and private sectors. There was debate as to when and who should undertake the training, with no consistency as to whether education should be included in foundation level courses or become a postregistration qualification for those with a specified clinical experience. Furthermore, rural physiotherapists identified that the distance to universities may act as a barrier to training as a prescriber, highlighting the need for educators to consider flexible learning methods such as online education and video teleconferencing to fulfil the academic requirements of a NMP course. It is therefore imperative that a robust, fit for purpose, transparent and future proof education framework is developed to ensure unity within the Australian physiotherapy profession and assurance for all stakeholders that physiotherapists prescribers would be adequately prepared for practice.

Participants' perceptions that physiotherapist prescribing in Australia would reduce costs to their patients, healthcare services and to the health economy as a whole is supported by an economic review commissioned by the APA. The report predicts savings to the Australian health economy of over $9.22 million per year if physiotherapist prescribing was implemented[37]; however, this is not currently reflected in the health economics literature. A robust low risk of bias systematic review investigating the clinical and cost-effectiveness of NMP found only one inadequately powered pilot randomised controlled trial investigating clinical effectiveness to date, concluding that the benefit of NMP to the health economy remains unclear.[4] This gap in the literature highlights the need for robust, adequately powered economic evaluation to investigate the cost–benefits perceived by physiotherapists across Australia.

Strengths and limitations

This is the first study investigating the perceptions of AHPRA-registered physiotherapists about the potential introduction of NMP among physiotherapists in Australia, and so, alongside the data from student physiotherapists presented in the related article, provides an important overview of the current associated professional landscape. The data should be used to guide the APA, health departments and political leaders towards successful implementation of physiotherapist prescribing in Australia. As with all survey-based research, limitations are inherent due to selection and response bias. The survey was anonymous, so participants may have biased the results by completing the online questionnaire multiple times. Furthermore, physiotherapists with strong views or vested interests may be more likely to complete the questionnaire, meaning that their answers may not reflect the views of the wider profession.

A representative survey response rate (as per precursory power calculations) was achieved.[13] Although only 3% of AHPRA responded, this reflected the response rate of a previous national evaluation of physiotherapists,[37] where similarly, it was not possible to contact all registered physiotherapists directly due to the AHPRA privacy policy. Physiotherapists who were not APA members at the time of the survey would have been unaware of the questionnaire unless they were provided with a link to the questionnaire through professional networks. It is impossible to determine why 97% of AHPRA registered physiotherapists did not participate; therefore, the risk of bias remains unknown and should be considered when interpreting the results. In line with recent Australian regulatory data,[38] the sample was representative of all registered physiotherapists in Australia in terms of age, gender and state in which they practise. Unfortunately, no national demographic data exist demonstrating the geographic location or health sector of registered physiotherapists' employment. It is therefore likely that the comparable demographic profile of the study's sample to contemporary national evaluations enhances generalisability of the data to the greater physiotherapist population in Australia and reduces risk of bias.

CONCLUSION

AHPRA-registered physiotherapists perceive that the introduction of autonomous physiotherapist prescribing would be beneficial for the Australian population and should be introduced. Acceptance of physiotherapist prescribing and the likelihood of physiotherapists to train as prescribers vary depending on location and the health sector in which a physiotherapist works. Legislation, regulation and governance around the use of physiotherapist prescribing all require careful consideration and consultation with experts and health consumers to ensure the safety and quality demanded by physiotherapy profession. Rigorous national educational frameworks should be developed within a transparent career development structure to ensure prescribing is used within a multimodal physiotherapeutic context, safeguarding the professional reputation of physiotherapy.

It is recommended that the APA, health departments and political leaders use the results of this study in conjunction with cost–benefit analyses, risk analysis as well as assessment of the health requirements and consultation with key stakeholders to redefine the scope of Australian physiotherapy to include NMP. Future research is required to investigate the concerns raised by participants. It would be valuable to interview current physiotherapist prescribers to interrogate the perceived benefits and concerns about physiotherapy prescribing identified by the Australian physiotherapists. Lessons learnt in the UK could thus be used to inform implementation internationally.

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8.18 Appendix 18: Article, BMJ Open, perceptions of Australian physiotherapy students about the potential implementation of physiotherapist prescribing in Australia: a national survey

Noblet T, Marriott J, Jones T, Dean C, Rushton A. Perceptions of Australian physiotherapy students about the potential implementation of physiotherapist prescribing in Australia: a national survey. BMJ open 2019;9(5): e026327

BMJ Open

Perceptions of Australian physiotherapy students about the potential implementation of physiotherapist prescribing in Australia: a national survey

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ABSTRACT

Objectives To explore the perceptions of Australian physiotherapy students about (1) the potential implementation and use of non-medical prescribing by physiotherapists in Australia and (2) how physiotherapist prescribing might impact the care that the physiotherapy profession can provide in the future.

Design A cross-sectional descriptive survey of physiotherapy students across Australia was completed using an online questionnaire developed by subject-experts and pretested (n=10) for internal consistency. A hyperlink to the questionnaire was emailed to all students enrolled in any accredited, entry-level Australian university physiotherapy programme. A reminder email was sent 4 weeks later.

Setting Participants completed an online questionnaire.

Participants 526 physiotherapy students from universities across all states with entry-level programmes.

Outcome measures Quantitative data underwent primary descriptive analysis. Thematic analysis was used to synthesise qualitative data.

Results 87% of participants supported the introduction of physiotherapist prescribing in Australia. 91% of participants stated that they would train to prescribe following introduction. Participants identified improvements in clinical and cost effectiveness, timely access to appropriate prescription medicines and optimisation of quality healthcare as key drivers for the introduction.

Conclusions Student physiotherapists support the introduction of physiotherapist prescribing in Australia, reporting potential benefits for patients, health services and the physiotherapy profession. Stakeholders should use the results of this study in conjunction with supporting literature to inform future decisions regarding physiotherapist prescribing in Australia.

Strengths and limitations of this study

- ► First survey of student physiotherapists investigating their perceptions about the potential implementation of physiotherapist prescribing in Australia.
- ► This evidence is required by the physiotherapy profession, politicians and educational institutions to inform the future direction of the profession in Australia.
- ► Selection and response bias are inherent in all survey research.
- ► Researchers were unable to identify the reasons for participant non-response.

INTRODUCTION

The ever-increasing healthcare requirements of the Australian population require additional healthcare workers across all disciplines.[1] The necessity for the physiotherapy workforce to meet the demands of the growing and ageing population requires the training of new physiotherapists alongside retention of senior physiotherapists with advanced clinical expertise.[1] Increasing numbers of junior physiotherapists are being educated through traditional and contemporary entry-level physiotherapy programmes across Australia,[2] resulting in physiotherapy being the third largest healthcare profession nationally.[3] Although attrition through retirement is inevitable, anecdotal evidence suggests a high-level of attrition in the early years following qualification owing to burnout, stress or ill health, family responsibilities or dissatisfaction with the profession.[1 3 4] Research demonstrates that a perceived lack of clinical and professional support, limited potential for promotion or formal career progression, alongside poor professional recognition and low remuneration contributes to 30% of clinicians being dissatisfied with their roles.[3]

The mounting prevalence of complex, chronic disease alongside the ageing and growing population in Australia is increasing the burden on healthcare systems.[5]

Innovation in practice is required to meet increasing demands, with many health professionals now working with an extended scope of practice.[6] Advanced physiotherapist roles have been introduced internationally, enabling innovative evidence-based care to optimise patient outcomes and develop the profession so that it is fit for the future.[7–10] In Australia, advanced musculoskeletal practitioners have been introduced to orthopaedic interface-services and emergency departments.[11] A recent systematic review examining the substitution of medical doctors for physiotherapists in the management of musculoskeletal disorders has supported this expansion of roles, with physiotherapists demonstrating parity of clinical outcomes with orthopaedic surgeons, with greater patient satisfaction.[9] Following the introduction of independent physiotherapist prescribing in the UK,[12] a proposal for the endorsement of registered physiotherapists as autonomous prescribers has been submitted to the Physiotherapy Board of Australia,[13] aiming to further address health service inefficiencies and improve access to medicines for all Australians, across all communities regardless of their geographical location[13]; as well as improving clinicians' job satisfaction, leading to increased retention of skilled physiotherapists.[13] However, conflict within a profession has been recognised as a significant barrier to successful implementation of non-medical prescribing (NMP).[14] Early identification of views and perceptions of both current practitioners and the next generation of physiotherapists is therefore required. To date, no research has evaluated the alignment between student physiotherapists and the greater profession with regard to the introduction of physiotherapist prescribing in Australia. It is therefore imperative that the views of the next generation of physiotherapists are explored as the Australian physiotherapy profession takes steps towards introducing physiotherapist prescribing responsibilities.

OBJECTIVES

To explore the perceptions of Australian physiotherapy students about the:

1. Potential implementation and use of NMP by physiotherapists in Australia.
2. How physiotherapist prescribing might impact the care that the physiotherapy profession can provide in the future.

METHODS

The study was conducted according to a predefined protocol[15] and is reported in accordance with the SUrvey Reporting GuidelinE[16] to ensure quality, reproducibility and transparency.[17] This article reports the data collected from student physiotherapists within a larger study evaluating the views and perceptions of Australian physiotherapists and physiotherapy students about the potential implementation of physiotherapist prescribing in Australia.[15] The data from Australian registered physiotherapists arefound in the related manuscript; perceptions about the implementation of physiotherapist prescribing in Australia: a national survey of Australian physiotherapists.[18]

Survey design

A cross-sectional descriptive survey design, using an online questionnaire enabled physiotherapy students from all geographical regions of Australia to participate at a convenient time.[19–21]

Participants

Students enrolled in any accredited, entry-level Australian university physiotherapy programme leading to Australian Health Practitioner Regulation Agency (AHPRA) registration as a physiotherapist, with legal capacity to consent, and who were able to read and understand written English, were eligible to participate. Data published by the Physiotherapy Board of Australia reported 8943 student physiotherapists enrolled across 20 Australian universities at the time of data collection.[22]

Procedure

A link to the online survey was distributed by university departments to students via an email endorsed by the Council of Physiotherapy Deans Australia and New Zealand. Student members (n=6973) of the Australian Physiotherapy Association (APA) also received the advertisement via the APA's electronic-communications.[23] A reminder email was sent via the same channels 4weeks later.[19–21] Data collection took place between 1 March 2017 and 30 April 2017 during university term time to facilitate recruitment, using online survey software, Qualtrics (Qualtrics, Provo, Utah, USA).[24] Participation was voluntary, with consent sought online following provision of information describing rationale, content and dissemination plans. All data provided by participants were confidential.

Questionnaire

A short, context specific questionnaire taking 5–10 min to complete was designed to maximise recruitment and minimise bias.[21 24 25] For transparency and reproducibility, a full version of the questionnaire including inbuild logic is found in online supplementary file 1. Questions were formulated from findings of a mixed methods systematic review evaluating the barriers to and facilitator of NMP, identifying personal and professional factors that could influence the implementation.[14] Student physiotherapists were directed via inbuild logic, to the specific questions designed to evaluate their views. Questions were categorised into four sections:

1. Demographic data including age, gender and state in which participants attend university.
2. Participants' perceptions of the positive and/or negative aspects of physiotherapist prescribing with regard to the profession.
3. Participants' perceptions of the impact of physiotherapist prescribing to them as an individual.

4. Participants' perceptions of the potential wider impacts of physiotherapist prescribing.

Experts in the fields of physiotherapy, NMP and Australian state/federal law/health policy were consulted to ensure optimal use of questions.[17 20] Pilot testing using a purposive sample of registered and student physiotherapists (total n=10, registered physiotherapists n=7, student physiotherapists n=3) was used to evaluate interpretation of instructions and questions and minimise reasons for a poor response rate.[17 20 21] Pilot participants were not excluded from the definitive survey.

Data management

Computer password protection and coding of any disclosed personal details within data files, were used to protect all electronic data produced. Data were only accessible to study investigators.[17 20 21] Data will be securely retained for 10 years in line with university policies.

Data analysis

Only data from fully completed questionnaires were analysed. Demographic data were tabulated.[20 21] Data retrieved in sections 2 and 3 were summarised via primary descriptive analysis completed using IBM SPSS Statistics for Macintosh V.22.0.[20 21] Thematic analysis was used to synthesise the qualitative data collected from open questions in section 4, enabling the identification of themes and subthemes. One researcher (TDN) independently coded the participants' answers line-by-line using NVivo V.11 software (QSR International, Melbourne, Australia). Preliminary themes and subthemes were reviewed by two researchers (TDN and TJ), then scrutinised by a panel of experts to ensure consensus.[26]

Patient and public involvement

Patient and public health priorities identified in the literature were key in the development of the research objectives and research design. As the study aimed to explore the perceptions of Australian physiotherapy students, the general public were not involved in the design/recruitment processes. Instead, registered physiotherapists, student physiotherapists and methodological experts were used. The results will be disseminated through publication and presentation at professional conferences.

RESULTS

Of the 8943 student physiotherapists enrolled at Australian universities at the time of the survey, 526 (6%) fully completed the online questionnaire.

Demographics

Demographic data are presented in table 1. 56.8% of participants were female with the majority (n=470, 89.4%) aged below 30 years. All states and territories with at least one university offering an entry-level physiotherapy programme were represented (no physiotherapy programmes existed in the Northern Territory or Tasmania at the time of data collection).

Table 1 Demographic data

Demographic	Student physiotherapists, n (%)
Total participants	526 (100)
Gender	
Male	227 (43.2)
Female	299 (56.8)
Age (years)	
17–29	470 (89.3)
30–39	42 (8.0)
40–49	12 (2.3)
50–59	2 (0.4)
60+	0 (0.0)
University State or Territory	
Australian Capital Territory	36 (6.9)
New South Wales	139 (26.4)
Northern Territory	0 (0.0)
Queensland	79 (15.0)
South Australia	123 (23.4)
Tasmania	0 (0.0)
Victoria	75 (14.3)
Western Australia	74 (14.1)

Participant perceptions of positive and/or negative aspects of physiotherapist prescribing with regard to the profession

Four hundred and thirty-eight (87%) participants strongly agreed (n=262, 52%) or agreed (n=176, 35%) that autonomous prescribing responsibilities should be introduced for physiotherapists in Australia, with 35 participants disagreeing (n=29, 6%) or strongly disagreeing (n=6, 1.2%) (figure 1). Benefits and concerns from participants are summarised in figure 1. Key benefits were directly linked to patients: potential improvement in the efficiency of service delivery (n=434, 83%), reduced costs of healthcare delivery for patients (n=337, 64%), improving the overall patient experience (n=335, 64%), and improved access to medicines (n=267, 51%). Participants identified additional potential benefits to be the reduction in currently overloaded general practitioners' (GPs) caseloads with a more collaborative approach to healthcare. Concerns focused on a lack of base-level pharmacological knowledge required to successfully complete an NMP course (n=210, 40%) and the potential increased safety risks to the patient (n=173, 33%). Additional comments highlighted a perceived lack of acceptance by older, more experienced physiotherapists, and potential conflict between the medical and physiotherapy professions due to the blurring of traditional roles.

Three hundred and fifty-seven participants (53%) felt that 1–5 years of clinical experience as a physiotherapist was necessary prior to being able to undertake an NMP course, with 41 participants (8%) feeling that >5 years would be preferable. One hundred and seventy-eight

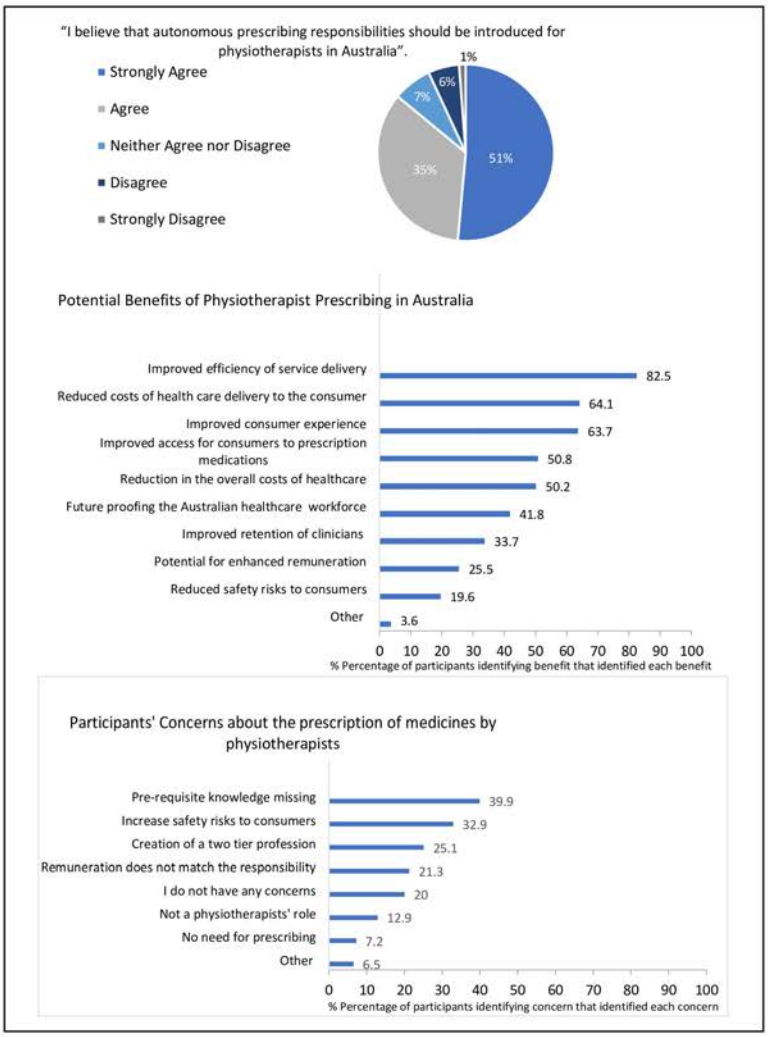

Figure 1 Graphs and charts showing agreement with the introduction of autonomous prescribing responsibilities, potential benefits and physiotherapists concerns.

participants (36%) reported that prescribing should be included in entry-level physiotherapy programmes; consistent with medicine and dentistry.

Participants' perceptions of the impact of physiotherapist prescribing to them as an individual

Figure 2 demonstrates the likelihood of the participants to want to train as a physiotherapist prescriber should a change in Australian federal and state or territory laws and regulations allow. Four hundred and forty-three participants (91%) stated that they were extremely likely (n=335, 69%) or somewhat likely (n=108, 22%) to want to complete an NMP course, with only 25 participants (5%) reporting that they were somewhat unlikely (n=18, 4%) or extremely unlikely to (n=7, 1.4%). The motivating factors and deterrents to pursuing autonomous prescribing responsibilities identified by the participants are detailed in figure 2. The potential for improvements in quality of care (n=450, 97%), alongside improved job satisfaction (n=246, 53%) and strengthened professional reputation (n=310, 67%) were identified as key

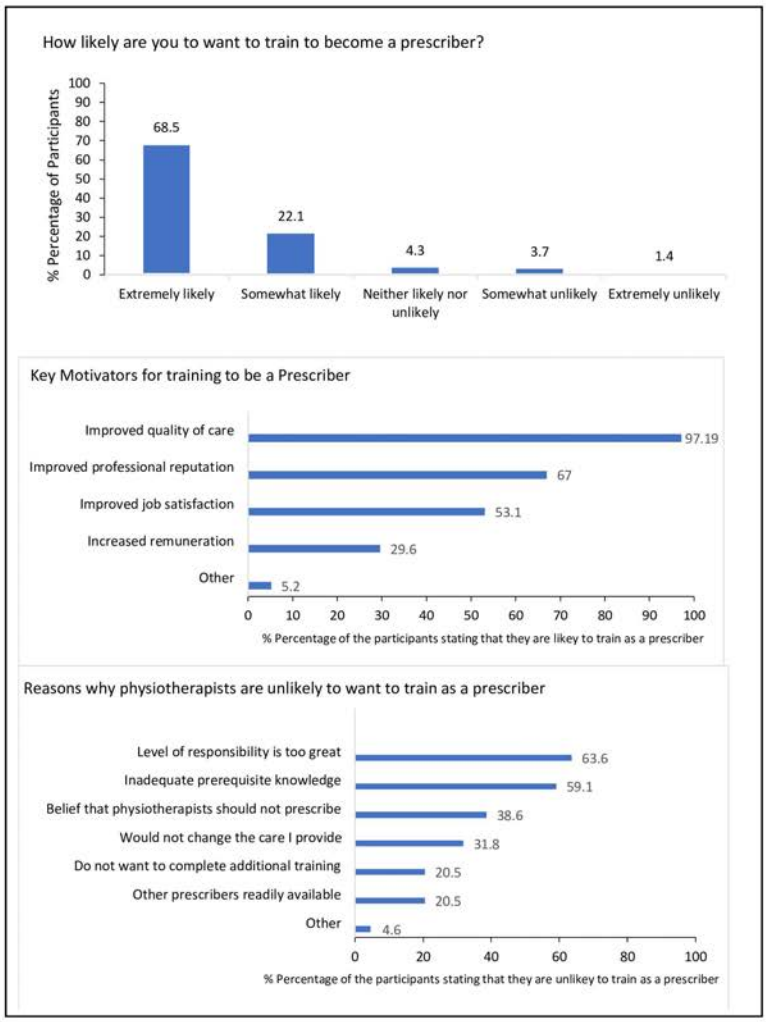

Figure 2 Training to be a physiotherapist prescriber: motivators and deterrents.

motivational factors. Of those that stated that they would not want to train as a prescriber, key reasons were identified as the level of clinical responsibility (n=28, 64%) and inadequate prerequisite knowledge required to successfully enter and complete an NMP course (n=26, 59%). Participants also highlighted a lack of remuneration for increased stress and responsibility.

Participants' perceptions regarding the potential wider impacts of physiotherapist prescribing

Participants' perceptions about how physiotherapist prescribing might 'impact the care which the profession is able to provide' were analysed and synthesised into three themes:

1. Clinical and cost efficiency.
2. Access to prescription medicines.
3. Quality of care.

Table 2 provides illustrative quotations to demonstrate each theme.

Clinical and cost efficiency

Sixty-one participants commented on the potential for physiotherapist prescribing to improve clinical and cost effectiveness for physiotherapy consumers and

Table 2 Comments that reported or discussed each theme and illustrative quotations from participants (quotations have been copied verbatim)

Theme	Comments (n)	Illustrative quotations
Clinical and cost efficiency	61	"It will reduce secondary referrals, increase the time doctors in hospitals or GP's can be dealing with other more major illness and reduce burden on the client" (Participant 234) "This is extremely positive for a patient's healthcare costs" (Participant 78) "It will save people the trouble from moving back and forth between General practitioners and Physiotherapists" (Participant 132) "It will be beneficial as patients will not have to see a number of different healthcare/medical workers, streamlining the care they receive" (Participant 15)
Access to prescription medicines	17	"Patients would not have to wait extended periods of time to see their doctor to attain a prescription that their physio had already prescribed/deemed important for their rehabilitation" (Participant 67) "....improved medication prescription for immigrants whom physiotherapists often build closer relationships through therapy sessions compared with short medical consultations" (Participant 404) "It would positively influence those in rural/regional areas or with less access to healthcare" (Participant 497) "....could provide a positive impact especially those patients in lower income brackets, and time restricted not requiring a follow-up GP appointment as well as a physiotherapist appointment" (Participant 21)
Quality of Care	13	"I believe it would increase client satisfaction" (Participant 398) "I feel like it is always a good thing to have more tools available to you" (Participant 501) "Prescription should not take precedence over equally effective manual therapy or pain education" (Participant 65) "It will enhance care because the physio will be able to follow through on explanations of pain to the client—why it hurts, what they can do about it without using medication, and when they do need medication, the best kind and most efficient way to take it, considering the particular condition and particular level of pain they are experiencing" (Participant 178)

services. Participants felt that with the imminent burden that the ageing population will place on the Australian healthcare system, having physiotherapists that are able to prescribe appropriate medicines could reduce costs resulting from patients attending multiple appointments with multiple practitioners for the same problem. Furthermore, physiotherapists could provide a more holistic approach to treatment, providing a 'one-stop-shop' service for patients. Participants also felt that waiting times would be reduced by off-loading the burden on GPs, emergency departments and specialist services, allowing medical/surgical practitioners to concentrate on other cases. Specifically, participants suggested that the ability to prescribe analgesia would accelerate the recovery of patients with acute conditions presenting in primary care, complementing traditional physiotherapeutic skills, and minimising the risk of developing chronic pain. Participants noted that, ultimately, improvements in time efficiencies would lead to improvements in cost effectiveness for Medicare and private health insurers.

Access to prescription medicines

Seventeen participants reported that physiotherapist prescribing would improve access to prescription medicines. Where GPs and specialist medical practitioners have time pressures, physiotherapists could provide appropriate medications for their patients in a timely manner, being especially beneficial in rural and remote locations where access to other healthcare providers may be limited. Specifically, improved access for minority groups such as refugees and asylum seekers was conveyed. It was also noted that physiotherapist prescribers could improve access where physical disability limits travel and where financial barriers prevent multiple appointments with multiple clinicians.

Quality of care

Thirteen participants commented that the quality of care that physiotherapists are able to provide could be improved if physiotherapist prescribers were optimally used. Participants stressed that prescribing should not take precedence over effective manual therapy and pain education. However, when used in conjunction as part of holistic management, physiotherapist prescribing might enhance patients' recoveries. It was emphasised that by reducing the to-and-fro from GPs for medication reviews the patient-therapist relationship would be strengthened. This continuity of care could allow physiotherapists to modify medications in-line with the outcomes of other physiotherapeutic interventions.

Table 3 Comments that reported or discussed each theme and illustrative quotations from participants (quotations have been copied verbatim)

Theme	Comments (n)	Illustrative quotations
Risks and responsibilities	37	"Unless a central database was made for every prescriber (doctor and physio) to access the patients complete drug history, it could become another way of people abusing the system and gaining more access to medicines than is necessary" (Participant 22) "There needs to be intense training and accreditation processes which assist physios with gaining the correct accreditation in order to prescribe medications. With this in place it has the ability help patients obtain better quality of care" (Participant 3) "Opens a window for error and serious complications" (Participant 215)
Education	19	"Unless physiotherapists undergo extensive study in relation to medications and prescribing them, I do not think it will be safe for the client" (Participant 144) "There should also be CPD requirements to uphold the prescribing rights" (Participant 51) "I believe that within the 5 year course of Physiotherapy that I am studying, there is room to acquire the knowledge to become a non-medical prescriber" (Participant 250) "I think pharmacology subject need to be one of the core physiotherapy modules in all Australian universities" (Participant 399) "Adding therapeutics to the curriculum might put people off studying physio due to extended course duration" (Participant 412)
Professional Relationships and Credibility	11	"I don't believe it would decrease the cross-referral to Medical Doctors, but it would certainly enhance our credibility with our patients and reduce unnecessary or excessive visits to the doctor" (Participant 501) "People will take us more seriously than before" (Participant 13) "It can have a negative impact on Physio as there can be physiotherapists who are negligent and prescribe the incorrect medications. There can also be physios who do not stick to their scope of practice giving the rest of the industry a bad name" (Participant 88) "…further enhances the reputations as primary care practitioners" (Participant 21)

Table 3 provides Illustrative quotations from participants.

Further Insights

Fifty-nine additional comments were received in response to the final open question. Three themes were identified:

1. Risks and responsibilities.
2. Education.
3. Professional relationships and credibility.

Risks and responsibilities

Thirty-seven participants described the increased risks and responsibilities that could occur with physiotherapist prescribing. Some participants stated that they chose to train as physiotherapists because they did not want the responsibility associated with the prescription of medicines that medical and dental practitioners carry. These participants worried that physiotherapist prescribing would reduce the use of other clinical skills such as exercise therapy. Other participants reported that they would happily take on the responsibility of prescribing, if remuneration reflected that of other autonomous prescribers such as medical practitioners. Participants also raised concerns about 'abuse of the system' by patients 'doctor shopping' to feed addiction, and physiotherapists driven by financial incentives. It was recognised that robust clinical governance, policies and procedures would be essential to limit poor practise, and that appropriate communication technology would be paramount in avoiding clinical errors, duplication of treatment and abuse of the system among healthcare professionals treating the same patient. Further, participants noted that any prescribing errors may be reported in the media, tarnishing the reputation of the profession as a whole.

Education

Nineteen participants commented on the educational requirements for physiotherapist prescribing. Participants recognised the need for a robust and accredited NMP programme that leads to registration with AHPRA as a physiotherapist prescriber. It was felt that prescribing should not be compulsory for all physiotherapists, and participants queried whether they possessed the prerequisite base-level knowledge of pharmacology to complete a prescribing course. Participants agreed that entry-level physiotherapy programmes should contain a compulsory preparatory pharmacology unit, however warned that this may deter potential candidates from applying to study physiotherapy. Participants studying longer (4–5 years) preregistration courses felt that these additional units could fit within the current curriculum. This was debated by those on shorter postgraduate entry-level programmes, who were concerned that these units would be taught to the detriment of other skills. Further, it was suggested that any proposed NMP qualification should be transferable internationally, to ensure that future generations of physiotherapists are able to gain experience outside Australia.

Professional relationships and credibility

Eleven participants raised the issue of interprofessional relationships and the credibility of the physiotherapy profession. Key thoughts centred around an improved professional image and increased credibility to the public, other health professionals and internationally. Participants were mindful that physiotherapist prescribing might cause conflicts between physiotherapists, medical professionals and pharmacists due to the blurring of professional boundaries but did not see this to be a deterrent.

DISCUSSION

This is the first study to explore the perceptions of student physiotherapists regarding physiotherapist prescribing in Australia. Most participants were positive about the potential introduction of autonomous physiotherapist prescribing due to benefits for patients, clinicians, the physiotherapy profession and the Australian health economy. The benefits to health consumers and services, such as improved clinical and cost effectiveness due to streamlined clinical-pathways, were perceived by participants as paramount, being more important than potential benefits to the profession, such as enhanced recognition. This concurs with the qualitative health literature evaluating the introduction of NMP by other professions, that report anecdotal improvements in clinical and cost effectiveness alongside excellent patient satisfaction as key elements to the successful long-term use of NMP.[27 28] However, a recent, rigorous systematic review of randomised controlled trials (RCTs) investigating the clinical and cost effectiveness of NMP, concluded that both the clinical and cost effectiveness of NMP currently remain unclear due to the existence of only a few inadequately powered unclear risk of bias trials, from a limited number of professions and clinical specialties.[29] This highlights the need for further trials with low risk of bias to rigorously assess the clinical and cost effectiveness of NMP.

The need for urgent and effective management of health inequalities and challenging shortfalls in doctors in rural and remote areas have been acknowledged in both the health literature and Australian health policy.[1 30 31] Improvements in access to medicines for all Australians due to the introduction of physiotherapist prescribing, especially those living rurally and minority groups, such as refugees and asylum seekers, was highlighted by participants. However, participants also echoed the findings of a rigorous systematic review investigating the barriers and facilitators of NMP, citing that improved access to medicines via the introduction of physiotherapist prescribing will require robust governance to ensure appropriate, quality and safe practice.[14] Participants' perceptions further concurred with the review's findings, acknowledging that divided opinions within the physiotherapy profession and conflicts with the medical profession would be inevitable if changes in scope were not managed effectively. This would compromise vital medical support and create barriers to the implementation of physiotherapist prescribing.

Over 90% of the student physiotherapists who completed the questionnaire stated that they would train to become a physiotherapist prescriber if prescribing rights were introduced, with potential improvements in quality of care identified as a key motivator. Greater job satisfaction and enhanced professional reputation were also highlighted as motivating factors, potentially improving retention of talented physiotherapists within the profession. This consensus among participants supports the hypotheses outlined within the profession's submission proposing the endorsement of registered physiotherapists as autonomous prescribers.[13] Although nurse prescribing has been shown to improve job satisfaction in senior clinicians, increased stress due to the level of responsibility associated with NMP has also been emphasised and is highlighted as a deterrent to training as a prescriber in the nursing and pharmacy literature.[14 32] Participants recognised that these deterrents may be mitigated by increased remuneration.[32–34] Further, enhancing remuneration alongside additional clinical responsibility may tackle interoccupational conflicts and competition due to pay inequalities reported in the health-sociology literature.[35] It is hoped that addressing inequalities in remuneration would facilitate professional equality between autonomous, diagnosing, treating and prescribing professions such as medicine, dentistry, optometry and physiotherapy, further strengthening quality, efficacy and collaborative patient management.

Unsurprisingly, the educational requirements supporting physiotherapist prescribing were an overt focus for the students. It was felt that prescribing should not be compulsory, with a small number of students identifying prescribing responsibilities as a reason for not pursuing a medical or dental career. The physiotherapy literature has identified the need for transformative practice and education to effectively equip the next generation of physiotherapists for a constantly developing healthcare industry.[2] The introduction of 'pharmacology and therapeutics' to all physiotherapy programmes to ensure prerequisite knowledge in preparation for postgraduate prescribing education may be a valuable initial step. However, educators should aim to prepare the profession for the future, developing a revolutionary education framework fit for the next generation of physiotherapists, while minimising the loss of time spent studying current evidence-based content. This will require innovation and contemporary programme design in consultation with those driving healthcare reform such as politicians, managers, insurers and patients.[2] The majority of the students felt that a prescribing qualification should follow a specific number of years of clinical experience. This was deemed essential for development of the physiotherapeutic assessment, treatment and reasoning skills required to ensure an holistic and multimodal approach

to patient management, emulating recommendations from the UK where physiotherapist prescribing is now established.[36 37]

This paper reports on the perceptions of physiotherapy students enrolled in educational facilities in Australia about the potential introduction of autonomous physiotherapist prescribing in Australia, and it is a subset of a larger study which also investigated the perceptions of registered physiotherapists.[15 18] When compared, both registered physiotherapists and student physiotherapists perceived that autonomous physiotherapist prescribing would lead to improved access to medicines, efficiency of services and reduced healthcare associated costs. Both shared similar concerns about prescribing practices and motivations for training to become a prescriber, however key differences existed regarding the reasons as to why a physiotherapist would be unlikely to choose to train as a prescriber. Registered physiotherapists recognised that prescribing might not enhance their individual roles especially if they already work closely with a prescriber or in a non-clinical role. They also worried about the practicalities of training to become a prescriber, noting additional stress and costs. The student physiotherapists focused on the increased clinical responsibility without enhanced remuneration, with some students recognising potential deficits in their knowledge that would limit their ability to complete an NMP course successfully. Decision makers using the results from this study when planning for the future should acknowledge these similarities and differences, integrating all viewpoints to ensure the success and longevity of the profession into the future.

Strengths and limitations

This is the first study investigating perceptions of student physiotherapists about physiotherapist prescribing, and it therefore provides important insights into the views and expectations of the next generation of Australian physiotherapists. The study was rigorous. As with all survey data, selection bias was potentially introduced by the distribution methods, as it is unknown whether the university departments were able to successfully distribute the link to the questionnaire to all students; and only student members of the APA received the additional advertisement via their electronic communications. There may have also been sharing of these links among student networks. The reasons why all physiotherapy students did not complete the online questionnaire are unknown; therefore, the level of bias remains unclear. It is possible that participants may have biased the results by completing the questionnaire multiple times. It is also plausible that the findings may be more representative of participants with stronger views, who were more motivated to participate, limiting generalisability. However, age and gender demographics were characteristic of the greater student physiotherapy population in Australia,[38] with students at universities across all states with preregistration physiotherapy programmes represented. Given this representative demographic profile, it is likely that the results are characteristic of the population studied. Due to the small number of study participants contributing to the qualitative data, the transferability of the thematic analysis may be limited. However, the themes agreed with those identified in the registered physiotherapist population, strengthening the likelihood of good transferability.

CONCLUSION

This rigorous survey has demonstrated that the next generation of physiotherapists support the introduction of physiotherapist prescribing in Australia. The students recognised the benefits to all stakeholders, highlighting improvements for patients and in turn, health services. It is anticipated that the introduction of physiotherapist prescribing may aid in retaining talent within the profession if the additional responsibility is supported and remunerated appropriately. Stakeholders should use the results of this study in conjunction with the supporting literature to inform planning that should not only focus on the introduction of physiotherapist prescribing but should be visionary, preparing the profession for the future. The development of a robust and contemporary education framework that will ensure quality and safe physiotherapist prescribing within a multimodal physiotherapeutic context is paramount. Low risk of bias RCTs are required to formally assess the clinical and cost effectiveness of physiotherapist prescribing across a range of clinical contexts.

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8.19 Appendix 19: Response to reviewers, BMJ Open, Perceptions about the implementation of physiotherapist prescribing in Australia: a national survey of Australian physiotherapists, 20th January 2019

Editors/Reviewers Comments	Changes made or Reason(s) for not making changes
Editor	
1. Along with your revised manuscript, please include a copy of the SRQR checklist for reporting of qualitative research, indicating the page numbers of your manuscript where the relevant information can be found.	Completed and attached as requested.
2. Please ensure that you have fully discussed your companion manuscript (bmjopen-2018-026327) and indicated how the results are similar or different and what each study adds to the literature.	Thank you for your feedback. The companion manuscript has been disclosed within the methods and comparisons noted: *'This article reports the data collected from registered physiotherapists from a larger study evaluating both registered and student physiotherapists in Australia.[178] The data collected from the student physiotherapists is presented a related article (bmjopen-2018-026327) published independently.'* *'The majority of physiotherapists agreed that autonomous prescribing responsibilities should be introduced for physiotherapists in Australia. Improvements in the efficiency of healthcare delivery, access to medicines and reductions in costs across the health economy were suggested as potential benefits. '**These findings concur with those reported by student physiotherapists in Australia as detailed in a related article, as well as reflecting an evaluation of physiotherapist and podiatrist independent prescribers in the UK,[25] strengthening the external validity and transferability of the results.'***

	'This is the first study investigating the perceptions of AHPRA registered-physiotherapists about the potential introduction of NMP among physiotherapists in Australia, and so, ***alongside the data from student physiotherapists presented in the related article****, provides an important overview of the current associated professional landscape.'*
Reviewer 1	
As a UK based NMP Physiotherapist this submission was of great interest and I recognise the commonality of participant viewpoints expressed in the study. I respectfully suggest a couple of minor revisions that I believe would improve the read;	Thank you for your comments and feedback.
Pg 6, line 3 should read "disseminated" (typo) Pg 7 line 15 recommend re-ordering of States and % list for more natural flow when read Pg 17 line 30 should read "wish" not which (typo)	Edits completed as recommended.
The data on page 8 in many sections does not add to the overall figure of 883 "full respondents" that you mention earlier in the piece. If there is missing data, you should acknowledge and make this clear in each section where it affects the data accuracy. Or the alternative is that you remove the statement that 883 participants fully responded if some of the data is missing / unusable.	As noted, demographic data were not fully completed by all participants as it was not compulsory as per ethical approval. For clarity and transparency, the first sentence in the demographic results (page 8) has been altered to: *'A total of 883 participants (3% of all AHPRA registered-physiotherapists) completed the questionnaire'* The number of participants that answered each demographic question has been added to Table 1.
Little emphasis is placed upon a significant finding amongst responders that believed having NMP rights would not change the	*'The most common deterrent for training to be a prescriber was the belief that this will not change the care that the individual physiotherapist would provide to their patients (n=152, 61.79%).'* …….. is stated clearing in the results. Unfortunately, no

care they delivered.....could you discuss this further or expand upon this thematic response?	further qualitative data discussed this finding, therefore, to reason why could potentially limit validity and transferability. Further research is required to interrogate this finding.
It may be wise to draw overt attention to the fact that the study participants represent 3% of the Physiotherapy fraternity in Australia.....in terms of interpreting the findings in light of potentially influencing future professional and legislative policy this is quite a significant point which potentially could be made clearer to avoid suggestions of bias	Thank you for your comment. Words have been added to the strengths and limitations to ensure this point is more explicit. It now reads: *'A representative survey response rate was achieved.* ***Although only 3% of AHPRA responded, this reflected the response rate of a previous national evaluation of physiotherapists,*** [53] ***where similarly, it was not possible to contact all registered physiotherapists directly due to the AHPRA privacy policy****. Physiotherapists who were not APA members at the time of the survey would have been unaware of the questionnaire unless they were provided with a link to the questionnaire through professional networks. It is impossible to determine why 97% of AHPRA registered physiotherapists did not participate; therefore, the risk of bias remains unknown and should be considered when interpreting the results.'*
Reviewer 2	
Thank you for the opportunity to review this paper. This subject area is relevant and highly topical across many of the allied health professions in Australia. The paper is well written and provides evidence to help inform policy change regarding the inclusion of physiotherapist prescribing in the physiotherapist scope of practice in Australia.	Thank you for your comments.
Page 3, line 12: "Difficulties in accessing medicines for Australians living in rural and remote areas alongside recognised health equities between minority groups…" I think you mean "health inequities" here?	Edit completed as recommended.

Page 6, line 3: “The results will be deiminated to all…” Do you mean “disseminated”?	Edit completed as recommended.
Page 13, line 30-32: This last sentence is an insightful and honest interpretation of the participants’ concerns about physiotherapist prescribing. Well done!	Thank you for your feedback.
Page 17, line 9: Incorrect use of the word “elude” in this sentence. You mean to use “allude” here. You could change to "…. alluding to the possibility that medical doctors might see the introduction of physiotherapist prescribing as a direct challenge to their authority and private businesses, leading them to reduce referrals to physiotherapy.”	Edit completed as recommended.
Page 20, lines 7-9: I don’t think that you can say "predicted". Participants were suggesting these as possible outcomes of introducing physiotherapist NMP, not predicting that these will happen.	Thank you for your comment. This sentence has been changed to reflect your feedback, now reading: *‘Improvements in the efficiency of healthcare delivery, access to medicines and reductions in costs across the health economy were suggested as potential benefits.’*
Reviewer 3	
A strength of this paper is the breadth of data gathered from Australian physiotherapists about the potential implementation of physiotherapist prescribing practices in Australia. However, there is no reference to other studies and reports investigating physiotherapist perceptions about the implementation of prescribing practices. For example, the national survey of South African physiotherapists undertaken by Unger and Lochner (2006) and a smaller study investigating physiotherapist opinions about enlisting as supplementary prescribers in Nigeria (Onigbinde and	Thank you for this comment. In order to aid in the situating this paper for international comparison the following has been added to the introduction: *‘Divided opinion between individual clinicians, academics and professional managers/leaders may lead to confusion across the healthcare community, resulting in unwarranted negative thoughts and perceptions about NMP roles and responsibilities.* ***Diverse perceptions regarding the implementation of physiotherapist prescribing and current physiotherapeutic pharmacological***

Tijani 2014). The findings of the public consultation on the proposal to introduce independent prescribing by physiotherapists in the UK (Department of Health 2012) may provide additional insight. Referring to these studies would help situate the paper in the field of physiotherapist prescribing practices and could enable comparison between countries.	***knowledge and practices have been reported in national evaluations in Nigeria, South Africa and the UK.*** [42-44 56] ***Data from these evaluations have been utilised to influence national policy and the political drive towards or against the adoption of NMP within the physiotherapy profession in these countries.*** [44 56] *Acceptance and support for prescribing by the Australian physiotherapy profession will be required for successful implementation into local and national health systems.* [1 39 47 48]'
The description of the analysis of the quantitative data is stated and the link to the confidence interval calculator is embedded in the text; this could be clarified by noting the Newcombe-Wilson method without continuity correction and making reference to the Newcombe (1998) paper. That way, if the website and/or spreadsheet are changed and or deleted, there will still be some reference to the actual calculations used.	Thank you for your advice. This has been actioned within the manuscript.
The authors present three figures in the manuscript that largely just repeat the data in the text. The paper could be improved by better integration of the text and figures.	Thank you for your comment. We hope that by integrating the reviewers' and editorial teams' feedback the manuscript will fulfil the needs of the readers.
The authors recommend interviewing current physiotherapist prescribers to further develop this research however, Carey et al. (2017) have published a recent evaluation of physiotherapist and podiatrist independent prescribing in the UK. Reference to this would enhance the discussion and conclusion of this paper.	Thank you for this comment. This reference has been added to the discussion and conclusion of the article: *'These findings concur with those reported by student physiotherapists in Australia reported a related article, as well as reflecting an evaluation of physiotherapist and podiatrist independent prescribers in the UK,* [25] *strengthening the external validity and transferability of the results.'* *'It would be valuable to interview current physiotherapist prescribers to interrogate the perceived benefits and concerns about physiotherapy prescribing identified by*

	the Australian physiotherapists. Lessons learnt in the UK could thus be utilised to inform implementation internationally.'
MINOR COMMENTS:	
Page 2 Abstract: The conclusion refers to AHPRA registered-physiotherapists. The acronym should be included at the first use, i.e. in line 13.	Edit completed as recommended.
Page 3: The authors refer to submission of a proposal for 'autonomous prescribing' by Australian physiotherapists, but there is no description within the text about what this is (it is described in one survey question in Supplementary File 1). As the framework for non-medical prescribing is different across and within countries, providing a brief explanation of what autonomous prescribing entails in relation to other models of non-medical prescribing (including those in Australia as set out by the Health Professionals Prescribing Pathway) would be beneficial. This would enable the paper to be positioned within the international literature about non-medical prescribing.	Thank you for this feedback. We have added an explanation for autonomous prescribing so that the reader is able to position this paper within the context of the international literature. *'In July 2015, the Australian Physiotherapy Association (APA) in collaboration with the Australia Physiotherapy Council (APC) and Council of Physiotherapy Deans Australia and New Zealand (CPDANZ) submitted a proposal for the endorsement of registered physiotherapists for autonomous prescribing to the Physiotherapy Board of Australia.* [39] ***To autonomous prescribe medicines, a practitioner must be responsible for the assessment and diagnosis the patient, prescribing drugs from a specified formulary within their individual scope of practice. The clinician manages ongoing therapy without the requirement of protocols or supervision.***[45]*'*
Page 3 line 12: Health equity is normally considered to be the absence of avoidable, unfair or remediable differences among groups of people. Do the authors mean health inequities among minority groups?	Edit completed as recommended. See Reviewer 2.
Page 3 line 19: The authors talk about their recent systematic review showing limited evidence of unknown risk of bias. It is not clear to what the 'limited evidence of unknown risk of bias' is referring.	This has been reworded to clarify for the reader: *'The clinical and cost-effectiveness of NMP remains unclear, with a recent systematic review finding only minimal empirical evidence with unknown risk of bias* [88]*'*

Page 4 line 42: 'The APA membership…representative of all physiotherapy specialities and levels of experience…' Could the authors state that students were included in the invitation to complete the survey?	Suggestion added. The sentence now reads: *'The APA membership was selected as the recruitment platform as it is representative of all physiotherapy specialities and levels of experience* ***(qualified and student physiotherapists)*** *across Australia'*
Page 4 line 43: Placing a comma after 23 in 23153 would make it easier to interpret this number.	Edit completed as recommended
Page 5 (line 17): '…closed questions collecting quantitative data' might scan better as 'closed questions to collect quantitative data'	Edit completed as recommended
Page 5 line 24: Could the authors state the proportions of qualified physiotherapists and physiotherapy students in the pilot sample?	Thank you for this comment, this information has been added. *'Ten participants* ***(n=7 registered physiotherapists, n=3 student physiotherapists)*** *were purposely sampled to represent the physiotherapy profession in Australia'*
Page 5: There is no mention of a power calculation although this is described in the protocol for the study. It would be helpful to understand the 3% response rate in relation to this.	Thank you for your comment. Additional words have been added within the strengths and weaknesses discussion to reference the power calculation featured in the protocol paper: ***'A representative survey response rate (as per precursory power calculations) was achieved.***[178] *Although only 3% of AHPRA responded, this reflected the response rate of a previous national evaluation of physiotherapists,* [53] *where similarly, it was not possible to contact all registered physiotherapists directly due to the AHPRA privacy policy.'*
Page 5 line 54: Could the authors clarify PPI in the development of the study?	This is clarified in the Patient and Public Involvement subsection and clearly states that due to the study's objectives, patients and the general public were not utilised in design of the study. The reasoning as to why (the study objectives) is explicit.

	'The development of this study was informed by the experiences of patients and the general public acknowledged in the literature. Due to the study's objectives, patients and ***the general public were not utilised in design of the study or in participant recruitment.*** *The results will be disseminated to all interested parties through publication and presentation at professional conferences.'*
Page 6 line 3: '…will be deiminated to all...'? typographical error	Edit completed as recommended
There is inconsistency in the use of decimal places when reporting percentages throughout the paper.	Thank you for this feedback. The use of decimal places is now standardised at 1 DP when required.
References – formatting is inconsistent.	Unfortunately, this was due to changes in the computer programmes used during review. This has been edited.

8.20 Appendix 20: Response to reviewers, BMJ Open, perceptions of Australian physiotherapy students about the potential implementation of physiotherapist prescribing in Australia: a national survey, 20th January 2019

Editors/Reviewers Comments	Changes made or Reason(s) for not making changes
Editor	
1. Please ensure that you have fully discussed your companion manuscript (bmjopen-2018-024991) and indicated how the results are similar or different and what each study adds to the literature.	Thank you for your comments and feedback. The companion manuscript has been disclosed by adding the following statement to the beginning of the methods section (page 4): *'This article reports the data collected from student physiotherapists within a larger study evaluating the views and perceptions of Australian physiotherapists and physiotherapy students about the potential implementation of physiotherapist prescribing in Australia.[178] The data from Australian registered physiotherapists is found in the related manuscript (bmjopen-2018-024991): perceptions about the implementation of physiotherapist prescribing in Australia: a national survey of Australian physiotherapists'.* An additional paragraph has been added to the discussion section to outline the similarities and differences between registered and student physiotherapists, and what this adds to the literature. Page 13: *This paper reports on the perceptions of physiotherapy students enrolled in educational facilities in Australia about the potential introduction of autonomous physiotherapist prescribing in Australia, and it is a subset of a larger study which also*

	investigated the perceptions of registered physiotherapists. When compared, both registered physiotherapists and student physiotherapists perceived that autonomous physiotherapist prescribing would lead to improved access to medicines, efficiency of services and reduced healthcare associated costs. Both shared similar concerns about prescribing practices and motivations for training to become a prescriber, however key differences existed regarding the reasons as to why a physiotherapist would be unlikely to choose to train as a prescriber. Registered physiotherapists recognised that prescribing might not enhance their individual roles especially if they already work closely with a prescriber or in a non-clinical role. They also worried about the practicalities of training to become a prescriber, noting additional stress and costs. The student physiotherapists focused on the increased clinical responsibility without enhanced remuneration, with some students recognizing potential deficits in their knowledge that would limit their ability to complete a non-medical prescribing course successfully. Decision makers using the results from this study when planning for the future should acknowledge these similarities and differences, integrating all viewpoints to ensure the success and longevity of the profession into the future.
2. Along with your revised manuscript, please include a copy of the STROBE checklist indicating the page/line numbers of your manuscript where the relevant information can be found (https://strobestatement.org/index.php?id=strobe-home)	Completed and attached.
3. Please check the numbers in the results section as some of the numbers do not add to a total of n=526 total participants (e.g., table vs results reported in the main text on page 6).	The numbers in the results section have been checked and the typographical errors edited.

4. Did the total n (i.e., total number of questionnaires analysed) change depending on the type of analysis done? Please check the percentages reported in the results as some may not be accurate if the overall n was always 526.	Thank you for your question. n=526 participants were included when the analysis included all respondents. In the analysis where a positive or negative orientation was received in the prior question, the total (n) of the positive or negative answer was used for analysis (e.g. motivators to becoming a prescriber was only asked of those who stated that they wanted to become a prescriber. This was built into the logic of the online questionnaire). The percentages have been checked and are accurate and did not require editing.
Reviewer 1	
P3/24, line 27 should read "parity" not parody P5/24 line 30 "disseminated" not deiminated p13/24 line 48 "in turn" not intern	Thank you for spotting these errors within the manuscript. As recommended, they have all be corrected.
P4/24 Are all students required to be members of APA or is this optional and if so, what is the take up rate?	All physiotherapy students in Australia are registered by their University with AHPRA. Membership of the APA is free for students but is optional. APA membership is advertised during University orientation sessions. n=6973 students were members of the APA at the time of recruitment. This figure has been added to the text and referenced Page 4: *'Student members (n=6973) of the Australian Physiotherapy Association (APA) also received the advertisement via the APA's electronic-communications.*[321]*'*
Data collection period 01.03.17-30.04.17 is this significant? term time or recess time? Does it potentially influence participation rate?	Data collection was specifically commenced during term time to aid in recruitment. This has been clarified in the text (page 4): *'Data collection took place between 1st March - 30th April 2017 during university term time to facilitate recruitment, utilising online survey software, Qualtrics (Qualtrics, Provo, UT)* [185]*.'*

Is the Questionnaire attached as an Appendix in the format intended?	Thank you for your question. The questionnaire is purposefully attached in the format required for use within the online survey software, Qualtrics to facilitate transparency and reproducibility.
Reviewer 2	
Thank for the opportunity to review this paper. This subject area is interesting and highly topical across many of the allied health professions in Australia. The paper is well written and provides informative insight from future practicing physiotherapists regarding the inclusion of the ability to prescribe medicines within the physiotherapist scope of practice in Australia.	Thank you for your comments and feedback.
Page 6 lines 11-12 and Page 13 lines 39-41 state that students at universities from all the states and territories in Australia were represented. However, Table 1 demographic data indicates that there were no survey respondents from Northern territory or Tasmania. The authors need to please clarify or amend these statements.	No physiotherapy courses existed at the time of data collection in Northern territory or Tasmania. This has been clarified in the text: Page 6: *'All States and Territories with at least one university offering an entry-level physiotherapy programme were represented (no physiotherapy programmes existed in the Northern Territory or Tasmania at the time of data collection).'* Page 13: *'However, age and gender demographics were characteristic of the greater student physiotherapy population in Australia, [205] with students at universities across all states with pre-registration physiotherapy programmes represented'*

Page 6 line 50: The potential increased safety risk is listed as 31%, however on Figure 1 this is listed as 32.9%. Does that the potential increased safety risk percentage on line 50 need to be amended to be more accurate with the result listed in Figure 1?	Thank you for spotting this error in the text. This has been edited to 33% (nearest whole number).
The authors need to acknowledge (in the Strengths and limitations section) that since only a small number of study participants contributed to the thematic results, these should be interpreted as only an indication of what the study participants reported, rather than any implication of being characteristic of the study population.	Thank you for your comment. Following the addition of information about the results of registered physiotherapists from the greater study, as requested by other reviewers/ editors the following statement has been added for clarity (page 13): *'Due to the small number of study participants contributing to the qualitative data, the transferability of the thematic analysis may be limited. However, the themes agreed with those identified in the registered physiotherapist population, strengthening the likelihood of good transferability.'*
Reviewer 3	
The paper brings a very interesting question for the current physiotherapy profession and health care system in Australia. The questions are far clear enough and well addressed on the methodological approach. The results reflect the rigors of the methodology and the limitations of the research are appropriately stated. This work seems unique in the current base of knowledge and is relevant at addressing questions and pointing out solutions. Results are well described, and the discussion are aligned with them. Discussion covers concerns of the NMP literature as related to que objectives of the research. It also opens room for further issues to be took into consideration for policy- and decision-makers and give future researches a direction to take. Ethical norms were obeyed appropriately. I am happy to recommend this important contribution to be accepted for publication.	Thank you for your comments and recommendation.

Reviewer 4	
The paper does not reflect the reporting of these data as a component of the results from a national survey investigating perceptions of physiotherapists registered with the Australian Health Professionals Registration Authority and student physiotherapists enrolled in any accredited Australian university physiotherapy programme about non-medical prescribing. Therefore, the questionnaire found in Supplementary file 1 requires explanation as questions relate to both groups of participants.	Thank you for your comments. We have added the following text to clarify that the data reported in this article is only part of the larger data collected. *'This article reports the data collected from student physiotherapists within a larger study evaluating the views and perceptions of Australian physiotherapists and physiotherapy students about the potential implementation of physiotherapist prescribing in Australia.*[178]*'* We have clarified that the questionnaire was used across the greater study, however the inbuild logic enabled direction of the student physiotherapist only to the questions concerning them. This logic is specifically included in the supplementary file for transparency and reproducibility. *'A short, context specific questionnaire taking 5-10 minutes to complete was designed to maximise recruitment and minimise bias.* [79 185 187] ***For transparency and reproducibility, a full version of the questionnaire including inbuild logic is found in Supplementary File 1.*** *Questions were formulated from findings of a mixed methods systematic review evaluating the barriers to and facilitator of NMP, identifying personal and professional factors that could influence the implementation.* [163] ***Student physiotherapists were directed via inbuild logic, to the specific questions designed to evaluate their views.'***

There is significant repetition of data presented in the text and figures. Better integration of figures and text would improve this manuscript. For example, if the authors wish to retain the bar chart in figure 2 showing how likely students are to want to train as prescribers, it would be sufficient to state in the text that four hundred and forty-three participants (91%) stated that were extremely likely or somewhat likely to want to train as non-medical prescribers.	Thank you for your feedback. Further editing of the transcript has occurred in line with the editorial team/ reviewers' comments. We have aimed to ensure clarity and transparency, alongside ease for the reader.
MINOR COMMENTS:	
Page 4, line 56: Could the authors state the proportions of student physiotherapists in the pilot sample?	This detail has been added as per request. *'Pilot testing using a purposive sample of registered and student physiotherapists (Total n=10, registered physiotherapists n=7, student physiotherapists n=3) was utilised…….'*
Page 5, lines 8-9: 'Computer password protection … were utilised to protect all electronic data'. The construction of this sentence is not clear to the reader.	This sentence has been reworded to read: *Computer password protection and coding of any disclosed personal details within data-files, were utilised to protect all electronic data produced.* For reader clarity.
Page 5, line 30: '…will be deiminated through publication...'? typographical error	Corrected as per recommendation.

Page 6, Table 1: There is no student representation from the Northern territory or Tasmania in Table 1. Could the authors clarify how this relates to the sentence on line 11 - 'All states and territories with at least one university offering an entry-level physiotherapy programme were represented'?	As per reviewer 2: No physiotherapy courses existed, at the time of data collection, in Northern territory or Tasmania. This has been clarified in the text: Page 6: *'All States and Territories with at least one university offering an entry-level physiotherapy programme were represented (no physiotherapy programmes existed in the Northern Territory or Tasmania at the time of data collection).'* Page 13: *'However, age and gender demographics were characteristic of the greater student physiotherapy population in Australia, [205] with students at universities across all states with pre-registration physiotherapy programmes represented'*
Page 10: Risks and responsibilities: Would the authors consider including the numbers of participants that commented about the burden of responsibility and the wish for remuneration of physiotherapists as autonomous prescribers?	Thank you for your comment. Following consideration and discussion with the author team and methodological experts at the University of Birmingham we have decided not to include the number of participants that commented about specific elements of the themes within the thematic analysis, as this may create a hierarchy within the evidence that the study is unable to validly support. This decision fits with the thematic analytical approach, which aims to synthesise the qualitative evidence, enabling the identification of significant themes within an iterative and organised, analytical framework. It is acknowledged that the iterative nature makes thematic analysis hard to define, as the analysis may be a combination of descriptive and interpretive, with analysis being structured towards themes of a high explanatory value, as well as those with a higher frequency, being acknowledged as the prominent influential factors [107 108]. The themes/sub-themes were scrutinised by a panel of experts to agree findings to ensure rigor and transparency.

Page 13, line 26: Could the authors add: This is the first study investigating perceptions of student physiotherapists about physiotherapist prescribing.	Thank you for your comment, this has been edited as per your recommendation.
Page 13, lines 47-19: Could the authors clarify the sentence 'The students recognised …improvements for patients and inter, health services'	Following an issue with autocorrection, this sentence has been clarified to read: *'The students recognised the benefits to all stakeholders, highlighting improvements for patients and in turn, health services.'*
Page 18 - Figure 1: The legend relating to the chart about the potential benefits of prescribing reads "% Percentage of participants identifying benefit that identified each benefit". This is not clear.	Think you for your insight. Following deliberation within the team and consultation with physiotherapists, the current legend was deemed to be clear in the context of the figure, and therefore remains un-edited.
References – formatting is inconsistent.	The transfer between computer programmes had changed the formatting. This has been re-edited and will not affect the published article.

8.21 Appendix 21: Article, BMJ Open, Independent prescribing by advanced physiotherapists for patients with low back pain in primary care: protocol for a feasibility trial with an embedded qualitative component

Noblet T, Marriott J, Rushton A. Independent prescribing by advanced physiotherapists for patients with low back pain in primary care: protocol for a feasibility trial with an embedded qualitative component. BMJ open 2019;9(4): e027745

BMJ Open

Independent prescribing by advanced physiotherapists for patients with low back pain in primary care: protocol for a feasibility trial with an embedded qualitative component

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ABSTRACT

Introduction Low back pain (LBP) is the most prevalent musculoskeletal condition in the UK. Guidelines advocate a multimodal approach, including prescription of medications. Advanced physiotherapy practitioners (APPs) are well placed to provide this care in primary care. Physiotherapist independent prescribing remains novel, with the first prescribers qualifying in 2014. This feasibility trial aims to evaluate the feasibility, suitability and acceptability of assessing the effectiveness of independent prescribing by APPs for patients with LBP in primary care, to inform the design of a future definitive stepped-wedged cluster trial.

Method and analysis (1) Trial component. An APP (registered prescriber) will complete the initial participant consultation. If prescription drugs are required within the multimodal physiotherapeutic context, these will be prescribed. Patient-reported outcome measures will be completed prior to initial assessment and at 6 and 12 weeks to assess feasibility of follow-up and data collection procedures. Accelerometers will be fitted for 7 days to assess physical activity, sedentary behaviour and feasibility of use. (2) Embedded qualitative component. A focus group and semistructured interviews will be used to evaluate the views and experiences of the participants and APPs respectively, about the feasibility, suitability and acceptability of the proposed full trial. A Consolidated Standards of Reporting Trials diagram will be used to analyse feasible eligibility, recruitment and follow-up rates. Descriptive analysis of the data will be completed to evaluate procedures. Thematic analysis will be used to analyse and synthesise the qualitative data.

Ethics and dissemination This feasibility trial is approved by the Health Research Authority (HRA). Ethical approval was sought and granted via the Integrated Research Application System (IRAS) ID 250734. Data will be disseminated via publication in peer reviewed journal and conference presentation. It is anticipated that the results of this study will be used in conjunction with ethical evaluation, economic and risk analyses, as well as consultation with key stakeholders including the British health consumer when contemplating change, enhancement or redesign of the essential full randomised controlled trial.

Trial registration number ISRCTN15516596, Pre-results.

Strengths and limitations of this study

- First rigorous investigation aiming to evaluate the methods required to assess the clinical and cost-effectiveness of independent prescribing by advanced physiotherapists for patients with low back pain in primary care.
- The design of this feasibility trial was developed by clinicians, academics, methodological experts, healthcare service managers, professional leaders and the public/patients.
- The methods will be tested across a range of cities, towns and villages in varying geographical areas across England.

BACKGROUND

Low back pain (LBP) is the most prevalent musculoskeletal condition in the UK, with 58%–84% of the population experiencing LBP in their lifetime.[1–3] At any time, 28.5% of adults >25 years are experiencing LBP.[2] Data indicate that 3.2 million work days are lost per year in the UK, with an average of 16.5 days lost per case.[4] Approximately 20% of those with LBP seek care from their general practitioner (GP),[1] with 7% of all GP consultations being due to LBP.[3 5]

Despite increased funding for treatments and a growing understanding of the complex biopsychosocial nature of LBP leading to improvements in assessment and management of the condition, up to 7% of the general population in the UK have chronic LBP associated with significant disability[1 2] and the health and function of this demographic continues to decline.[6] In an attempt to address this, novel approaches have been adopted to inform shared decision-making, and stratification tools are being used to improve outcomes through recognising clinical heterogeneity, ensuring that

all biopsychosocial risk factors are addressed, improving patient management and reducing the overall cost of healthcare.[6–8] Early assessment, diagnosis and treatment of LBP has been seen to reduce chronicity.[1] However, the complex and multidimensional nature of LBP combined with a current deficit in the availability of GPs in the UK[9 10] has prompted the redesign of outdated traditional LBP clinical pathways, and the introduction of new treatment models designed to maximise clinical and cost-effectiveness, while readying the health services for the future.[10–12]

Physiotherapists are experts in the assessment, diagnosis and treatment of musculoskeletal disorders.[13] For >30 years, physiotherapists have been working in advanced practice roles across the country, using their scope of practice to optimise patient care, providing support in health services where the availability of medical practitioners does not meet the demands of a local community.[13 14] Advanced musculoskeletal physiotherapists have been shown to be clinically and cost-effective when working in a variety of settings including orthopaedic and emergency care departments as well as in primary care in musculoskeletal interface services.[14–16] Recently, the success and experience of these practitioners, alongside changes in demographics and predictions that GP numbers will further reduce by 2020, have prompted successful pilot studies investigating the effectiveness of first contact advanced physiotherapy practitioners (FCPs) in primary care.[11 17] As a result, Health Education England, in collaboration with NHS England, the Royal College of General Practitioners (RCGP), the British Medical Association and the Chartered Society of Physiotherapy have committed to introducing these roles across England.[17–19]

Recently published guidelines from the National Institute for Health and Care Excellence (NICE)[8] for LBP and sciatica, advocate for a holistic, multimodal approach to assessment and management.[3] Advanced physiotherapists are well placed to provide this care owing to their competency in physical therapies including manual and exercise therapy; knowledge and skills associated with the management of psychosocial factors and ability to appropriately refer for blood tests, imaging, spinal injections, denervation and surgery.[20 21] Further, the NICE guidelines recommend the use of drugs that are helpful and minimise harm.[3 8] It is therefore envisaged that independent physiotherapist prescribing will be a key competency required for the successful implementation of first contact advanced physiotherapists working in primary care.

Independent physiotherapist prescribing remains relatively new, with the first prescribers qualifying in 2014. Evaluation of physiotherapist and podiatrist independent prescribing has shown good acceptance by patients and a good safety record to date.[22] A recent mixed-methods systematic review of investigating the barriers and facilitators of non-medical prescribing (NMP) concludes that the successful implementation and utilisation of NMP is dependent on adequate preparation and organisation of a range of factors.[23] Considerations such as the use of advanced physiotherapists in primary care were seen to facilitate successful implementation of NMP as long as clinical governance, policy development and service practicalities and logistics are adequately developed and established prior to implementing NMP. To ensure longevity and future growth, education, support and financial factors alongside the management of personal and professional considerations were also deemed paramount.[23]

For clinical services to be successful, they must deliver positive clinical outcomes in a safe and economically sound manner.[24] Our recent rigorous systematic review investigating the clinical and cost-effectiveness of NMP across all professions and clinical settings, identified limited evidence with unclear risk of bias.[25] We concluded that quantifiable benefits of NMP remain unknown and called for adequately powered, low risk of bias randomised controlled trials (RCTs) in specific patient groups, professions and clinical settings.[25] Owing to the contemporary nature of independent physiotherapist prescribing, no trial has examined the clinical or cost-effectiveness of this intervention in the complex context of LBP. Trial design required careful consideration, particularly, as independent physiotherapy prescribing is within the process of implementation across private health services and NHS Trusts. A feasibility study is therefore required to inform a multicentre RCT investigating physiotherapist independent prescribing by advanced physiotherapists for patients with LBP, in primary care. The project will aim to evaluate the feasibility, suitability and acceptability of procedures and outcomes for use in the full trial, also assessing the commitment and burden on participants, clinicians and researchers as well as infrastructure and technological requirements.

AIM

To evaluate the feasibility, suitability and acceptability of assessing the effectiveness of independent prescribing by advanced physiotherapy practitioners (APPs) for patients with LBP in primary care to inform the design of a future definitive stepped-wedged cluster trial.

OBJECTIVES

General objectives

- To assess the feasibility, suitability and acceptability of the proposed full trial[26] including the following:
  - Eligibility criteria.[27–29]
  - Recruitment strategy.[27–29]
  - Data collection methods.[27–29]
  - Follow-up procedures.[27 28]

Specific objectives

Feasibility

- To evaluate participant recruitment rates.[26–28]
- To evaluate the ease of fitting participants with accelerometers and ease of data collection.[27 28]

- To evaluate the capacity (time and effort) of clinicians and researchers to complete trial-related tasks.[27 28]
- To evaluate the necessary training required by clinicians to successfully implement a full trial.[27 28]

Suitability

- To evaluate the range of participants' scores on the Roland and Morris Disability Questionnaire (RMDQ), assessing for floor effects and therefore the appropriateness of outcome measure for use in a full trial.[28–29]
- To evaluate participant compliance with wearing the accelerometer device.[27 28]
- To evaluate the time required to conduct each stage of the protocol.[27 28]
- To evaluate the appropriateness and availability of services and infrastructure such as access to national and institutional communication and information technologies required to undertake a full trial.[27 28]

Acceptability

- To evaluate the acceptability of the intervention to patients and the public.[26–29]

METHODS

To ensure transparency and reproducibility, this feasibility trial protocol has been registered on the ISRCTN database and is reported in line with the CONSORT 2010 statement: extension to randomised pilot and feasibility trials,[30–32] with all patient and public involvement (PPI) reported in line with the GRIPP2 short form reporting checklist.[33 34]

The feasibility trial will use a mixed-methods research approach, comprising the following:

- A quantitative one-armed feasibility trial.
- Qualitative semistructured interviews and patient focus groups, using thematic analysis.

Mixed-methods designs are recognised to enable a richer synthesis, generating data that will facilitate appropriate change.[35–37]

Design

RCTs are considered the gold standard for evaluating the effectiveness of an intervention.[38] Cluster RCTs (cRCTs) allowing for randomisation by group have been developed to overcome practical issues in clinical settings, where individual randomisation is not convenient or feasible.[38–40] When evaluating contemporary interventions, parallel deigns requiring the new intervention to be simultaneously provided to multiple clusters of participants are often too costly or not practical owing to the necessary clinician training required to deliver the intervention safely.[38 39] A stepped-wedge cluster randomised controlled trial (SWcRCT) design will therefore be used to evaluate the clinical and cost-effectiveness of physiotherapist prescribing for LBP in the future. This design is valuable when evaluating innovative clinical interventions where there is a strong ethical belief that the intervention will benefit patients.[39 41 42] SWcRCTs allow each experimental cluster to begin in the control arm then cross over to the experimental arm at specified time points (figure 1).[41] As the implementation of independent physiotherapy prescribing and the utilisation of APPs working as FCPs are both relatively contemporary innovations, there are limited numbers of clinicians currently working in these innovative roles who are registered to prescribe. This research design allows for the use of fewer clinicians than those required for a parallel design and is therefore more reflective of current practice. APPs who are not prescribers will start in the control group and cross to the experimental group following registration as an independent prescriber. APPs who are not prescribers start in the control group and cross to the experimental group.[39–42]

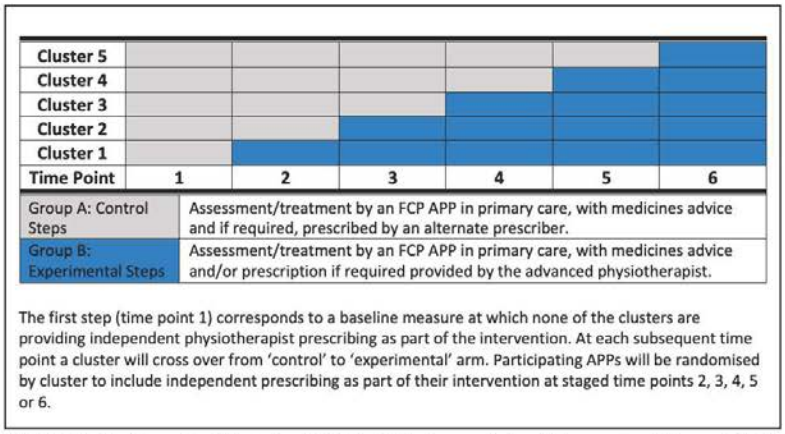

Figure 1 The SWcRCT design for potential use in a full trial. APP, advanced physiotherapy practitioner; FCP, first contact advanced physiotherapy practitioner; SWcRCT, stepped-wedge cluster randomised controlled trial.

Currently, no clear framework exists describing the requirements for best practice when completing feasibility trials in preparation for SWcRCTs.[43] Two-arm feasibility trials that have aimed to calculate intracluster correlation coefficients required for sample size calculations in preparation for full cRCTs have demonstrated insufficient accuracy, unless the feasibility trial is equal in size to the proposed full trial.[43] Therefore, a single-arm feasibility design will be employed to test specific aspects of the trial protocol in terms of feasibility, suitability and acceptability on the experimental arm of the future SWcRCT, without sample size estimation.[27 44 45]

Trial component

A prospective, mixed-methods, single-group feasibility trial will be used to evaluate the trial objectives.[29 44] Participant consent forms (online supplementary file 1) and patient-reported outcome measures (online supplementary file 2) will be completed digitally via an online survey at initial assessment (baseline) and at 6 and 12 weeks (12 weeks is the planned primary end point of the definitive trial) following a prescription being issued, to evaluate the feasibility of follow-up data collection procedure.[45 46] Follow-up time points have been selected in line with the prognostic literature showing that 40% of patients presenting to primary care with LBP will be pain-free 6 weeks post onset, with 58% pain-free by 12 weeks.[47–49] The online outcome measures survey will be built using REDCap (Research Electronic Data Capture) software (hosted in the Centre for Precision Rehabilitation for Spinal Pain [CPR Spine] at the University of Birmingham, UK), enabling data to be captured and stored in real time, on a range of electronic devices.[50] Baseline measurements will be completed by the participants within the clinical setting. A link to the online outcome measures survey with instructions will be emailed to participants for completion at 6 and 12 weeks. If participants forget to complete the outcome questionnaire on the required day, a reminder to complete it will be sent at 24 and 48 hours after the deadline to facilitate compliance.[45 51] To evaluate the feasibility of fitting participants with accelerometers in clinic, the ease of data collection and participant compliance with wearing the accelerometer device,[27 28] n=10 participants at one research site will be fitted with an accelerometer to wear for 7 days immediately following completion of patient-reported outcome measures at the first consultation. Participants will be provided with stamped/addressed envelopes in which to return the devices after use.

Participants

Potential participants will be identified by the APPs at each clinical site, by using the STarT Back Tool at initial assessment, to stratify all patients presenting with LBP.[7] Patients stratified into the medium risk group by the STarT Back Tool will be eligible for recruitment if they meet the inclusion criteria following assessment (box 1). This group of patients have been recognised as predominant cohort presenting for assessment and treatment of LBP in primary care; exhibiting both physical and psychosocial prognostic factors and may require physiotherapist prescribing to optimise their multimodal physiotherapeutic treatment.[7 52–54] Convenience sampling will be adopted, as this method has the advantages of fluid recruitment and follow-up required by feasibility trials, with good retention of participants where time is limited.[28 45 46 55] Patients who are interested in participating will be provided with a participant information sheet (online supplementary file 3) explaining the rationale, content and research dissemination plans to ensure ethical recruitment of participants. The physiotherapist will answer any questions and if the patient wishes to participate, consent will be obtained using an online consent form. Contact details for the research team will be provided to give the participants the opportunity to have any further questions answered. Contact details for an independent advisory service (PALS at each site) will also be provided in case external advice is desired by participants. Participants will be free to withdraw at any time, without any impact on their care.[45 46]

Box 1 Participant eligibility criteria

Inclusion Criteria

- Male and female patients, aged >18 years.
- Non-specific LBP with or without leg pain requiring medication advice and drug prescription on assessment.
- Classified as moderate risk using the STarT Back Tool (classified as potentially benefiting from medicines and active physiotherapy treatment[7]).
- Able to read/communicate in English (owing to funding restrictions for interpreters and translators).
- Capable of following the demands inherent of the study.

Exclusion Criteria

- Signs of lumbar nerve root compression.[82]
- Red Flags including potential spinal fracture, inflammatory disease, infection or malignancy.[82]
- Spinal stenosis.[83]
- Suspicion of or confirmed cauda equina syndrome.[84]
- Does not have capacity to consent.[85]
- Unable to receive email and/or complete online questionnaires.

LBP, low back pain.LBP, low back pain.

Interventions

As the control arm of the definitive trial will be 'current normal practice', the intervention designed for the experimental arm of the definitive trial will be used to evaluate the feasibility trial objectives.[26–29] As per 'current normal practice', an APP acting as an FCP will complete the initial assessment and physiotherapeutic treatment of participants as deemed appropriate through evidence-based clinical reasoning and best practice (traditional role). In addition to the physiotherapist's traditional role, the APP will have the competence and legal ability to prescribe medicines independently. If advice about medication or prescription drugs are required/no longer required

Table 1 Secondary outcome measures and their rationale

Outcome	Measure	Rationale
Health-related quality of life (QALY)	EQ-5D 5 L	The EQ-5D 5 L is used to measure health-related quality of life demonstrating good reliability and validity through psychometric testing.[86] If feasibility is found, this measure will inform cost utility in a full RCT.
Pain-related fear of movement	The TSK	The TSK is a 17-item tool that was developed to measure a person's fear of movement owing to LBP. Ongoing fear of movement has been linked to the development of long-term persistent pain.[87] This outcome measure has been found to show good validity and reliability when measuring pain-related fear of movement.[88]
Physical activity and	ActivPal 3 Accelerometer	Anecdotal evidence suggests that decreasing sedentary behaviour in people with LBP may have significant health benefits,[53] reducing risks of obesity, metabolic syndrome, type 2 diabetes and mortality.[89] Systematic reviews have revealed that physical activity of people with LBP is lower or equal to the healthy population[90–92]; however, there appears to be differing patterns of physical behaviour, with the back-pain population engaging in shorter bouts of physical activity that are not long enough to incur health benefits (>10 min).[92 93] An accelerometer will be used to collect data including steps count and sedentary periods.[94] To date, no individual brand/model of accelerometer has been identified as gold standard. The ActivPal 3 has been selected for use in this feasibility trial as it has been seen to be more precise and sensitive than other accelerometers.[94 95]
Sleep	ActivPal 3 Accelerometer	50%–60% of people experiencing either acute or persistent LBP experience high levels of sleep disturbance.[96] Poor sleep over long periods of time may lead to depression, obesity, diabetes and cardiovascular disease.[96 97] Patients with LBP suffering with sleep disturbance have been reported as twice as likely to be hospitalised.[98] Improved sleep has been seen to modulate pain intensity,[99] with poor quality sleep associated with increased pain intensity, fatigue, decreased function and psychological stress. An accelerometer will be used to collect sleep duration data alongside physical activity and sedentary behaviour.[100]
Time to return to work and nature of return to work (eg, full time, part time and light duties)	Days	Work absence owing to sick leave for work disability is a key issue clinically, socially and economically. The minimally clinically important change (MCIC) for time to return to work has not been defined due to the specific measurement (days on sick leave) being widely accepted and recognition of the measure's value in social and economic issues rather than an indicator of morbidity.[82] This measure would therefore be useful when conducting economic evaluation of physiotherapist prescribing.
Prescription utilisation, participant	Days	Time requiring drugs for the treatment of non-specific LBP discussed/prescribed by the advanced physiotherapists will be monitored to evaluate the necessity of this measure for future cost-effectiveness analysis within a full trial.
Number of appointments with other healthcare professionals about this episode of LBP	Number of appointments with each type of healthcare professional	The number of appointments with other healthcare professionals about the specific episode of LBP being studied will be recorded via a question in the outcome questionnaire to evaluate the necessity of this measure for future cost-effectiveness analysis within a full trial.

within the multimodal physiotherapeutic context, these will be prescribed/de-prescribed by the APP immediately, rather than referring the patient back to their GP for assessment for medications as per current normal practice. The medications provided should be taken by the patient as prescribed in the time frames discussed in the clinical consultation.

Outcomes

The literature reports that the use of a core outcome set assessing pain intensity, health-related quality of life and physical function is required for the assessment of non-specific LBP.[56] However, no consensus exists with regards to the instruments most suitable to measure these domains.[56] The outcome measures selected for use within the trial were informed by a team of subject-experts including physiotherapists, pharmacists, medical practitioners, academics and health-service managers and deemed most appropriate to evaluate the study's objectives while attempting to minimise the burden on participants. Two primary outcome measures (detailed below) were selected as they jointly evaluate the core outcome set requirements.[56] Details of the secondary outcome measures and rationale for selection are found in table 1.

Primary outcome measures

- Overall pain, Numerical Rating Scale (NRS): The NRS is a unidimensional 11-point scale (0–10) used to measure pain intensity, where 0 represents no pain and 10 represents maximum pain (eg, the worse pain you can possibly imagine).[57] Patients with pain have been shown to prefer the NRS over other pain measure including the pain Visual Analogue Scale owing to simplicity and clarity.[57 58] The NRS has demonstrated good reliability, validity and responsiveness and has been used extensively in pain research.[59–61] A reduction of 2.5 points on the NRS has been shown to be clinically important for chronic LBP.[60–62] Participants will score pain in three categories: 'worst pain over the last 2 weeks', 'least pain over the last 2 weeks' and 'average pain level today'.
- RMDQ: The RMDQ is one of the most widely used outcome measures for LBP, with well-established good levels of validity and reliability.[63] The RMDQ has

been selected over its counterparts owing to its superior measurement properties in patients reporting moderate disability demonstrated by those stratified into the medium risk group by the STarT Back Tool.[7 62 63] The 24-item questionnaire takes approximately 5 min to complete and includes items assessing physical activity, sleep, psychosocial factors, activities of daily living, appetite and pain.[64] Scores range from 0 (no disability) to 24 (maximum disability), with a change of 3.5 points deemed clinically significant.[62]

Sample size

As the number of FCP physiotherapists that are registered to prescribe is currently limited,[65] three first contact APPs (n=3), across three primary care sites representative of English geography (x1 capitol city, x1 regional city, x1 rural town), will recruit, assess and treat n=10 participants per APP, to enable the evaluation of recruitment rates across clinicians and the feasibility of the trial methods in both metropolitan and rural healthcare services.[27 43 44] This feasibility trial does not aim to estimate the sample size required for the full trial as feasibility trials for cRCTs have been shown not to adequately predict sample size, therefore large numbers of participants are not required.[43 66] A total sample of n=30 patients will be recruited as a sample size of n>20 is regarded as adequate when testing feasibility objectives for cRCTs.[27 28 43 44] This allows for some loss to follow-up of participants.

Data analysis

A CONSORT diagram will be used to describe the flow of participants and lost to follow-up rates. This will be used to analyse feasible eligibility, recruitment and follow-up rates.[30] Only data from fully completed outcome questionnaires will be included in the data analysis; however, the number of partly completed outcome questionnaires will be noted and reasons for this explored in the embedded qualitative component of the trial. Data will be tabulated, and primary descriptive analysis of the data will be completed to test procedure.[27 45 46] Causality will not be statistically analysed as this is not within the scope of this feasibility trial.[45 46] The distribution of the scores on the RMDQ will be evaluated at baseline, 6 and 12 weeks following initial intervention. The percentage of scores equalling 0/24 at 12 weeks will be used to measure a potential floor effect.[67]

EMBEDDED QUALITATIVE COMPONENT

Design

An embedded qualitative component will be used as recommended by current guidance, to address trial objectives and to refine and adapt the proposed full trial design following evaluation.[68 69] The methodology was designed and is reported using the Consolidated Criteria for Reporting Qualitative Health Research.[70]

Advanced physiotherapy practitioners

Semistructured in-depth face-to-face interviews with all of the APPs (n=3) will be used to evaluate their views and experiences about the feasibility, suitability and acceptability of the trial, specifically evaluating trials objectives.[26–29 71 72] Interviews will be undertaken by one researcher (TN) following completion of participant data collection, to evaluate the research objectives and to gather qualitative data regarding the participants' views, perceptions and experiences about taking part, future risks and how the trial might be improved.[27 28] Question design was informed by the methodological literature and developed by a team of experts in the fields of physiotherapy, primary care, NMP, health policy and trial methodology.[45 55] A patient and public involvement group reviewed the questions for appropriateness and clarity.[73] Prior to completing the interviews, the APP participants will be provided with an information sheet and will have the opportunity to ask the researcher any questions about the interview process. Consent to taking part will be gained using a consent form. Interviews will be recorded and transcribed verbatim. Transcripts will be returned to participants for inspection, comments and corrections prior to analysis, to ensure all views and thoughts are captured.[71]

Patients

A focus group of patients will take place following the 12 weeks assessment point, specifically to evaluate the research objectives.[27 74] Focus groups are recognised to produce data on collective views, generating a rich understanding of participants' experiences.[75] A purposive sample of six to eight patients, representative of ages and sexes will be used; this sample size is reported in the literature as the optimum.[74] The focus group will meet in the qualitative laboratory within the CPR Spine at the University of Birmingham, UK, ensuring confidentiality. The focus group will be conducted by two researchers (facilitator and observer) using a predetermined topic guide designed to assess the research objectives, developed by a team of experts in the fields of physiotherapy, primary care, NMP, health policy and trial methodology and informed by the methodological literature.[45 55] The topic guide has been reviewed by a patient and public involvement group to ensure appropriateness and clarity.[73] Consent to participate in the focus group will be taken prior to the focus group commencing. The participants will receive an information leaflet and have the opportunity to have any questions answered by the researchers. The focus group will be recorded and transcribed verbatim. Transcripts will be returned to participants for comments/correction to ensure all views are represented.[70]

Analysis and findings

To fulfil the trial objectives, a thematic analysis approach will be used to analyse and synthesise the qualitative data.[45 76 77] This systematic, inductive and interactive

method is recognised to be useful in identifying the key thoughts and views of the population being studied. The method is useful where there are likely to be both similarities and diversity of opinion and where the intervention is novel, often providing explanations alluding to how the concerns may be resolved or processed in preparation for a full trial.[76–79] Focus group and interview transcripts will be coded line-by-line using NVivo 11 software (QSR International, Melbourne, Australia) by one researcher (TN) and be verified by a second researcher (AR).[46 77 78] Rigorous comparative analysis will be completed by one researcher (TN) to identify similarities and differences within the data, informing the development of descriptive categories which will be linked, merged or split to synthesise a conceptual understanding of the data.[77 78] To avoid single researcher bias, a second researcher (AR) will re-interrogate the data to validate or contradict findings.[77] Outcomes will then be discussed with a panel of experts for confirmation and agreement.[76 77 79]

Integration: feasibility, suitability and acceptability

Following data analysis of the trial and embedded qualitative components, the quantitative and qualitative data will be assessed against a success criterion outlined a priori (table 2). The predetermined success criteria were developed by a team of experts in the fields of physiotherapy, primary care, NMP, health policy and trial methodology and informed by the methodological literature.[45 55 80] Trial objectives will be considered successful if the success criteria are satisfied following the integration of the quantitative and qualitative findings.[80]

Patient and public involvement

Patients with LBP are part of our research team/co-investigators to ensure that the patient perspective is central. There is a PPI representative on both the Trial Management Group and Trial Steering Group to ensure that patients and the public are involved at all steps in the research process.

Patients have contributed to the development of the interview/focus group questions, participant information sheet, consent form, and importantly to the processes of data analysis and interpretation and producing a lay summary of findings. They have reviewed this protocol and have helped to ensure that their involvement is fully considered.

Data storage

All data will be electronic and stored in password-protected computer files that can be accessed only by study investigators at the University of Birmingham. Participants who choose to disclose personal details will be additionally protected via coding on data files. This coding will be kept in a password protected computer file on the University of Birmingham server, only accessible to the research team ensuring confidentiality.[45 81] These personal data and participant contact details (stored during study to arrange focus groups and interviews) will be securely

Table 2 Success criteria

General objectives	Success criteria
Eligibility criteria	A favourable number of patients fit the eligibility criteria to enable the stipulated recruitment rate
	APPs agreed with the eligibility criteria
Recruitment strategy	Participants were recruited within the time constraints of the local clinical environment
	Patients and APPs report that they were happy with the recruitment strategy
Data collection methods	Data were collected with ease via REDCap and no complications were experienced
	Data completeness of ≥80%
	Patients and APPs report that they were happy with the data collection methods
Follow-up procedures	100% of participants were contacted for follow-up
	≥80% completion of follow-up outcome measures
	Patients and APPs report that they were happy with follow-up procedures
Specific objectives	**Success criteria**
Feasibility	
Participant recruitment rates	Recruitment target of n=10 per clinician met in the time available (3 months)
Ease of fitting accelerometers	Accelerometers were fitted within the allocated clinical time allowed with the FCP APP
	Patients and APPs report that accelerometers were fitted with no issues
Accelerometer data collection	REDCap was able to capture the data from the accelerometers with no errors or data loss
	Patients report that they were happy with data collection using accelerometers/burden within subjectively appropriate limits
Capacity (time and effort) of clinicians' complete trial-related tasks	APPs report that adequate time was allowed to complete all tasks required by them during the trail
Training required by clinicians	APPs report that they had adequate training to be able to complete the tasks required by them during the trial
Suitability	
Outcome measures	Data completeness of ≥80%
	Patients and APPs report that the outcome measures were appropriate and self-explanatory
Compliance with wearing the accelerometers	Data collected ≥80% of the requested time (16 hours/day for 7 days)

Continued

Table 2 Continued

Specific objectives	Success criteria
Time required to conduct each stage of the protocol	APPs report having adequate time to complete each stage of the protocol
Service infrastructure	Recruitment targets met Data completeness of ≥80% APPs report that adequate service infrastructure is in place to allow for a full trial to be completed
Acceptability	
Intervention	Patients and APPs report that the intervention was appropriate/ satisfactory

APPs, advanced physiotherapy practitioners; FCPs, first contact advanced physiotherapy practitioners.

destroyed at the end of the study. No participants will be identifiable in data presentation or dissemination. The confidentiality of data will be preserved when the data are transmitted to sponsors and co-investigators by maintaining the de-personalised data format and ensuring that no data are traceable to an individual participant. The password-protected files will be retained for 10 years, in a confidential, locked storage unit, satisfying university code of practice.

ETHICS AND DISSEMINATION

Ethical considerations

The feasibility trial will be conducted in accordance with the principles of the Research Governance Framework for Health and Social Care. To ensure that the study is conducted in an ethical manner within best research practice, Health Research Authority (HRA) ethical approval was sought via the Integrated Research Application System (IRAS) ID 250734.[45 81] Approval was granted on 30 October 2018. Participants' inclusion within the study will be entirely voluntary, with no incentives offered to participants to minimise bias.[45 46] Participant consent will be gained using an online consent form following the provision of information explaining the rationale, content and research dissemination plans to ensure ethical recruitment of participants.[45 81] Participants will be free to withdraw at any time.[45 46]

Dissemination of findings

The study's findings will be disseminated via study reports, publication in academic peer-reviewed journals and conference presentations.[45 46] The results will be communicated to participants as a summary report written in lay language including key findings and plans for future research.

DISCUSSION

The results from this prospective, mixed-methods, single-group feasibility trial with an embedded qualitative component will serve to inform researchers about the feasibility, suitability and acceptability of the specific methods evaluated, in preparation for a full RCT to assess the clinical and cost-effectiveness of physiotherapist prescribing for LBP in primary care. Evidence is required by researchers, policy-makers and health-service managers to inform decisions regarding the selection of appropriate, rigorous, clinically safe and economically sound design of a robust, high-quality full RCT with low risk of bias. It is anticipated that the results of this study will be used in conjunction with ethical evaluation, economic and risk analyses, as well as consultation with key stakeholders including the British health consumer when contemplating change, enhancement or redesign of the essential full RCT.

Contributors TDN is a clinical advanced practice physiotherapist and PhD candidate at the University of Birmingham (UK). ABR is a reader in musculoskeletal rehabilitation sciences and lead supervisor. JFM is a professor of clinical pharmacy and co-supervisor. Both supervisors ensured the rigour of methods and analyses. All authors have contributed to the content of this article. TDN wrote the first draft of this article and has worked with all authors to develop subsequent drafts. All authors gave final approval prior to publication. Patients and the general public were involved in the design of this study via PPI evaluation groups.

Funding Health Education England funding has allowed for the procurement of accelerometers and the associated IT programmes to ensure that innovative physical measures can be evaluated alongside patient-reported outcome measures. The Private Physiotherapy Educational Fund has allowed for the procurement of x3 tablet computers for use in data collection and 7.5 hours per week of the principal investigators time for 18 months.

Competing interests None declared.

Patient consent for publication Not required.

Ethics approval This trial is approved by the Health Research Authority (HRA). Ethical approval was sought via the Integrated Research Application System (IRAS) ID 250734.

Provenance and peer review Not commissioned; externally peer reviewed.

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8.22 Appendix 22: CONSORT Checklist, Feasibility Trial

Section/Topic	Item No	Checklist item	Reported Yes/No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	Yes
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	N/A
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	Yes
	2b	Specific objectives or research questions for pilot trial	Yes
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	Yes
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	Yes
	4b	Settings and locations where the data were collected	Yes
	4c	How participants were identified and consented	Yes
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Yes

Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	Yes
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	N/A
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	Yes
Sample size	7a	Rationale for numbers in the pilot trial	Yes
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	N/A
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	N/A
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	N/A
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	N/A
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	N/A
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	Yes

Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	Yes
	13b	For each group, losses and exclusions after randomisation, together with reasons	Yes
Recruitment	14a	Dates defining the periods of recruitment and follow up	Yes
	14b	Why the pilot trial ended or was stopped	Yes
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Yes
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	Yes
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	N/A
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	N/A
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Yes
	19a	If relevant, other important unintended consequences	N/A
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	Yes
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	Yes
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and	Yes

		considering other relevant evidence	
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	Yes
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	Yes
Protocol	24	Where the pilot trial protocol can be accessed, if available	Yes
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Yes
	26	Ethical approval or approval by research review committee, confirmed with reference number	Yes

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CONSENT FORM: Person with Back Pain

Title of Project: Prescribing medications for low back pain by physiotherapists

Name of Participant: ……

Please initial box

1. I confirm that I have read and understand the information sheet, for the above study. I have had the opportunity to consider the information, to ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that all data will be confidential and securely stored for a period of 10 years. I understand that if I withdraw from the study my data up to the point of my withdrawal will be used in the analysis ☐
4. I agree to take part in the above study ☐
5. I agree to be contacted to take part in the focus group ☐

Name of Participant	Date	Signature
Name of Person taking consent (if different from researcher)	Date	Signature
Researcher	Date	Signature

8.24 Appendix 24: Outcome Measures Questionnaire

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Outcome Measures Questionnaire

Participant Questionnaire

Q1 What is your gender?

Male

Female

Other

Q2 What is your age?

17-29

30-39

40-49

50-59

60 or older

The Keele STarT Back Screening Tool

Patient name: _____ Date: _____

Thinking about the **last 2 weeks** tick your response to the following questions:

		Disagree 0	Agree 1
1	My back pain has **spread down my leg(s)** at some time in the last 2 weeks	☐	☐
2	I have had pain in the **shoulder** or **neck** at some time in the last 2 weeks	☐	☐
3	I have only **walked short distances** because of my back pain	☐	☐
4	In the last 2 weeks, I have **dressed more slowly** than usual because of back pain	☐	☐
5	It's not really safe for a person with a condition like mine to be physically active	☐	☐
6	**Worrying thoughts** have been going through my mind a lot of the time	☐	☐
7	I feel that **my back pain is terrible** and **it's never going to get any better**	☐	☐
8	In general I have **not enjoyed** all the things I used to enjoy	☐	☐

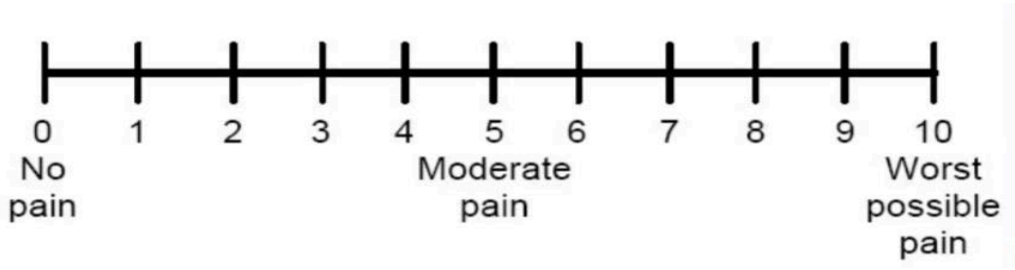
9. Overall, how **bothersome** has your back pain been in the **last 2 weeks**?

Not at all	Slightly	Moderately	Very much	Extremely
☐ 0	☐ 0	☐ 0	☐ 1	☐ 1

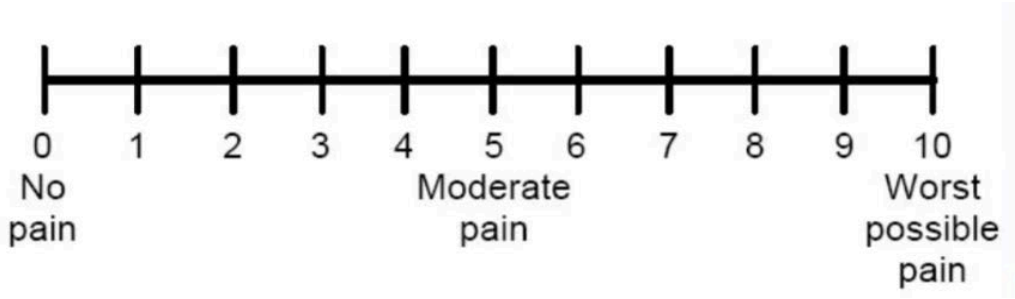
Funded by Arthritis Research UK

On the scales below (0-10), please mark the amount of back pain that you have experienced:

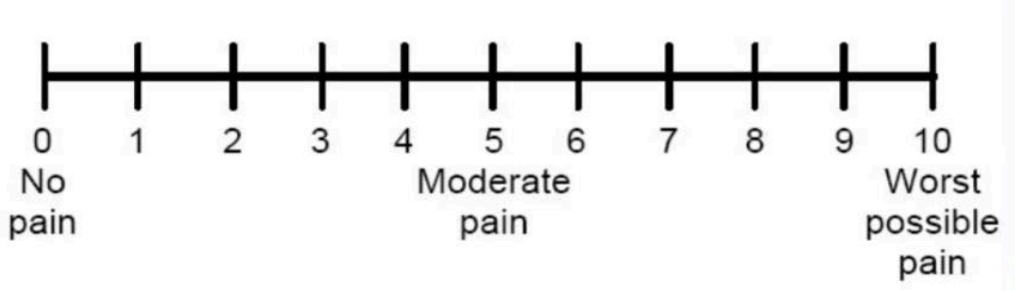
Worst pain over the last two weeks



Least pain over the last two weeks



Average pain level today



The Roland-Morris Disability Questionnaire

When your back hurts, you may find it difficult to do some of the things you normally do.

This list contains sentences that people have used to describe themselves when they have back pain. When you read them, you may find that some stand out because they describe you *today*.

As you read the list, think of yourself *today*. When you read a sentence that describes you today, put a tick against it. If the sentence does not describe you, then leave the space blank and go on to the next one. Remember, only tick the sentence if you are sure it describes you today.

1. I stay at home most of the time because of my back.
2. I change position frequently to try and get my back comfortable.
3. I walk more slowly than usual because of my back.
4. Because of my back I am not doing any of the jobs that I usually do around the house.
5. Because of my back, I use a handrail to get upstairs.
6. Because of my back, I lie down to rest more often.
7. Because of my back, I have to hold on to something to get out of an easy chair.
8. Because of my back, I try to get other people to do things for me.
9. I get dressed more slowly than usual because of my back.
10. I only stand for short periods of time because of my back.
11. Because of my back, I try not to bend or kneel down.
12. I find it difficult to get out of a chair because of my back.
13. My back is painful almost all the time.
14. I find it difficult to turn over in bed because of my back.
15. My appetite is not very good because of my back pain.
16. I have trouble putting on my socks (or stockings) because of the pain in my back.
17. I only walk short distances because of my back.
18. I sleep less well because of my back.

19. Because of my back pain, I get dressed with help from someone else.

20. I sit down for most of the day because of my back.

21. I avoid heavy jobs around the house because of my back.

22. Because of my back pain, I am more irritable and bad tempered with people than usual.

23. Because of my back, I go upstairs more slowly than usual.

24. I stay in bed most of the time because of my back.

Tampa Scale:

Please mark how much you agree or disagree with the following statements:

1= Strongly disagree

2= Disagree

3= Agree

4= Strongly agree

1. I'm afraid that I might injury myself if I exercise	1	2	3	4
2. If I were to try to overcome it, my pain would increase	1	2	3	4
3. My body is telling me I have something dangerously wrong	1	2	3	4
4. My pain would probably be relieved if I were to exercise	1	2	3	4
5. People aren't taking my medical condition seriously enough	1	2	3	4
6. My accident has put my body at risk for the rest of my life	1	2	3	4
7. Pain always means I have injured my body	1	2	3	4
8. Just because something aggravates my pain does not mean it is dangerous	1	2	3	4
9. I am afraid that I might injure myself accidentally	1	2	3	4
10. Simply being careful that I do not make any unnecessary movements is the safest thing I can do to prevent my pain from worsening	1	2	3	4
11. I wouldn't have this much pain if there weren't something potentially dangerous going on in my body	1	2	3	4
12. Although my condition is painful, I would be better off if I were physically active	1	2	3	4
13. Pain lets me know when to stop exercising so that I don't injure myself	1	2	3	4
14. It's really not safe for a person with a condition like mine to be physically active	1	2	3	4
15. I can't do all the things normal people do because it's too easy for me to get injured	1	2	3	4
16. Even though something is causing me a lot of pain, I don't think it's actually dangerous	1	2	3	4
17. No one should have to exercise when he/she is in pain	1	2	3	4

Since receiving your prescription from the physiotherapist, how many days have you taken the medication to date?

Have you seen any other healthcare professionals for your back pain since your initial assessment?	Yes		No	

If YES, which type of health professional(s) have you seen, and on how many occasions?	Number of occasions

Have you had to take any time off work due to your back pain?	Yes		No	

If YES, how many days have you had to take off work due to your back pain?

Thank you for completing this questionnaire

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Participant Information Sheet: Person with Back Pain

Study title: Prescribing medications for low back pain by physiotherapists

We would like to invite you to take part in a research study. Before you decide to take part, it is important for you to understand why the research is being done and what it will involve for you. The study is part of a larger PhD being completed by Tim Noblet (Researcher). Someone in our research team will go through the information sheet with you and will answer any questions that you have. Please ask if anything is not clear or if you would like more information.

What is the purpose of the study?

1 in 5 people with Low Back Pain (LBP) see their General Practitioner (GP) and this makes up almost 1 in 10 GP Consultations. Each year in the UK over 3 million working days are lost because almost 1 in 3 adults experience LBP at any one time. Early assessment and management of LBP is important to reduce long term problems.

The NHS is committed to providing the best services for all its patients, and due to the growing demand on health services, new and innovative ideas are being trialled to maximise quality care. A range of organisations including the British Medical Association and the Chartered Society of Physiotherapy have committed to enabling patients with LBP to be able to book appointments directly with the NHS physiotherapists in their local health centre without having to see a GP first. In addition to the normal treatment, physiotherapists are now able to prescribe medicines such as pain killers which patients usually need to get from their GP. To do this the physiotherapists complete a programme of education the same as your doctor or dentist.

Patients being able to access physiotherapists who can prescribed medicines directly is a new system in England. This study is intended to help decide how we will best assess what and what does not work, to enable provision of the best healthcare for people in England. This will be undertaken by asking approximately 30 people to complete questionnaires. A small number of people may also be asked to wear monitoring equipment (like 'fitbits') for a week, which assesses how active they are during each day, and 6-8 people will also be invited to participate in a focus group where they will be asked to share their opinions on how the study was conducted and how we could improve the evaluation process for the future. Physiotherapists will also have an opportunity to voice their opinions and experiences in a 1:1 interview. The results will be used to plan a large clinical trial to access how well the new services work for patients.

Why have I been invited?

You have been invited to take part because you have attended an appointment with the physiotherapist for your LBP and require a prescription to support your treatment. We aim to recruit 30 people across England.

Do I have to take part?

It is up to you to decide whether or not to take part. Feel free to ask any questions. After you have asked any questions, if you agree to take part, the researcher will ask you to sign a consent form. You are free to withdraw from the study at any time, without giving a reason. This would not affect the normal treatment that you would receive.

What will happen to me if I take part?

If you choose to take part in the study, you will be asked to fill out a short questionnaire on a tablet computer at your appointment with the physiotherapist. You will be asked to complete the same questionnaire 6 weeks later and 12 weeks later- these can either be sent to you by email or hard copies provided with stamped addressed envelopes so that you can return the questionnaires by post.

Some patients will also be asked to wear a small monitoring device like a 'fitbit' on their belt for 7 days. The monitoring devices measure the amount of time people spend moving and being still as well as your sleep pattern.

6-8 patients will be invited to attend a focus group at a local venue, and again it is up to you whether you choose to attend or not.

What will I have to do?

The questionnaire will take approximately 15 minutes to complete, asking you for your contact details and for information about how your back pain is affecting your everyday life at that point in time. For the 6 & 12week questionnaire you will be able to choose either a paper (postal) or email version for you to complete. Support from your physiotherapist will always be available to you to help in completing the questionnaire.

What are the possible disadvantages of taking part?

It is possible that when talking about your back pain or filling in the questionnaire we may ask you to relive events which are emotional for you. However, we will make every effort to ensure that you are comfortable at all times. The only cost to you is the time needed to complete the questionnaire and (for some people) attend a focus group.

What are the possible benefits of taking part?

We are not able to make any promises on the benefits at this stage until we have analysed the information you provide, which may help you and other patients in the future. It will not change the treatment that you receive for your back pain.

What will happen when the research stops?

When the research is complete, your future treatment will not be affected in any way. Decisions about your future care will be in-line with standard procedures at the GP practice/health centre that you have been attending.

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

If you do not wish to carry on with the study, you are free to withdraw at any time, without having to give a reason. Your decision to withdraw will not influence your current or future health care. It is important for us that information collected up to the point of your withdrawal is included in the analysis.

What if there is a problem?

It is unlikely that there will be any problems during the study. If you have a concern about any aspect of the way that you have been approached or treated during the course of this study, you can speak to Mr. Tim Noblet (researcher) or Dr Alison Rushton (Chief Investigator) who will answer any questions you have. If you remain unhappy and wish to complain formally, you can do this by following the National Health Service complaints procedure. You can get advice from the Patient Services Teams at your GP practice/ health centre (all contact details below).

In the unlikely event that you are harmed whilst participating in this study, there are no special compensation arrangements, but if this is due to someone's negligence then you may have grounds for legal action. The normal National Health Service complaints mechanism will still be available to you. You may obtain advice from the Patient Services Teams at your GP practice/ health centre (contact details at the end of this information sheet).

Will my taking part in the study be kept confidential?

All information that is collected about you during the course of the study will be kept confidential. Your name or contact details will not appear on any data and you will not be identifiable from any report or publication of the findings. Your contact details will be held on a computer database so that questionnaires can be sent to you and the focus groups can be organised. This will be password protected and only accessible by the researchers. Passwords will not be used by or given to anyone outside the research team. Contact details will be destroyed at the end of the study. All information from the questionnaires that you complete and the 'fitbits' (if you wear one) will be kept securely by University of Birmingham for ten years following the study. After that period, all information will be disposed of in a secure manner through confidential waste.

What will happen to the results of the study?

Results from this study will be used to develop a clinical trial that will evaluate the use of physiotherapists who can prescribe medications in GP practices and health centres. This trial will aim to improve the patient experience and their outcomes.

The results will be published in scientific journals and through presentation at research conferences. You will not be identifiable in any report, publication or presentation. If you are interested in the results of this investigation you can obtain a summary of the results by contacting Mr. Tim Noblet or Dr Alison Rushton (contact details below).

Who is organising and funding this study?

The research is sponsored by the University of Birmingham and funded by Health Education England and the Private Physiotherapy Educational Fund. The research will be conducted by physiotherapists at Guys and St Thomas' NHS Foundation Trust, the Sheffield Teaching Hospitals NHS Foundation Trust or Windemere/ Ambleside Health.

Who has reviewed the study?

All research in the NHS is reviewed by the Research Ethics Committee, engaged to protect your interests and those of the researchers. This study has been reviewed and given favourable opinion by the IRAS and the Research and Development Directorates, Guys and St Thomas' NHS Foundation Trust, the Sheffield Teaching Hospitals NHS Foundation Trust and Windemere Health Centre.

The role of the University of Birmingham

The University of Birmingham is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Birmingham securely keep identifiable information about you for 10 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible.

Your physiotherapists will collect information from you for this research study in accordance with our instructions. The NHS site will keep your name and contact details confidential. If you consent to be approached to participate in a focus group, the University of Birmingham will have access to your name and contact details to arrange the focus group. The researchers who analyse the information collected will not be able to identify you and will not be able to find out your name or contact details.

The NHS site will keep identifiable information about you from this study 10 years after the study has finished.

You can find out more about how we use your information by contacting Legal Services at dataprotection@legalservices.contacts.ac.uk.

Contact for further information or any questions about this study:

Tim Noblet (researcher)

Tel:

Email:

Dr Alison Rushton (Chief Investigator / supervisor)

Tel:

Email:

Centre of Precision Rehabilitation Spinal Pain, School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham, Edgbaston, Birmingham, B15 2TT

Site PALS Information:

One Medical Group-Windermere Health Centre & Ambleside Health Centre

Telephone No:015394 45159

Email Address:

Sheffield Teaching Hospital NHS Foundation Trust

Telephone No: 0114 271 2400

Email Address: PST@sth.nhs.uk

Guy's and St Thomas' NHS Foundation Trust

Telephone No: 020 7188 8801

Email Address: pals@gstt.nhs.uk

Thank you for taking the time to read this information sheet.

8.26 Appendix 26: Topic guide for semi-structured interviews

Category of question	Sub-category	Questions
Intervention content and delivery	Intervention development	To what extent does the planned intervention need to be refined or adapted to make it more acceptable to APPs or more relevant or useful to LBP?
	Intervention components	Consider the different aspects of the intervention e.g. completion of the outcome measures in clinic/at home, methods of completion paper/electronic, application of the accelerometer etc. Do these aspects work in the different clinical locations/different practices? If aspects of the process require changing- how can we do this to ensure interventions are delivered consistently in the full trial?
	Mechanisms of action	Do you think that your advice with the additional prescription make you more confident about the outcome of your treatment? Do you think that the presence of the accelerometer makes the patients move more?
	Perceived value, benefits, harms or unintended consequences of the intervention	Did you think that being able to prescribe in your FCP clinics is useful? What benefits/harms do you feel the addition of independent prescribing has for physiotherapists working in these roles? Were these benefits/harms measured by the outcome questionnaire?
	Acceptability of intervention in principle	Were you unhappy with any aspect of the content or delivery of the intervention?
	Feasibility and acceptability of intervention in practice	What are your views about the implementation of the intervention? Has implementation varied due to the setting? Are there any important intervention-context interactions? Should implementation be tailored by setting?
	Fidelity, reach and dose of intervention	Is the right amount of time etc. given to the appointments to enable the intervention to be completed to a satisfactory standard?

Category of question	Sub-category	Questions
		Were you able to adhere to the planned intervention? If not, what are the reasons for this? What are the limits of acceptable tailoring of the intervention?
Trial design, conduct and processes	Recruitment and retention	How do the planned recruitment practices work in clinical practice? Do recruitment practices need to be improved to increase recruitment rates and levels of informed consent? If so, how? Are clinicians willing to recruit patients, or are they uncomfortable? Are there ways in which trial procedures could be improved to increase retention rates?
	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?
	Trial participation	How was the planned trial communication e.g. provision of the information sheet, 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 trial in principle	Is the trial design acceptable to you in principle?
	Acceptability of the trial in practice	Is the trial design acceptable to you in practice, if not why? Are there ways in which you (participants/ APP) try to alter the procedures?
	Ethical conduct	Are the informed consent procedures appropriate and acceptable to likely trial participants?
	Adaptation of trial conduct to local context	Will the planned trial procedures allow the trial to operate effectively for patients with LBP in primary care? Do any changes need to be made to these procedures?

Category of question	Sub-category	Questions
	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)?
	Patient and public involvement	How is patient and public involvement best achieved in the trial?
Outcomes	Breadth and selection of outcomes	Are outcomes important to service users selected for measurement in the full trial—both primary and secondary? Have you experienced or noticed improvements in some outcomes that need to be included in the full trial?
Measures	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	Did the outcome measure used, successfully measure the variables requiring measurement? Do we need to develop other outcome measures to be able to successfully measure the outcome of the trial?

Questions adapted for best practice in the qualitative assessment of feasibility trials in preparation for RCTs from literature; with further development and consensus from a committee of clinicians, subject- matter and methodological experts and patients [241].

UNIVERSITY OF BIRMINGHAM

CONSENT FORM physiotherapist interviews

Title of Project: Independent Prescribing by Advanced Practice Physiotherapists for Patients with Low Back Pain in Primary Care: a feasibility trial with an embedded qualitative component

Physiotherapist interviews

Name of Participant: ……

Please initial box

1. I confirm that I have read and understand the information sheet, for the above study. I have had the opportunity to consider the information, to ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐

3. I understand that all data will be confidential and securely stored for a period of 10 years. I understand that if I withdraw from the study my data up to the point of my withdrawal will be used in the analysis ☐

4. I agree to take part in the above study ☐

Name of Participant	Date	Signature
Name of Person taking consent (if different from researcher)	Date	Signature
Researcher	Date	Signature

8.28 Appendix 28: Topic Guide for Focus Group

Stage of Focus Group	Content
Introduction: Tim Noblet	PhD Candidate Advanced Physiotherapy Practitioner Facilitator for the Focus Group today
Welcome from Tim and Alison. Explanation as to the aim of the FG.	The focus group is being carried out as part of a larger feasibility trial evaluating the feasibility, suitability and acceptability of assessing the effectiveness of independent prescribing by advanced physiotherapy practitioners for patients with Low Back Pain in primary care, to inform the design of a future full trial.
Questions referring to Participant Information Sheet	Any questions about the project?
Consent	Confirm: • All consent forms are completed • Confidentiality is fully understood by participants ➢ All information collated is confidential ➢ Participants will not be identified from the discussion
Audio Recording and transcription	Advise the participants that the FG is being audio-recorded. Recordings will be transcribed and coded.

Participant introduction	Introductions and setting of ground rules: • TN to outline roles and responsibilities/ code of conduct. • Explanation re. the FG processes • The role of the observer • Agreement of ground rules – all points are valid, don't talk over others, confidentiality

Objective	**Sub-category**	**Questions**
General Objectives: Trial design, conduct and processes	Eligibility criteria	Did you feel that you were the appropriate person to take part in the trial? If not, how might recruitment practices be improved?
	Recruitment strategy	Did the recruitment process work in practice? Do recruitment practices need to be improved to increase recruitment rates? If so, how? Are there ways in which trial procedures could be improved to increase retention rates?
	Trial participation	Were the information sheets easy to understand? Did the information sheets provide you with enough information? How can trial communication be improved to ensure the research team understand patients' views about participating in the trial?
	Ethical conduct	Are the consent procedures appropriate?
	Adaptation of trial conduct to local context	Did the trial procedures work for the GP practice setting? Do any changes need to be made to these procedures to make the trial run more smoothly?

Objective	Sub-category	Questions
Specific Objectives: Feasibility of using accelerometers	Accelerometers	Were the accelerometers fitted easily? Were the instructions of how and when to use the device clear?
	Burden	Was wearing the accelerometer for 7 days easily achievable?

Objective	Sub-category	Questions
Specific Objectives: Suitability of questionnaire	Breadth and selection of outcomes	Did the questionnaires make sense? Were the problems that the questions asked about important to you? Did the questionnaire miss any important points?
	Accuracy of measures	Did you have enough time to complete the questionnaires? Did you have the support you needed to be able to complete the questionnaires?
	Completion of measures	How could we make it easier to complete the questionnaire?

Objective	Sub-category	Questions
Specific Objectives: Acceptability	Intervention development	How does the planned trial process need to be changed or adapted to make it more acceptable to patients or more relevant or useful to people with LBP?
	Intervention components	Let's consider the different aspects of the trial e.g. completion of the outcome measures in clinic/at home, methods of completion paper/electronic, application of the accelerometer etc. Do all these aspects work in the different clinical locations/different practices? Do you feel different aspects of the process require changing- how can we do this to ensure interventions are delivered consistently in the full trial?
	Mechanisms of action	Did the physiotherapist's advice with the additional prescription made you more confident about the potential outcome of your treatment? Do you think that wearing the accelerometer make you move more?
	Perceived value, benefits, harms or unintended consequences of the intervention	Did you think that being able to get painkillers from your physiotherapist was valuable? What benefits, do you feel you have experienced from the physiotherapist's treatment? Were these benefits measured by the questionnaire?
	Acceptability of intervention in principle	Were you unhappy with any aspect of the content or delivery of your treatment?
	Acceptability of intervention in practice	Did the physiotherapists prescribing the pain killers work for you? Could the service be provided in a better way?
	Fidelity, reach and dose of intervention	Is the right amount of time etc. given to the appointments? Were you able to adhere to the plan? If not, what are the reasons for this?
	Impact of trial on staff, researchers, participants and the health system	Does this trial have any unanticipated negative impacts on participants? How can these impacts be minimised?

Prompts for further comments	Is there anything that we should have discussed that we have not? Do you have any further views or comments that you would like to share?
Summary & Close	Short summary of the findings discussed in the FG Confirm Transcription will be supplemented with field observation notes and emailed to ensure accuracy and prompt any further reflections within the next 2 weeks. Thank participants for attending and their contributions.

Questions adapted for best practice in the qualitative assessment of feasibility trials in preparation for RCTs from literature; with further development and consensus from a committee of clinicians, subject- matter and methodological experts and patients [241].

8.29 Appendix 29: IRAS approval

NHS
Health Research Authority

London - West London & GTAC Research Ethics Committee

30 October 2018

Dr Alison B Rushton

School of Sport, Exercise and Rehabilitation Sciences, College of Life and Environmental Sciences
University of Birmingham

Edgbaston, Birmingham B15 2TT

Dear Dr Rushton

Study title:	**Independent Prescribing by Advanced Physiotherapists for Patients with Low Back Pain in Primary Care: a feasibility trial with an embedded qualitative component**
REC reference:	**18/LO/1793**
Protocol number:	**RG_18-101**
IRAS project ID:	**250734**

Thank you for your letter of 24th October 2018, responding to the Proportionate Review Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact please contact [redacted] outlining the reasons for your request.

Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

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.

Conditions of the favourable opinion

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

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

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System, at www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where an 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 management permissions from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publicly accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC, but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact . The expectation is that all clinical trials will be registered, however, in exceptional circumstances nonregistration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

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).

Ethical review of research 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" above).

Approved documents

The documents reviewed and approved by the Committee are:

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Confirmation insurance]	1	20 September 2018
GP/consultant information sheets or letters [GP letter]	2	21 August 2018
Interview schedules or topic guides for participants [Topic guide focus groups]	1	19 July 2018
Interview schedules or topic guides for participants [Topic guide interviews]	1	19 July 2018
IRAS Application Form [IRAS_Form_20092018]		20 September 2018
Letter from sponsor [Confirmation sponsorship]	1	20 September 2018
Non-validated questionnaire [Outcome Measures Questionnaire]	2	25 October 2018
Other [General insurance letter]	1	20 September 2018
Other [Public and products liability]	1	20 September 2018
Other [Employers liability]	1	20 September 2018
Other [CV Tim Noblet]	1	26 September 2018
Other [Confirmation of funding award HEE]	1	27 September 2018
Other [Response to pre-validation queries]		28 September 2018
Other [Response to ethics committee]	1	24 October 2018
Other [HRA Protocol V3 Clean]	3	25 October 2018
Other [HRA Protocol V3 Tracked Changed]	3	25 October 2018
Participant consent form [Consent focus group]	2	21 August 2018
Participant consent form [Consent interviews]	2	21 August 2018
Participant consent form [Consent Form Person with Low Back Pain]	3	25 October 2018
Participant consent form [Consent Form Person with Low Back Pain Tracked changed]	3	25 October 2018
Participant information sheet (PIS) [PIS Person with Back Pain]	4	25 October 2018
Participant information sheet (PIS) [PIS person with Back Pain tracked changes]	4	25 October 2018
Participant information sheet (PIS) [PIS Focus Group]	4	25 October 2018
Participant information sheet (PIS) [PIS Focus Group Tracked Changed]	4	25 October 2018
Participant information sheet (PIS) [PIS Physiotherapist interviews]	4	25 October 2018
Participant information sheet (PIS) [PIS APP Physiotherapist interviews tracked changed]	4	25 October 2018
Referee's report or other scientific critique report [Confirmation of funding PPEF]	1	27 September 2018
Summary CV for Chief Investigator (CI) [CV Chief investigator]	1	19 July 2018

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 HRA 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 Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:

http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance

We are pleased to welcome researchers and R & D staff at our RES Committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

18/LO/1793	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

Reverend Keith Lackenby Chair

8.30 Appendix 30: HRA approval

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Dr Alison B Rushton
School of Sport, Exercise and Rehabilitation Sciences, College of Life and Environmental Sciences
University of Birmingham Edgbaston, Birmingham B15 2TT
Email:

30 October 2018

Dear Dr Rushton

HRA and Health and Care

Research Wales (HCRW)

Study title: Independent Prescribing by Advanced Physiotherapists for Patients with Low Back Pain in Primary Care: a feasibility trial with an embedded qualitative component
IRAS project ID: 250734
Protocol number: RG_18-101
REC reference: 18/LO/1793
Sponsor: University of Birmingham

I am pleased to confirm that HRA and Health and Care Research Wales (HCRW) Approval has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

How should I continue to work with participating NHS organisations in England and Wales?

You should now provide a copy of this letter to all participating NHS organisations in England and Wales, as well as any documentation that has been updated as a result of the assessment.

Following the arranging of capacity and capability, participating NHS organisations should **formally confirm** their capacity and capability to undertake the study. How this will be confirmed is detailed in the "*summary of assessment*" section towards the end of this letter. You should provide, if you have not already done so, detailed instructions to each organisation as to how you will notify them that research activities may commence at site following their confirmation of capacity and capability (e.g. provision by you of a 'green light' email, formal notification following

a site initiation visit, activities may commence immediately following confirmation by participating organisation, etc.).

It is important that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details of the research management function for each organisation can be accessed here.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?

HRA and HCRW Approval does not apply to NHS/HSC organisations within the devolved administrations of Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) has been sent to the coordinating centre of each participating nation.

You should work with the relevant national coordinating functions to ensure any nation specific checks are complete, and with each site so that they are able to give management permission for the study to begin.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?

HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

I am a participating NHS organisation in England or Wales. What should I do once I receive this letter? You should work with the applicant and sponsor to complete any outstanding arrangements, so you are able to confirm capacity and capability in line with the information provided in this letter.

The sponsor contact for this application is as follows:

Name: Dr Sean Jennings

Tel:
Email:

Who should I contact for further information?

Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **250734**. Please quote this on all correspondence.

Yours sincerely

Juliana Araujo Assessor

Email:

8.31 Appendix 31: Response to reviewers, BMJ Open, Independent Prescribing by Advanced Physiotherapists for Patients with Low Back Pain in Primary Care: protocol for a feasibility trial with an embedded qualitative component, 4th March 2019

Editors/Reviewers Comments	Changes made or reason(s) for not making changes
Editor	
Along with your revised manuscript, please provide a completed copy of the CONSORT extension checklist for feasibility trials: http://www.consort-statement.org/extensions/overview/pilotandfeasibility Please remember to include the relevant page number(s) from the manuscript next to each reporting item or state 'n/a' next to items that are not applicable to your study (we appreciate that, as this is protocol, a number of items will not be applicable)	Completed and attached as per request.
Reviewer 1	
An interesting and well written paper that thoroughly addresses each stage of the proposed feasibility study. A couple of thoughts as the work progresses, unclear how the issue of patients who don't have access to the internet or non-users would be supported to participate- or should this be more clearly specified as exclusion criteria.	Thank you for your comments. We agree that this is an issue that in a full trial we would work around via provision of paper copies of the questionnaire being provided, and ability to send completed questionnaires back in the post via stamped addressed envelopes provided. The feasibility trial aimed to evaluate the feasibility and acceptability of the online version of the questionnaire for patients and the feasibility of data collection using this method in a full trial. To clarify we have added the following wording to the exclusion criteria: *"Unable to receive email and/or complete online questionnaires".*

It is slightly unclear, and this may be the limits of the scope of the current paper, how when the number of APP in FCP is small the service will be able to switch between "normal care" APP minus prescribing to intervention normal care plus IP. Is the assumption that by the time the work progresses to full trial that any service included in the study would have more than one APP FCP? It is a bit unclear if the switch would involve the same person (just not using the prescribing qualification) or a 2nd APP FCP	Thank you for your comments and questions. It is the assumption that as FCP numbers grow (as per NHS England mandate) and services will have more than x1 FCP. It will take time for these clinicians to qualify as independent prescribers. Clinicians who are not prescribers will start in the control group but would switch to the experimental group following qualification. To clarify this point for the reader the following text has been added: 'As the implementation of independent physiotherapy prescribing and the utilisation of APPs working as FCPs are both relatively contemporary innovations, there are limited numbers of clinicians currently working in these innovative roles who are registered to prescribe. This research design allows for the use of fewer clinicians than those required for a parallel design and is therefore more reflective of current practice. *APPs who are not prescribers will start in the control group and cross to the experimental group following registration as an independent prescriber.*[230-233]'
Reviewer 2	
*Page 9, lines 41-46. Currently, controlled drug restrictions mean that Physio IP's cannot prescribe a number of medicines used in the management of LBP including codeine preparations, tramadol, and (from April 2019) gabapentin and pregabalin. CD restrictions have been highlighted as a significant barrier to NMP practice in the past. Can authors clarify how this scenario will impact data collection in the experimental arm.	Current and pending restrictions to physiotherapist independent prescribing will, as identified by the reviewer, effect the ability of FCPs to prescribe in line with current NICE guidelines for LBP and associated leg pain. This scenario will not impact this feasibility trial and the issue will be resolved prior to completion of a full trial. We are in close communication with both the Chartered Society of Physiotherapy (CSP) and Health Education England with regards to the points raised. It is predicted by the professional advisors at the CSP, following Brexit, the highlighted issues will be dealt with by government. Time is also required for the embedding of FCP services across CCGs in England following the current national pilot over the next year. It is therefore expected that the full trial will commence following this time period.
*An Evaluation of physiotherapy, podiatrist independent prescribing, mixing of medicine and prescribing of controlled drugs funded by the dept of Health was published by Carey et al.	The following wording has been added to enhance the readers knowledge re the evaluation completed.

in 2017. Authors may wish to demonstrate consideration of this work in the background section.	*'Independent physiotherapist prescribing remains relatively new, with the first prescribers qualifying in 2014.* ***Evaluation of physiotherapist and podiatrist independent prescribing has shown good acceptance by patients and a good safety record to date.*** [25]*'*
*Page 3, line 9 & page 4, lines 55-56. Although law changes allowing physio IP occurred in 2013, it is my understanding that the first Physio IP's were registered with HCPC in April 2014.	Thank you for this comment. This is correct and the typographical error has been corrected.
Reviewer 3	
I was asked by the Editor to perform only the Statistical review The authors are clear about their study design which is a single arm feasibility study. They justify why sample calculation was not necessary. Both quantitative and qualitative data analysis are adequate.	Thank you for your comments.
Reviewer 4	
The protocol is very well written, and I look forward to seeing the results of the feasibility trial. My only comment is that, even though there are concerns in estimating intraclass correlation coefficient (ICC) using the feasibility data, such attempts should be warranted and documented in the protocol. One could use the ANOVA estimator to estimate ICC, and the resulting estimates should be more informative than random guesses. If no attempts are made for the ICC estimation, it is generally difficult to find ICC values in prior literature since these designs are just becoming popular.	Thank you for your comment. We decided not to estimate ICC based on the current literature which expresses concern re feasibility data. Our reasoning for our analysis is stated in the manuscript and the literature is referenced. As the feasibility trial objectives do not aim to assess how strongly the data within the control arm resemble each other, estimation of ICC was not thought necessary at feasibility level. The decisions regarding statistical analysis were evaluated to be appropriate by researchers at the University of Birmingham and by statistical expert reviewer 3: Fikrim Abu-Zidan Institution and Country: Department of Surgery, College of Medicine and Health Sciences, UAE University, Al-Ain, UAE

8.32 Appendix 32: Response to reviewers, PLOS One, Independent Prescribing by Advanced Physiotherapists for Patients with Low Back Pain in Primary Care: a feasibility trial with an embedded qualitative component, 20th December 2019

Editors/Reviewers Comments	Changes made or reason(s) for not making changes
Editor	
Please ensure that your manuscript meets PLOS ONE's style requirements, including those for file naming.	Thank you, this has been completed.
Thank you for submitting your clinical trial to PLOS ONE and for providing the name of the registry and the registration number. The information in the registry entry suggests that your trial was registered after patient recruitment began. PLOS ONE strongly encourages authors to register all trials before recruiting the first participant in a study.	Thank you for your comment. There has been some confusion here. The feasibility trial was registered on 11th Sept 2018 (11.09.18), this date is stated on the ISRCTN website: https://www.isrctn.com/search?q=ISRCTN15516596+ Recruitment began at the first site 28th Nov 2018 after both registration (11th Sept 2018) and ethical approval (30th Oct 2018).
As per the journal's editorial policy, please include in the Methods section of your paper: 1) your reasons for your delay in registering this study (after enrolment of participants started); 2) confirmation that all related trials are registered by stating: "The authors confirm that all ongoing and related trials for this drug/intervention are registered".	Thank you for your comments: 1) This is not the case- please see above. 2) The required sentence has been added to page 6- Methods The manuscript now reads: *"To ensure transparency and reproducibility, the feasibility trial was registered on the ISRCTN database (ISRCTN15516596a-* ***registered 11th September 2018****) and a detailed protocol was published [223] (S1: Published protocol).* ***The authors confirm that all ongoing and related trials for this intervention are registered."***

Please also ensure you report the date at which the ethics committee approved the study as well as the complete date range for patient recruitment and follow up in the Methods section of your manuscript.	1. The date that ethical approval was granted has been added- see above. 2. Date range for participant recruitment and follow up have been added to the methods section as advised: *Page 7: "A single-arm feasibility trial design was used to evaluate the trial objectives [222 235]. Patient reported outcome measures (S3: Outcome Measures Questionnaire) were completed digitally via an online survey at initial assessment (baseline), 6 and 12 weeks following recruitment, to enable the evaluation of the data collection tool and the feasibility of follow up data collection* ***(Date range for participant recruitment and final follow up: Rural town 3rd December 2018-11th January 2019, final follow up 15th April 2019; Regional city 28th November- 19th December 2018, final follow up 13th March 2019; Capital city 28th February-18th July 2019, final follow up 10th October 2019)*** *[78 79]."*
Your ethics statement must appear in the Methods section of your manuscript. If your ethics statement is written in any section besides the Methods, please move it to the Methods section and delete it from any other section. Please also ensure that your ethics statement is included in your manuscript, as the ethics section of your online submission will not be published alongside your manuscript.	Thank you for your comment. We have edited as instructed. The Ethics statement is now included on page 6 (Methods) and reads: ***"Ethics Approval and Consent to Participate*** *To ensure that the trial was conducted in an ethical manner within best research practice, ethical approval obtained on the 30th October 2018 (IRAS project ID: 250734, Protocol number: RG_18-101, REC reference: 18/LO/1793) and HRA approval obtained, with R&D obtained from all sites [78 179]."*
Reviewer 1	
1. In the Introduction the authors have presented a good rationale for the need for the trial from the current evidence base but have not given any justification for the stepped wedge trial design proposed which first appears in the Methods. A brief rationale for this trial design in the Introduction would strengthen this section.	Thank you for your comments. We appreciate your input to optimise the quality of this article. A rationale has been added as recommended. This reads (page4-5): ***"A stepped-wedge cluster randomised controlled trial (SWcRCT) design is proposed for use in a definitive trial owing to the contemporary nature of both the implementation of independent physiotherapy prescribing and the utilisation of APPs working as FCPs. This research design allows for the use of fewer clinicians than those required for a parallel***

	design. It is useful in the evaluation of the implementation of new interventions, being more reflective of current practice [230-233]. Although selection bias is considered a risk in cluster trials, the design is valuable when evaluating innovative clinical interventions where there is a strong ethical belief that the intervention will benefit patients. *A feasibility trial is required to inform the design of a definitive, low risk of bias, adequately powered, multi-centre SWcRCT investigating physiotherapist independent prescribing by APPs for patients with LBP in primary care."*
2. Similarly, within Table 1 specific objectives under Feasibility it is proposed to evaluate the ease of fitting participants with accelerometers but there is no explanation within the Introduction section to justify this.	Thank you for this comment. The following paragraph has been added to introduce the use of accelerometers. *"The use of core outcome measures for LBP assessing pain intensity, health related quality of life and physical function are established in the literature [246]. To date, there is no agreement regarding the 'gold standard measures' for each of these outcomes. Patient reported outcome measures are frequently used for assessing pain intensity, health related quality of life and some aspects of functional activity. Quality systematic reviews have revealed that the physical activity of people with LBP is lower or equal to the healthy population [260-262]. The use of accelerometers to collect physical activity and sedentary behaviour data is advised in the literature, however the feasibility of use with patients with LBP in a trial has not been evaluated to date."*
3. There are also no objectives related to adverse events associated with prescribing and I would be interested to know if this was considered by the authors?	Thank you for this question. Adverse events were indeed considered when designing the feasibility trial. As each site followed the pre-tested and established, UK national standard governance procedures for reporting adverse prescribing events, the testing of these procedures/ methods was not deemed necessary in the feasibility trial. We agree that the collection of this data would be essential in a definitive trial design.

4. Outcome measures - please clarify how participants unable to complete these measures online were dealt with and the implications of excluding people for these reasons alone	Thank you for your comments. The rationale for choosing to test the feasibility of digital data collection "*To allow real-time data capture and storage"* is reasoned in the methods. The following statements have been added to the manuscript to clarify how the data about participants that were unable to complete the surveys online were dealt with. Methods *"To allow real-time data capture and storage, the online outcome measures survey was built using REDCap (Research Electronic Data Capture) software hosted at the Centre for Precision Rehabilitation for Spinal Pain (CPR Spine) at the University of Birmingham, UK* [238]. ***The number of participants that declined to participate as they were unable to complete the outcome measures survey online were collated to evaluate the suitability of only using digital data collection in a full trial."*** Results ***"No patients refused to participate owing to the inability to complete the outcomes measure survey online."***
5. Accelerometer - Provide more details of how 10 participants were selected, and the Accelerometer data being collected and how it was fitted. Justify why there was only one data collection point as presumably in the definitive trial they will be used at follow up and you have not tested the feasibility of this data collection method.	Details of how the 10 participants were selected has been clarified and the reason for a 7day testing period justified. The paragraph now reads: *To evaluate the feasibility of fitting participants with accelerometers in clinic, ease of data collection and participant compliance with wearing the accelerometer device for a 7 day period, the ten participants recruited at the rural town site had an accelerometer fitted to their left thigh for 7 days following the first consultation* [220 221]*. Stamped/addressed envelopes were provided to enable return of the devices after use.* The data collected by the accelerometers has been clarified in Table 3 (Outcome measures).

6. Participants - state how and who identified interested patients and the stage in their management they were identified.	Thank you for this comment. This has been clarified in the text, now reading: *The STarT Back Tool was used **at initial assessment by the APPs** to identify patients stratified into the medium risk LBP group [210].*
7. Intervention - clarify if participants had been prescribed medications by their GP prior to entry into the study. More detail of the protocol for the intervention is needed as it is not clear how it was operationalised or documented in practice regarding medication advice/prescribing/repeat prescribing. Which medications did the APP have a license to prescribe? What additional training or insurance was required to include this within their clinical practice?	We have edited the introduction to make it clear that patients do not see a GP prior to seeing a musculoskeletal FCP: *"NHS England have mandated the introduction of musculoskeletal first contact practitioners (FCPs) in primary care. This innovation aims to enable timely access to specialist musculoskeletal practitioners such as Advanced Practice Physiotherapists (APPs), **without the patient first seeing a GP** [55 213]."* To clarify the role and scope of physiotherapist independent prescribers the following text has been added to the introduction: *"Physiotherapist independent prescribers in the UK, have completed a post-registration iNMP programme and are regulated as 'independent prescribers' by the Health and Care Professions Council (HCPC). They are able to prescribe, administer or direct the administration of any medication (including those unlicensed), within their individual competence, scope and expertise, for any healthcare problem."* Collecting data regarding 'what' the APPs prescribed was not within the scope of the feasibility trial which aimed to evaluate the methods specified in the objectives.
8. Outcomes - clarify the restriction in technology that prevented sleep measurement.	Wording has been altered to clarify the validity limitations associated with assessing sleep with accelerometers. *"Assessment of sleep via accelerometer was detailed in the published protocol [223], unfortunately, limitations in validated accelerometer technology measuring sleep available at the time of testing prevented evaluation. This was the only deviation from the feasibility trial protocol."*

9. Sample size -the target recruitment rate of 10 participants per APP over a 6month period seems very low and unrealistic for testing feasibility for a definitive trial. Please provide justification for this.	Thank you for this comment. This is justified by the literature on page 12. *"A sample size of n>20 is regarded as adequate within the literature, when testing feasibility objectives for cRCTs, however a total sample of n=30 participants was planned to allow for under-recruitment within the specified time period and loss to follow up* [220 221 234 235]*."*
10. Qualitative Studies APP interviews - could the authors provide the interview schedule for these interviews for consistency with the Focus Group topic guide which is provided	The topic guide for the interviews has now been included.
11. Integration - within the methods reference is made to the a priori success criteria -but these are not evident until further into the Results section - reference to Table 10 and/or a short synopsis in the text would be useful at this point in the manuscript.	The success criteria have been submitted as a supplementary file due to the number of tables within the manuscript. To clarify, the following text has been added: *"Following quantitative and qualitative analysis, data were assessed against a priori defined success criterion developed by experts and informed by the methodological literature* [78 241 283]*.* ***Success criteria can be found in supplementary file 8 (S8: Success Criteria).*** *Trial objectives were considered successful if the success criteria were satisfied following the integration of the quantitative and qualitative findings* [221 283]*."*
12. The recruitment rate of two practices appears notably higher than the target 6 months - could you clarify this in the text	This has been actioned. Text now reads: *"Two sites recruited the pre-defined n=10 participants within the 6month recruitment period (3 and 4.5 weeks). The capital city site recruited n=9 participants over the 6month period."*
13. Flow chart - please check the n= under Fulfilled eligibility criteria - as it states 7 participants were excluded but 29 were allocated to the Intervention - should this be 36?	Thank you for spotting this error. The flow diagram has been updated to read n=36.

14. In reporting loss to follow up rates please state the expected rates were 20% a priori in the text	Thank you for this comment. This has been actioned in the text. *"Successful loss to follow up was defined a priori as <20%. 48% of participants were lost to follow up at 6 weeks, with 65.5% at 12 weeks (Fig 1). One site had a loss to follow up of 89%, suggestive of site-specific issues."*
15. Accelerometery Add the gender of n=10 participants Clarify if there were any missing data or non-wear times	Actioned in the text as per comments: *"Ten participants **(n=2 male, n=8 female**) wore an ActivPal accelerometer 24 hours a day for seven days. Data collected by the accelerometers are displayed in Table 6. **There were no missing data.** Participants spent an average of 18.57hrs (SD=1.54) sitting per day, 4.14hrs (SD=1.17) standing and 1.3hrs (SD=0.39) walking. Participants completed 5884.66 steps per day (SD=2255.11), with a mean activity score of 32. 94MET.h (SD=1.03)."*
16. Please provide some demographic details of the three APPs - age, level of experience, current job title and postgraduate qualifications	This has been completed as requested.
17. Recruitment - could the authors discuss how selection bias was minimised in this feasibility trial as APPs were recruiting	Thank you for your comment. The following text was added to the methods to clarify (page 9-10): *"Convenience sampling was used as this method has the advantages of fluid recruitment. To minimise selection bias, patients fitting the eligibility criteria were recruited consecutively [322]."*
18. Follow up - As all participants returned Accelerometers in person the trial has not demonstrated the feasibility of using postage as a follow up method which should be acknowledged in the text.	Thank you for this comment. We have added the following text as requested: *"All participant returned the accelerometer in person, therefore the feasibility of returning the device by post was not formally evaluated."*
19. Qualitative Interviews - Patients Clarify if the n=6 participants were compliers or drop-outs and if compliers, how reasons for drop-	To clarify compliers and drop-outs the following was added to the text:

out will be identified and dealt with in the definitive trial.	*"Six participants from the trial component of the feasibility trial consented to participate in the focus group. Purposive sampling enabled a representative spread of ages. 66% (n=4) of the participants were female, 66% (n=4) of participants completed the feasibility trial, with 33% (n=2) lost to follow up at 12 weeks."*
20. Eligibility criteria - Discuss the implications of including all three STarT back subgroups in a definitive trial as proposed. State the proposed long-term follow up time point(s) being considered for a definitive trial.	Thank you for your comments. The implications of including all STarT back groups are spread throughout the different sections of the discussion to illustrate points e.g. the effects on recruitment rates: *"However, it is posited that with the expansion of the proposed eligibility criteria to include all patients with non-specific LBP +/- leg pain, the full scope of physiotherapist prescribing and the adoption of additional recruitment capacity via research assistants and administrative staff, that recruitment rates and retention at all sites would be acceptable."* As specified within the design and discussion sections, this feasibility trial did not attempt to estimate proposed sample size. The rationale for this is explained within the Methods-design section: *"Two-arm feasibility studies aiming to calculate intra-cluster correlation coefficients (ICCs) required for sample size calculations have been shown to exhibit insufficient accuracy [234]. Therefore, a prospective, mixed-methods, single-arm feasibility trial, exclusive of sample size estimation was employed to evaluate the trial objectives on the experimental arm of the future SWcRCT [78 220 235]."* Additional words have been added regarding rescheduling the proposed primary end point for a definitive trial: *"If a definitive trial is to include all STarT Back stratification groups, additional longitudinal follow up procedures should be incorporated, rescheduling the trial primary endpoint to 1 year to allow for evaluation of patients in the long term."*

21. Explain how the prescribing practice of APPs was recorded in this feasibility trial and would be recorded in a definitive trial as this is not evident from the data presented and is a key variable to report to demonstrate APPs prescribing practice.	The evaluation of prescribing practice was therefore not in the scope of this feasibility trial, but is being addressed in a parallel audit.
22. It would also be informative to include literature on the views of GPs on APPs taking on a prescribing role and how it is proposed this role will be shared in future practice.	We agree, but unfortunately, this literature does not exist to date.
23. The statement that a definitive trial is feasible with minor modifications needs some tempering as there are a lot of proposed changes to the trial protocol including increasing its eligibility criteria, increasing the number of outcome measures, follow up methods and follow up points and providing additional training of APPs and recruiting and training research assistants to name a few, some of which will need to be piloted. I would consider these to be more than minor modifications and would encourage the authors to revise this wording in the Discussion, Conclusions and Abstract.	The 'minor' refers to the size of the changes required rather than the number of changes required. This fits with terminology used by the NIHR in the UK. Following discussions with the trial steering committee including PPI representation, authors would like to maintain the wording of 'minor'.
Reviewer 2	
To my opinion, this is an excellent manuscript about an interesting study. However, I recommend the authors to look closer on following: 1. ensure that all abbreviations are explained the first time they occur.	Thank you for your comments. We appreciate your input to optimise the quality of this article. Thank you for your comment, this has been actioned.

2. help the readers to interpret the primary and secondary outcomes measure data, both in the text and in the Table 5.	Additional words have been added based on this recommendation. The text now reads: *"Table 5 presents mean primary and secondary outcome measure data collected from the outcome measure questionnaire with variability reported by the use of standard deviations (SD). Reductions in pain were found for all pain categories as time progressed. Mean scores on the RMDQ reduced from 9.21 (SD 5.58) at base line to 8.07 (SD 5.82) at six weeks, then increased to 9.70 (SD 5.33) at 12 weeks. Between baseline and 12week, improvements were seen across all components of the secondary outcome measures other than anxiety and depression (EQ-5D 5L) which increased with time. No participants scored the distinct lower limit in any of the outcome measures; therefore, no floor effects were found. As primary and secondary outcomes improved, absence from work and prescription utilisation reduced."*
3. demographic data of the participating APP seem to be missing.	This has been added as requested.
Reviewer 3	
1. The authors seem to have tried to combine a desire to pilot their future trial and assess the feasibility of the intervention... however, their design only permits them to assess the feasibility of their intervention... I can understand that the stepped wedge component may have been difficult to do but I was unclear why a cluster feasibility pilot trial design was not undertaken? If the objective was not to pilot the future trial but to only examine the feasibility of intervention - then it's unclear why the authors report success criteria for the recruitment and retention rates?	Thank you for your comments. We appreciate your input to optimise the quality of this article. In planning this trial we have carefully considered the issue you raise. The NIHR (UK) state that "Feasibility studies are pieces of research done before a main study in order to answer the question 'Can this study be done?'" and states that a feasibility trial often consists of evaluating 1 arm of the planned definitive trial. As specified in the article, the study was designed as a feasibility trial to evaluate specific design objectives aiming to answer the question- can this study be done? Further rationale for this has been added to the introduction as per reviewer 1. The success criteria were reported for the recruitment and retention rates to aid in the evaluation of the general objectives assessing the feasibility, suitability and acceptability of the recruitment and follow up strategies, not the evaluation of the 'feasibility of the intervention' (physiotherapist independent prescribing).

2. The authors have chosen an RCT design to test an intervention of something that is not a new or novel intervention, but actually a different professional role that's part of a new service delivery approach - that's very specific to the NHS in the UK. I was therefore uncertain about the wisdom of a trial design and of the international relevance of the study. I wonder if a service evaluation might have been a better design?	Thank you for your comment. The 4 expert peer reviewers that reviewed the feasibility trial protocol and reviewers 1 & 2 have commented on the merits of evaluating the novel use of physiotherapist independent prescribing for LBP in primary care by APPs. To further clarify the rationale for evaluation by trial, additional reasoning has been added to the background section- see response to reviewer 1. The rigor of a definitive trial is required to ensure low risk of bias findings regarding effectiveness. Although physiotherapist independent prescribing is only legal in the UK at present, other countries such as Australia, Nigeria and South Africa are considering the introduction. The World Confederation of Physical Therapy (WCPT), part of the World Health Organisation (WHO), are closely involved in evaluating the potential benefits of physiotherapist prescribing internationally. https://www.wcpt.org/policy/ps-advanced-pt-practice
3. If the authors feel this is a new intervention worth testing for effectiveness, then some background information on how it was developed and the key targets of the intervention.	Thank you for your comments. These comments are reflective of reviewer 1. The authors have added detail to the 'Background' section of the article for clarification. Please see responses to reviewer 1.
4. It was unclear how and where patients were recruited and identified and from what denominator of those invited?	Thank you for your comment. Please see response to reviewer 1, comment number 6.
5. A major concern for cluster trials is recruitment selection bias. This was not mentioned.	Thank you for your comment. Please see response to reviewer 1, comment number 17.
6. What was the purpose of collecting accelerometer data in relation to the feasibility study? Was that a key treatment target? Or was that actually piloting an outcome for the main trial?	The purpose of collecting the accelerometer data was to "*evaluate the ease of fitting participants with accelerometers and ease of data collection"*, as per the specific objectives. If the use of accelerometers is to be feasible it was essential to ensure that no data was lost. To clarify this finding additional text has been added in the results section: *"Ten participants **(n=2 male, n=8 female**) wore an ActivPal accelerometer 24 hours a day for seven days. Data collected by the accelerometers are displayed in Table 6. **There were***

	no missing data. *Participants spent an average of 18.57hrs (SD=1.54) sitting per day, 4.14hrs (SD=1.17) standing and 1.3hrs (SD=0.39) walking. Participants completed 5884.66 steps per day (SD=2255.11), with a mean activity score of 32. 94MET.h (SD=1.03).”*
7. The authors collected a range of outcome measures they plan to use within a future main trial – but these seemed to be primarily to be about piloting them for the main trial and were largely unrelated to questions about the feasibility of the intervention.	Thank you for your comment. Collecting the range of outcome measures enabled the feasibility trial to assess: • the feasibility, suitability and acceptability of the proposed full trial [219] including the data collection methods. • the capacity (time and effort) of clinicians and researchers to complete trial related tasks • the time required to conduct each stage of the protocol These are explicit in the feasibility trial objectives and are essential to evaluate “whether the trial can be done” as per the NIHR (UK) definition of feasibility studies/trials.
8. The qualitative aspects seem to lack any theoretical framework…	The qualitative aspects follow a grounded theory- thematic analytical framework as detailed in the methods section: *“A grounded theory theoretical framework enabled a thematic analytical approach to analyse and synthesise the qualitative data. This method enables identification of the important thoughts and views of the population being studied, providing explanations alluding to how the concerns may be resolved or processed in preparation for a full trial [78 279 280]. Transcripts were coded line-by-line using NVivo 11 software (QSR International, Melbourne, Australia) by one researcher (TN) and verified by a second researcher (AR) [79 280 281]. Rigorous comparative analysis was completed to identify similarities and differences within the data, informing the development of descriptive categories which were linked, merged or split to synthesise a conceptual understanding of the data [280 281]. To avoid single researcher bias, the second researcher (AR) re-interrogated the data to validate or contradict findings. Following this process, to ensure trustworthiness, outcomes were discussed with a panel of experts for confirmation and agreement [279 280 282].”*

9. In the results it appears that physical function decreased over 3 months and that anxiety and depression worsened…. How do these disappointing results suggest feasibility or any promise from the intervention?	As stated in the article, the feasibility trial was not powered to evaluate efficacy. Researchers are therefore unable to conclude any cause or effect based on the data collected. The positive findings within the qualitative data promote the need for a definitive trial to evaluate effectiveness. The trial should integrate the findings from this feasibility trial and the pilot studies recommended to ensure quality and low risk of bias.
10. The attrition rates at 12 weeks were awful…. unacceptably low.	The authors agree with this statement and have discussed this in detail within the article, alongside potential changes to the design that aim to improve dropout. It is recommended that these changes are piloted prior to a full trial (discussion/conclusion).
11. Table 5, I wondered why the EQ-5D utility score was not given?	The feasibility trial was not powered to assess health utility therefore the EQ-5D-5L UI was not processed.
12. For an intervention study about prescribing - the measure called "Total prescription utilisation" seems a very blunt and inadequate measure… Could we not know what APPs prescribed for these patients? Perhaps provided in categories such as NSAIDs, opioids, atypical analgesics etc…	A parallel multi-site service evaluation is on-going at present collecting this data. The authors acknowledge that in a definitive trial prescribing data will be key. It is acknowledged that this data would be collected in a definitive trial but was not an objective needing evaluation in this feasibility trial. This information should be collected in the piloting of the data collection tool recommended within the discussion and conclusion of the article.

8.33 Appendix 33: STROBE checklist

	Item No	Recommendation	Yes/No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Yes
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	N/A
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Yes
Objectives	3	State specific objectives, including any prespecified hypotheses	Yes
Methods			
Study design	4	Present key elements of study design early in the paper	Yes
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow up, and data collection	Yes
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	Yes
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Yes
Data sources/ measurement	8	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Yes
Bias	9	Describe any efforts to address potential sources of bias	Yes
Study size	10	Explain how the study size was arrived at	Yes
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Yes
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	Yes
		(*b*) Describe any methods used to examine subgroups and interactions	N/A
		(*c*) Explain how missing data were addressed	N/A
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	Yes
		(*e*) Describe any sensitivity analyses	N/A

Results			
Participants	13	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow up, and analysed	Yes
		(b) Give reasons for non-participation at each stage	N/A
		(c) Consider use of a flow diagram	N/A
Descriptive data	14	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Yes
		(b) Indicate number of participants with missing data for each variable of interest	N/A
Outcome data	15	Report numbers of outcome events or summary measures	Yes
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	N/A
		(*b*) Report category boundaries when continuous variables were categorized	N/A
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Yes
Discussion			
Key results	18	Summarise key results with reference to study objectives	Yes
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Yes
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Yes
Generalisability	21	Discuss the generalisability (external validity) of the study results	Yes
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Yes

8.34 Appendix 34: SRQR checklist

Title and abstract	
Title - Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended	Yes
Abstract - Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions	N/A
Introduction	
Problem formulation - Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement	Yes
Purpose or research question - Purpose of the study and specific objectives or questions	Yes
Methods	
Qualitative approach and research paradigm - Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/ interpretivist) is also recommended; rationale	Yes
Researcher characteristics and reflexivity - Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability	Title page of thesis
Context - Setting/site and salient contextual factors; rationale	Yes
Sampling strategy - How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale	Yes
Ethical issues pertaining to human subjects - Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	Yes

Data collection methods - Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale	Yes
Data collection instruments and technologies - Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	Yes
Units of study - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	Yes
Data processing - Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/de-identification of excerpts	Yes
Data analysis - Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale	Yes
Techniques to enhance trustworthiness - Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale	Yes
Results/findings	
Synthesis and interpretation - Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	Yes
Links to empirical data - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	Yes
Discussion	
Integration with prior work, implications, transferability, and contribution(s) to the field - Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field	Yes
Limitations - Trustworthiness and limitations of findings	Yes

Other	
Conflicts of interest - Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	N/A
Funding - Sources of funding and other support; role of funders in data collection, interpretation, and reporting	Yes

8.35 Appendix 35: COREQ Checklist

No. Item	Guide questions/description	Yes/No
Domain 1: Research team and reflexivity		
Personal Characteristics		
1. Inter viewer/facilitator	Which author/s conducted the interview or focus group?	Yes
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	Title page
3. Occupation	What was their occupation at the time of the study?	Yes
4. Gender	Was the researcher male or female?	Title page
5. Experience and training	What experience or training did the researcher have?	Title page
Relationship with participants		
6. Relationship established	Was a relationship established prior to study commencement?	Yes
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	Yes
8. Interviewer characteristics	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	Yes
Domain 2: study design		
Theoretical framework		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	Yes
Participant selection		
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	Yes
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	Yes
12. Sample size	How many participants were in the study?	Yes
13. Non-participation	How many people refused to participate or dropped out? Reasons?	Yes
Setting		
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	Yes
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	Yes
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	Yes

Data collection		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Appendix 28
18. Repeat interviews	Were repeat inter views carried out? If yes, how many?	N/A
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	Yes
20. Field notes	Were field notes made during and/or after the interview or focus group?	N/A
21. Duration	What was the duration of the inter views or focus group?	Yes
22. Data saturation	Was data saturation discussed?	Yes
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	Yes
Domain 3: analysis and findings		
Data analysis		
24. Number of data coders	How many data coders coded the data?	Yes
25. Description of the coding tree	Did authors provide a description of the coding tree?	Yes
26. Derivation of themes	Were themes identified in advance or derived from the data?	Yes
27. Software	What software, if applicable, was used to manage the data?	Yes
28. Participant checking	Did participants provide feedback on the findings?	Yes
Reporting		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	Yes
30. Data and findings consistent	Was there consistency between the data presented and the findings?	Yes
31. Clarity of major themes	Were major themes clearly presented in the findings?	Yes
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Yes

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