Improving access to evidence-based information and care for people with musculoskeletal conditions:
‘The right care at the right time’

A thesis presented by

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A thesis submitted to fulfil of the requirements for the degree of

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I, Andrew Robert Gamble, hereby declare that I was the principal researcher of all work contained in this thesis, including work published with multiple authors.

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I, Andrew Robert Gamble hereby declare that I made the following contributions to each Chapter presented in this thesis:

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ABSTRACT

Musculoskeletal conditions such as neck or back pain or sporting injuries affect almost 1.7 billion people worldwide and are the leading contributor to years lived with disability globally. The World Health Organization estimates that there are 335 million new cases of musculoskeletal conditions annually and there is a need for a more sustainable approach to managing these conditions. Examples of musculoskeletal conditions include those where the injury or disease can be specified such as degenerative cervical myelopathy and osteoarthritis, and non-specific pain conditions such as primary low back pain which are presumed to have musculoskeletal origin.

The onset of musculoskeletal conditions can be sudden or occur gradually which can impact the timing of a diagnosis, management and subsequent patient outcomes. Anterior cruciate ligament rupture is an example of a condition which often occurs suddenly due to a clear mechanism of injury (e.g. pivoting during sport) which can prompt early diagnosis and management. In contrast, other conditions such as degenerative cervical myelopathy, a slowly evolving degenerative spinal cord injury, may progress slowly over time which can make a timely diagnosis and management challenging.

Musculoskeletal conditions can have immediate and ongoing impact on people's mobility, dexterity, quality of life, work productivity. People living with musculoskeletal conditions experience significant changes in their quality of life and are a significant contributor to health care costs. Musculoskeletal conditions account for an estimated 17% of the total years lived

with disability globally. Global healthcare systems cannot cope with the increasing number of people with musculoskeletal conditions needing care.

Clinical practice guidelines present evidence and recommendations which aims to guide the management of musculoskeletal conditions. For most acute musculoskeletal conditions (duration of 6 weeks or less) which are not due to clear trauma, guidelines suggest the primary aim is to exclude serious pathology then focus on controlling pain and restoring function via self-management advice, education and exercises. For chronic or degenerative musculoskeletal conditions (duration of 12 weeks or more) guidelines suggest that health professionals should initially select non-pharmacologic treatment such as advice on self-management or home exercises and use multidisciplinary rehabilitation as needed. For sporting injuries, guidelines suggest management based on if injuries are classified as acute, chronic, or a combination to determine return to play. Unfortunately, many patients with musculoskeletal conditions do not receive recommended care due to unnecessary surgery and long waiting times to access care. There is potential for simple and innovative ways to help patients receive recommended care, such as better online information, patient decision aids and development of a new model of care.

The three main aims of the thesis were therefore:

1) Evaluate if online information on the management of anterior cruciate ligament (ACL) rupture is aligned with the best available evidence
2) Develop patient decision aids for people with musculoskeletal conditions considering surgery where management recommendations are uncertain
    - Children and adolescents with anterior cruciate ligament (ACL) rupture
    - Adults with degenerative cervical myelopathy (DCM)

3) Develop and evaluate a new model of care utilising early assessment and telehealth that could reduce waiting times for adults with musculoskeletal pain referred to outpatient clinics in Australian public hospitals

To address the first aim of this thesis, a content analysis summarises the percentage of webpages on the management of anterior cruciate ligament (ACL) ruptures that are aligned with the best available evidence (Chapter 2). Searches for webpages were conducted via the Google search engine using terms synonymous with 'ACL' and 'management' and the term 'knee surgeon' linked to each Australian capital city (e.g. knee surgeon Sydney). One hundred and fifteen webpages were analysed, including webpages from non-for-profit and for-profit organisations, government funded institutes, and health insurers. Less than half of webpages (48%) suggested people can return to at least some form of sport with non-surgical management which evidence shows is feasible. Additionally, only one in four webpages acknowledged the risk of re-injury when returning to sport following surgery. This identified the need for evidence-based consumer resources on the management of ACL ruptures.

To address the second aim, a patient decision aid was developed for children and adolescents who have an ACL rupture (Chapter 3). Children and adolescents playing sport have a particularly high risk of ACL rupture yet there is a lack of high-quality evidence comparing surgery and non-surgical management in this population. Due to an increase in ACL injuries and subsequent surgery among children and adolescents, there was an urgent need to develop a patient decision aid to help guide whether surgery or non-surgical management is most appropriate. The decision aid was developed with a multidisciplinary steering group including health professionals (e.g. physiotherapists, surgeons) and people who had ruptured their ACL.

Thirty-two interviews were conducted with people who ruptured their ACL when they were younger than 18 years old, their parents, and health professionals. Most rated the decision aid as acceptable and 87% of participants who had ruptured their ACL, and their parents, agreed the decision aid would have made their decision easier.

To further address the second aim, a patient decision aid was developed for another musculoskeletal condition where there is uncertainty regarding the benefit of surgery, degenerative cervical myelopathy. Degenerative cervical myelopathy is the most common non-traumatic spinal cord injury, and it can be managed with or without surgery in its mild, early stages. A decision aid was needed due to the lack of awareness of the condition and a common belief that surgical management is always needed. A patient decision aid was developed for adults with degenerative cervical myelopathy (Chapter 4) guided by a multidisciplinary steering group including health professionals (e.g. physiotherapists, surgeons) and people with degenerative cervical myelopathy. Thirty-two interviews were conducted with health professionals (e.g. neurosurgeons, specialists) and people with degenerative cervical myelopathy who provided feedback on content and design. Most rated the decision aid as acceptable and 89% of participants with degenerative cervical myelopathy agreed the decision aid would have made their decision easier.

To address the third aim, a three-staged process was used to develop, conduct early evaluation and refine a model of care to reduce waiting times for adults with musculoskeletal pain referred to outpatient musculoskeletal clinics in Australian public hospitals. The model triaged patients based on their risk of developing persistent disabling pain (using the STarT MSK tool) to identify patients with musculoskeletal conditions who could be effectively managed with less

resources (e.g. brief telephone call, App-based exercises), thereby allowing patients with complex symptoms to be seen in-person sooner. A mixed-methods development paper describes the three-stage development of the model of care (Chapter 5). Development was guided by current research, successful overseas models of care, findings from a feasibility and pilot randomised controlled trial (Chapter 6), and analysis of 23 semi-structured interviews with patients, health professionals and key stakeholders. The single-blinded, single site, two arm parallel feasibility and pilot randomised controlled trial with nested qualitative interviews (Chapter 5) evaluated if the innovative model of care was feasible to deliver and evaluate in a larger, multi-site randomised controlled trial. The feasibility and pilot randomised controlled trial included 40 patients with low back pain (the most common musculoskeletal condition) and achieved over half of the pre-specified feasibility targets (e.g. acceptability via interviews with patients and clinicians).

Together the findings reported in this thesis show online information may be misleading patients with musculoskeletal injuries to have unnecessary surgery, patient decision aids can align patients' management decisions to their values and evidence and potentially reduce unnecessary surgery. The innovative triage and treatment model of care for people with musculoskeletal conditions seeking care in the outpatient public hospitals could reduce waiting times for millions of Australians to access care. The findings of this thesis could help patients receive recommended care by reducing unnecessary surgery and reducing waiting times to access care.

TABLE OF CONTENTS

CHAPTER SEVEN

CITATIONS OF PUBLISHED PAPERS AND PAPERS UNDER REVIEW FORMING PART OF THIS THESIS

Parts of the work presented in this thesis have been published or under review for publication as follows:

Published peer-reviewed papers forming part of this thesis

Chapter Two:

Gamble AR, McKay MJ, Pappas E, Dale M, O'Keeffe M, Ferreira G, Richardson K, Zadro JR. Online information about the management of anterior cruciate ligament ruptures in Australia: A content analysis. *Musculoskeletal Science and Practice.* 2022;59:102555. https://doi.org/10.1016/j.msksp.2022.102555

Chapter Three:

Gamble AR, McKay MJ, Anderson DB, Pappas E, Alvarez Cooper I, Macpherson S, Harris IA, Filbay SR, McCaffery K, Thompson R, Hoffmann TC, Maher CG, Zadro JR. Development of a patient decision aid for children and adolescents following anterior cruciate ligament rupture: an international mixed-methods study. B*MJ Open.* 2024;14(4):e081421. https://doi:10.1136/bmjopen-2023-081421

Papers submitted for publication forming part of this thesis (under review)

Chapter Four:

Gamble AR, Anderson DB, McKay MJ, Davies B, Macpherson S, Van Gelder J, Hoffmann TC, McCaffery K, Stevens S, Ammendolia C, Chauhan R, Zipser CM, Boerger TF, Lindsay TA, Fehlings MG, Dustan E, Nugent C, Holmgren H, Demetriades AK, Lantz JM, Dhillon R, Maher CG, Zadro JR. Development and acceptability of a patient decision aid for people with degenerative cervical myelopathy: an international mixed-methods study (2025) (under review)

Chapter Five:

Gamble AR, McKay MJ, Anderson DB, Needs C, Harvey L, Hutton JM, De Campos TF, MacPherson S, Foster NE, Halliday M, Chu J, Han C, Zadro JR. The development and early evaluation of a model of care to reduce waiting times in outpatient musculoskeletal clinics: a mixed-methods study (2025) (under review)

Chapter Six:

Gamble AR, Needs C, Maher CG, McKay MJ, Anderson DB, Hutton JM, De Campos TF, Foster NE, Martens D, Coombs DM, Machado GC, Adams C, Han CS, Zadro JR. The feasibility of delivering and evaluating stratified care integrated with telehealth (‘Rapid Stratified Telehealth’) for patients with low back pain: a feasibility and pilot randomised controlled trial (2025) (under review)

CHAPTER ONE

Introduction

INTRODUCTION

1.1 Background

1.2 Introduction to musculoskeletal conditions

1.2.1 Epidemiology of musculoskeletal conditions

Musculoskeletal conditions affect almost 1.7 billion people worldwide and are the leading contributor to years lived with disability globally.[1] There are over 150 distinct musculoskeletal conditions comprising injuries and diseases affecting muscles, tendons, bones, cartilage, ligaments and nerves.[2] Examples of musculoskeletal conditions include those where the injury or disease can be specified such as degenerative cervical myelopathy[3] and osteoarthritis,[4] and non-specific pain conditions which are presumed to have a musculoskeletal origin such as primary low back pain.

The World Health Organization estimates that there are 335 million new cases of musculoskeletal conditions annually[5,6] and highlights the need for a more sustainable approach to managing these conditions.[1] The most prevalent forms of musculoskeletal conditions are low back pain, neck pain, and pain associated with osteoarthritis and rheumatoid arthritis.[2] Globally, an estimated 619 million people were affected by low back pain in 2020, the most common musculoskeletal condition, and this number is projected to increase to 843 million by 2050.[7] Neck pain is the second most common musculoskeletal condition[8] and was estimated to affect 289 million people in 2017.[9] Chronic musculoskeletal conditions – those where symptoms persist for 12 weeks or greater – make up a substantial proportion of all musculoskeletal conditions. In Australia, 7 million (29%) of people were estimated to be living with chronic musculoskeletal conditions in 2022 and prevalence has not changed since 2017.[10]

Sporting injuries which occur during any type of sport or exercise are less common than chronic musculoskeletal conditions but are most likely to occur in young active people. The prevalence of sporting injuries also does not appear to be reducing over time and in some cases, the percentage of injuries in adolescents may be increasing linked to earlier sport specialisation and training intensity.[11] For example, the total annual incidence of Anterior Cruciate Ligament (ACL) ruptures increased in children and adolescents by 2% each year between 1994 to 2013 in the United States based on insurance claims and the overall annual rate increased by 148% between 2005 to 2015 in Australia based on hospital admissions.[12,13] Some sporting injuries also increase the risk of chronic conditions such as knee osteoarthritis making them particularly problematic.[14]

The onset of musculoskeletal conditions can be sudden or occur gradually which can impact the timing of a diagnosis, management and subsequent patient outcomes.[15] An accurate and early diagnosis of musculoskeletal conditions is necessary to align management with guideline recommendations. ACL rupture is an example of a condition which often occurs suddenly due to a clear mechanism of injury (e.g. pivoting during sport) which can prompt early diagnosis and management.[16] In contrast, other conditions such as degenerative cervical myelopathy, a slowly evolving, degenerative spinal cord injury, may progress slowly over time and go undetected, which makes a timely diagnosis challenging.[17]

1.2.2 Burden and cost of musculoskeletal conditions

Musculoskeletal conditions can have an immediate and also ongoing impact on people's mobility, quality of life, and work productivity; and the global burden of musculoskeletal conditions is increasing.[18] Musculoskeletal conditions account for an estimated 17% of the total years lived with disability globally.[19] In Australia, musculoskeletal conditions accounted for

13% of the total disease burden in 2022 and were the second leading contributor to years lived with disability after mental health and substance use disorders.[10]

Musculoskeletal conditions such as low back pain and neck pain are examples of conditions which are significant contributors to individuals' expenses and healthcare systems costs.[20] For example, low back pain is the leading cause of disability in 160 countries[19] and the leading cause of both reduced work productivity and early retirement in Australia.[21,22] Low back and neck pain had the highest health care spending in the United States in 2016 of any health condition (estimated 134.5 billion) with spending on other musculoskeletal conditions second (estimated $129.8 billion).[23] In Australia, an estimated $14.7 billion of expenditure in the health system in 2020-21 was attributed to musculoskeletal conditions which was almost 10% of the total health expenditure. This financial burden of musculoskeletal conditions provides a strong case for the need to improve cost-effectiveness of prevention and management of these conditions.

1.3 Guidelines for the management of musculoskeletal conditions

The management of musculoskeletal conditions can often begin with conservative management such as a wait-and-see approach, advice on self-management, exercise therapy and simple pain medications. If initial management of musculoskeletal conditions has not been effective, then more invasive options such as injections or surgery may be considered. A recent systematic review of high-quality clinical practice guidelines identified eleven consistent recommendations for the management of musculoskeletal conditions which included 1) patient-centred care, 2) screening for serious pathology, 3) assessing psychosocial factors, 4) discouraging imaging, 5) a physical examination, 6) use of outcome measures to monitor progress, 7) education, 8) exercise therapy, 9) manual therapy as an adjunct, 10) evidence-informed non-surgical care prior to surgery unless specifically indicated and 11) strategies to allow continuation or resumption of work.[24] There are however important differences in guideline recommendations depending on the type of musculoskeletal condition, largely owing to whether the conditions is acute, chronic or degenerative, a sporting injury, or a combination of an acute and chronic condition (e.g. acute ‘flare up’ of a chronic condition following sport participation such as patellofemoral pain of the knee).

1.3.1 Acute musculoskeletal conditions

Acute musculoskeletal conditions are commonly defined as those which have a duration of 6 weeks or less from onset.[1,25] Guidelines for managing presumed acute musculoskeletal conditions generally recommend excluding serious pathology that may require immediate intervention (e.g. a fracture, infection, spinal cord compression) before focusing on controlling pain and restoring function.[26] After excluding serious pathology, guidelines generally recommend advice on self-management as first-line treatment, alongside patient-centred education and exercise therapy.[24] Advice provided to patients should include individualised education about prognosis, possible psychological contributors to pain, simple analgesia, graded return to activities, home exercises and strategies to return to work if needed.[24,26] For example, guidelines for acute low back pain typically recommend education on self-management techniques to help patients manage their pain independently (e.g. encourage continuing normal activities), exercise therapy (e.g. trunk muscle strengthening), use of validated prognostic tools to identify specific treatment needs (e.g. STarT Back tool) and reassurance that most acute cases improve within 4-6 weeks.[25,27,28] Another example is guidelines for acute neck pain such as whiplash associated disorders which recommend education to maintain an active lifestyle and avoid using a cervical collar, exercise therapy to decrease pain and increase range of motion (e.g. postural and mobility exercises), and reassurance that most people recover without treatment in 2 to 3 months.[29] Sub-acute conditions are commonly defined as those which have a duration of 6 weeks to 12 weeks from symptom onset, and guideline recommendations for these conditions are largely similar to recommendations for acute musculoskeletal conditions.[30]

1.3.2 Chronic and degenerative musculoskeletal conditions

Chronic musculoskeletal conditions are commonly defined as those which have persisted for 12 weeks or more from symptom onset.[28] Degenerative conditions are commonly defined as those due to static or dynamic changes to the intensity of tissue loading anywhere in the body or congenital factors over time (e.g. microscopic repetitive spinal cord damage caused by instability or congenital spinal canal stenosis).[31,32] Guidelines for chronic or degenerative musculoskeletal conditions generally recommend health professionals provide non-pharmacologic treatments as first-line management, including home exercises and multidisciplinary rehabilitation.[2] For example, for chronic low back pain, the 2016 National Institute for Health and Care Excellence (NICE) guidelines recommend tailored advice and education, shared decision making, and tailored exercise therapy (e.g. strengthening, stretching) as first line care.[33] Guidelines often recommend that surgical management is reserved for severe cases or those with progressive symptoms where non-surgical management has not improved patient symptoms.[34] For example, for degenerative cervical myelopathy, The Association of the Study of Internal Fixation (AO Spine) 2017 guideline recommends non-surgical management as first-line care for patients with mild clinical symptoms (e.g. no signs or symptoms of radiculopathy), and reserving surgery for those with moderate or severe symptoms (e.g. significant muscle weakness or numbness).

1.3.3 Sporting injuries

Sporting injuries are commonly defined as an impairment sustained in isolated events denoting the loss of bodily function or structure that is the object of observations in clinical examinations.[35] Sporting injuries can be classified as acute (e.g. sudden onset) or chronic (e.g. overuse injuries) and management will often include complex decisions about return to sport or the need for surgical management.[36] Acute injuries, such as soft tissue injuries, often need immediate medical attention to protect the injury and reduce the risk of aggravation.[37] Following this, management will typically be guided by healing stages and individual patient progression (e.g. gradual progression of movement rather than movement limited by specific time frames).[38] For example, following ACL rupture, guidelines from the American Academy of Orthopaedic Surgeons suggest non-surgical and surgical management options should be considered for patients wishing to return to sport.[39] For children and adolescents, guideline recommendations from the International Olympic Committee Consensus also suggest non-surgical management is a viable and safe treatment option despite many believing surgery is the only option.[40]

Chronic sporting injuries such as tendinopathies are often caused by changes to repetitive low-intensity load ‘events’ over time. Guidelines for the management of these conditions typically recommend advice on load management and activity modification and appropriate resistance exercises.[41] For example, for Achilles tendinopathy, guidelines from the Dutch Association for Sports Medicine multidisciplinary guideline suggest surgery be reserved for patients who do not recover after at least six months of active treatment (e.g. individualised and progressive calf muscle strengthening for at least 12 weeks).[42]

1.3.4 Poor use of recommended care for musculoskeletal conditions

Many patients with musculoskeletal conditions do not receive guideline-recommended care which is a significant global problem.[43] A recent systematic review (n=94 studies from 19 countries) showed that only two out of three physiotherapists deliver care that is recommended in clinical guidelines for the management of musculoskeletal conditions and about one in four physiotherapists provide care that is specifically recommended against in guidelines.[44] Alarmingly, this trend does not appear to be improving over time.[45,46] The Australian CareTrack study also found poor use of recommended care in primary care, with only 55% of people with osteoarthritis and 72% of people with low back pain receiving recommended care when visiting a primary care provider in Australia.[47] Poor use of recommended care is not solely a problem in the management of musculoskeletal conditions. For example, studies show that only two in three patients presenting to family medicine physicians in the Netherlands receive recommended care.[48] In the United States, up to 20% or more of care provided is not needed or potentially harmful to patients.[49]

There are numerous barriers to patients receiving guideline-recommended care which may explain these concerning trends. Key barriers to patients receiving recommended care include a lack of access to evidence-based resources which patients can understand.[50] A recent overview of 25 systematic reviews suggested barriers to patients receiving recommended health care include a lack of clinician time to see the increasing number of patients on waiting lists, education of staff personnel on evidence-based medicine and financial constraints for adopting new interventions.[50] Barriers specific to musculoskeletal conditions reported in other studies include unclear guideline recommendations, poor credibility of evidence, a culture of health care consumption, clinical environments that discourage exercise prescription, enthusiasm for medical interventions, inappropriate clinician training, overreliance on manual therapy, beliefs and personal experiences, and poor use of shared decision making.[51] Health professionals may also not be aware of guidelines, lack knowledge about them or may disagree with them. Some studies have shown that only 12% of physiotherapists[52] are aware of clinical practice guidelines for low back pain and only 46% agree guidelines should inform the management of low back pain.[53] Patients may also have negative attitudes towards implementation of new evidence due to a lack of knowledge about the guidelines and sociocultural beliefs.[50] Some of these barriers could be overcome by leveraging potential facilitators aiming to reduce the overuse of healthcare services. An example is successful implementation of a chronic illness model for diabetes care in family medicine in the United States facilitated by leadership committed to change which created enthusiasm and a clear objective of care.[54] Other factors shown to facilitate recommended care include the commitment of the members of multidisciplinary teams, support of administrators and application of technology to improve practice (e.g. education via electronic guideline systems).[50,55]

One of the most prevalent examples of non-recommended care for musculoskeletal conditions is unnecessary surgery. Use of surgery is increasing for a range of conditions, despite evidence that particular surgeries are not recommended (e.g. knee arthroscopy for knee arthritis),[56] provide similar outcomes to non-surgical management (e.g. ACL reconstruction surgery)[57-59] and provide similar outcomes to sham surgery (arthroscopic sub-acromial decompression for shoulder pain).[60] To overcome the increasing rate of potentially unnecessary surgery there is a need to improve timely access to evidence-based and patient-friendly information.[51] Two particularly promising strategies are 1) improving online information and 2) developing patient decision aids to help patients understand the benefits and harms of surgery compared to non-surgical management options. Patient decision aids are examples of evidence-based resources which facilitate shared decision-making and patient involvement.[61,62]

Another reason patients do not receive recommended care is long waiting times to access care. Long waiting times can prevent timely access to a health professional who can provide advice on the most appropriate course of management. Delayed access to care can contribute to patients being unaware of how to manage their condition which can mean symptoms can become increasingly disabling, complex and costly to manage.[63-65] There is a need to identify innovative models of care and evaluate if these new models could improve access to care for people with musculoskeletal conditions.[66] A potential solution to reduce waiting times for people with musculoskeletal conditions is a model of care which identifies cases that can be managed with less resources (e.g., brief telephone appointments, self-management advice, App-based home exercise programmes), thereby freeing up clinic-based resources for more complex cases.

1.4 Simple and innovative ways to align management of musculoskeletal conditions with guidelines

1.4.1 Online information to reduce unnecessary surgery

The internet has great potential to provide timely access to evidence-based information, but unreliable information may be leading to increasing rates of unnecessary surgery. Online information can be visual (e.g. video, infographics), audio (e.g. podcasts) or artificial intelligence generated which can be accessed via different platforms (e.g. websites, research papers, social media posts)[67] on various devices (e.g. smart phones, tablets, laptops). The way health professionals and patients search for information online is rapidly changing due to advances in search engines, artificial intelligence and increasing use of large language models.[68-70] Misleading online information may be partially responsible for the increasing rates of unnecessary surgery as it influences treatment expectations and subsequent interactions with health professionals.[71] A particular concern is misleading online information[72] promoting surgery prior to seeing a physiotherapist or surgeon.[73] In the field of sports medicine, it is unknown if online consumer information about the management of ACL rupture[59] – one of the most prevalent and career impacting sporting injuries – is potentially contributing to increasing rates of surgery.

1.4.2 Patient decision aids to reduce unnecessary surgery

Patient decision aids are evidence-based resources that present balanced information on the benefits and harms of different treatment options in a user-friendly format (e.g. by incorporating dot points, graphs, and visuals).[74] Existing patient decision aids have focused on decisions about surgery (e.g. mastectomy for breast cancer, cardiac revascularization and bariatric surgery), screening (e.g. prostate cancer, colon cancer, prenatal), genetic testing (e.g. for breast cancer), and long-term medication use (e.g. insulin injections for diabetes, or statins for high cholesterol).[74] A 2017 Cochrane review of 105 trials[74] found that using patient decision aids improved knowledge, accuracy of risk perceptions, alignment of care with patient values and preferences, patient involvement in decision making, decision quality and decisional conflict. Patient decision aids offer a potential solution to the overuse of unnecessary or harmful care by presenting the best available evidence on management options to patients and their health professionals.

Exposure to patient decision aids has been shown to reduce the number of patients choosing unnecessary elective surgery in favour of conservative treatment approaches.[74] For example, patient decision aids for people considering major surgery (e.g. mastectomy, coronary revascularisation) led to a 21-42% reduction in the number of patients electing to have major surgery (relative risk =0.74, 95% confidence interval 0.6 to 0.9).[62,75] Patient decision aids may also be particularly helpful when there is uncertain evidence guiding management recommendations.[62] For example, children and adolescents who rupture their ACL and adults with degenerative cervical myelopathy both face uncertainty when deciding between surgery and non-surgical management as evidence comparing these management approaches is scarce. A decision aid could be extremely beneficial for people living with these conditions to better align treatment choices with patient values and guideline recommendations.

1.4.3 New models of care to improve timely access to recommended care

Long waiting times for people with musculoskeletal conditions referred to public hospital outpatient clinics are a major barrier to them receiving recommended care.[76] Innovative new approaches to care delivery using a triage approach and incorporating telehealth, offer opportunities to reduce waiting times and improve access to care.[77] In Australia, over half the population (55%) do not have private health insurance. This creates a huge demand for care in the public hospital system and extensive waiting times.[78] Delayed access to care for people with musculoskeletal conditions can lead to people developing symptoms which are more disabling, complex and costly to manage.[63-65] There is an urgent need for a new model in Australia[79,80] that could allow early identification of patients who can be managed with less resources (e.g. a brief telephone appointment, self-management advice), thereby freeing up clinic-based resources for people with more complex management needs.[81]

PhysioDirect is a UK model of care that could be particularly useful to reduce waiting times for people with musculoskeletal conditions seeking care in Australia's public health system. PhysioDirect used a telephone call with a physiotherapist to determine those who needed minimal intervention (e.g. brief telephone advice, App-based exercises) due to a good prognosis and those who require clinic-based physiotherapy.[82] If this model is appropriately adapted to the Australian healthcare context, it holds promise for reducing waiting times for people with musculoskeletal conditions referred to public hospital outpatient clinics and ensure these patients receive recommended care sooner.

1.5 Aims of the thesis

The broad aims of the thesis were to evaluate if improved online information and patient decision aids are potential targets to reduce unnecessary surgery for musculoskeletal conditions and evaluate if a new model of care could reduce waiting times for people with musculoskeletal conditions referred to public hospital outpatient clinics. Both broad aims address the issue of patients not receiving recommended musculoskeletal healthcare.

The specific aims were:

1. To summarise the portion of webpages on the management of ACL rupture that are aligned with the best available evidence using a content analysis (Chapter Two)
2. To describe the development and evaluate acceptability of a patient decision aid for children and adolescents who have an ACL rupture using mixed methods (Chapter Three)
3. To describe the development and evaluate acceptability of a patient decision aid for adults with degenerative cervical myelopathy using mixed methods (Chapter Four)
4. To describe the development of an innovative model of care for people with musculoskeletal conditions that aims to reduce waiting times in public hospital outpatient clinics using mixed methods (Chapter Five)

5. To evaluate if the innovative new model of care is feasible to deliver and evaluate for adults with low back pain referred to an outpatient back pain clinics in Australia using a single-blinded, single site, two arm parallel feasibility and pilot randomised controlled trial (RCT) with nested qualitative interviews (Chapter Six)

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CHAPTER TWO

Online information about the management of anterior cruciate ligament ruptures in Australia: A content analysis

PREFACE

Chapter Two presents a content analysis which summarises the portion of webpages on the management of anterior cruciate ligament (ACL) rupture that are aligned with the best available evidence. The need for this study was identified due to increasing rates of ACL surgery and previous content analyses of online information on the management of musculoskeletal conditions suggesting supposably trustworthy webpages may be misleading patients to have unnecessary surgery. Most people who suffer an ACL rupture have been shown to search for information online before having surgery, but no study had examined if information on ACL rupture management is aligned with the best available evidence.

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Original article

Online information about the management of anterior cruciate ligament ruptures in Australia: A content analysis

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ABSTRACT

Background: Most people who suffer an anterior cruciate ligament (ACL) injury search for information online.
Objectives: Summarise the proportion of webpages on ACL rupture management that present evidence-based information.
Design: Content analysis.
Methods: We examined webpage information on ACL ruptures identified through (1) Google searches using terms synonymous with 'anterior cruciate ligament rupture' and searching 'knee surgeon' linked to each Australian capital city, and (2) websites of professional associations. The primary outcome was the proportion of webpages that suggest people can return to at least some form of sport with non-surgical management. Secondary outcomes included webpage information on return to sport with ACL reconstruction (ACLR) and non-surgical management, benefits, harms, and risk of osteoarthritis related to these options, and activity modification.
Results: Out of 115 webpages analysed, 48% suggested people can return to at least some form of sport with non-surgical management. Almost half of webpages suggested most people will return to some form of sport following ACLR (41%) and mentioned benefits of ACLR (43%). Fewer webpages mentioned benefits of non-surgical management (14%), approximately two in three people return to pre-injury level of sport following ACLR (4%), risk of re-injury following ACLR (23%), most people return to sport within 9 months of ACLR (27%), activity modification as a management approach (20%), and ACLR will reduce the risk of osteoarthritis (23%).
Conclusion: Most online information on ACL rupture management isn't aligned with the best available evidence. Inaccurate information could mislead patients' treatment choices and create unrealistic expectations for return to sport.

1. Introduction

The annual incidence of anterior cruciate ligament (ACL) ruptures is estimated at 68.6 per 100,000 person-years in the United States (Sanders et al., 2016). Surgical treatment of ACL ruptures in people have been studied extensively in orthopaedic sports medicine, and ACL reconstruction (ACLR) has been widely advocated to be essential for return to sport (Casteleyn and Handelberg, 1996). However, guidelines from the American Academy of Orthopaedic Surgeons suggest that non-surgical treatment should be considered, particularly for people without concomitant injuries who are not participating in pivoting and cutting sports (American Academy of Orthopaedic Surgeons Appropriate Use Criteria for ACL Prevention Programs). This recommendation is supported by two randomised controlled trials (n = 121 and n = 167) which found people who have rehabilitation alone with the option for delayed ACLR following an ACL rupture can achieve largely similar outcomes compared to those who have early ACLR (Frobell et al., 2010; Reijman et al., 2021). The risk of osteoarthritis is similar between people who are managed using either approach, contrary to popular belief that ACLR prevents osteoarthritis (Bennell et al., 2016; Harris et al., 2017; Webster

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and Hewett, 2021).

Despite this evidence, rates of primary and revision ACLR continue to rise in Australia (Zbrojkiewicz et al., 2018) and globally (Sanders et al., 2016). One explanation is that people overestimate the benefits of ACLR. For example, two surveys of young athletes undergoing ACLR (n = 675 (Webster and Feller, 2019); n = 181 (Feucht et al., 2016)) showed that 84–91% expect to return to their previous level of sport following ACLR. However, only 65% of people return to their pre-injury level of sports participation following ACLR, and of those who return to pivoting and cutting sports, nearly one in four experience a subsequent ACL rupture (Ardern et al., 2014). Another explanation for the increasing use of ACLR is that people do not consider non-surgical management as they are not aware that it is a viable treatment option (Thorstensson et al., 2009).

As with many topics, people frequently seek information on prognosis, diagnosis and treatment options by searching online. In Australia, 84% of people who had an ACLR used the internet to search for information about their procedure preoperatively (Devitt et al., 2017). However, research to date has only evaluated limited aspects of online information on management of ACL ruptures, such as the accuracy of information and whether information is supported by references (Gosselin et al., 2013) or focused on specific media platforms such as YouTube (Springer et al., 2020). It currently remains unknown if webpages acknowledge that return to some form of sport using non-surgical management is a viable treatment option following ACL rupture. Misleading online information about the benefits of ACLR and non-surgical management may contribute to non-evidence-based beliefs among people who have ruptured their ACL. It is also unknown whether webpages on the management of ACL ruptures acknowledge important information on return to sport rates, benefits, harms, and risk of osteoarthritis related to ACL reconstruction (ACLR) and non-surgical management, and activity modification as a management option.

The purpose of our study was to summarise the proportion of consumer webpages on the management of ACL ruptures that suggest people can return to at least some form of sport with non-surgical management. Secondary aims were to summarise the proportion of consumer webpages that discussed information within the following categories: return to sport following ACLR and non-surgical management, benefits, harms, risk of osteoarthritis following ACLR and non-surgical management, and activity modification.

2. Methods

2.1. Study design, and inclusion and exclusion criteria

We performed a content analysis of online consumer information about the management of ACL ruptures. We included any online information that was written in English, targeted to consumers and discussed management options following an ACL rupture. This included links downloadable as Portable Document Format (PDFs) or videos featuring relevant information (e.g. resources routinely provided to patients by orthopaedic surgeons). We excluded webpages that did not mention management options (e.g. only discussed anatomy, risk factors), only mentioned partial ACL tears, journal articles without a consumer summary, post-operative rehabilitation protocols, YouTube links, webpages aimed at health professionals, advertisements promoted by Google, and duplicate webpages. Appendix A outlines the inclusion and exclusion criteria and search strategy.

2.2. Search strategy and selection of webpages

Internet searches using the Google search engine in Google Chrome were conducted in May 2021. We only searched Google because approximately 92% of all internet searches performed in Australia per annum are performed via Google (GlobalStats). Chrome is the most commonly used internet browser, accounting for 65% of all internet searches (GlobalStats & Browser). First, we performed separate searches using terms synonymous with ‘anterior cruciate ligament’ and ‘management’ (Appendix A). We limited searches to the first 30 webpages identified, excluding advertised links, as people are unlikely to explore webpages beyond the second page of a Google search (SISTRIX.). Second, we searched the term ‘knee surgeon’ linked to each capital city of Australia (e.g. knee surgeon Sydney), limited to the first page of results, excluding advertised links and Google Maps results due to geo-locating algorithms. Browser history was cleared between each Google search. Finally, we searched the websites of the Australian Orthopaedic Association (AOA), Australian Physiotherapy Association (APA), Royal Australian College of General Practitioners (RACGP), Australian Rheumatological Association (ARA), Sports Medicine Australia (SMA), and Ottawa Hospital Research Institute Patient Decision Aids for any eligible webpages.

Two researchers (see acknowledgements) independently performed the above searches and selected documents according to the inclusion criteria. Any disagreements were resolved by discussion with a third researcher.

2.3. Data extraction

Two researchers independently extracted data from each webpage, resolving disagreements by discussion with a third researcher. The following information was extracted from each webpage: how the webpage was identified (i.e. search term used, professional society website searched), webpage owner, webpage title, URL, type of health professional(s) who authored the webpage (e.g. physiotherapists, orthopaedic surgeons), whether we followed links (only done in cases where relevant information was not on the landing webpage and it was clear the link would lead to this information), date webpage was published or updated, any disclosed conflicts of interest, funding or sponsorship, whether the webpage included a reference list, and outcome data detailed below. See Appendix B for coding framework.

3. Outcomes

Primary and secondary outcomes and the justification for their inclusion are listed in Table 1.

3.1. Data analysis

We summarised data from webpages using counts and percentages. We performed a sensitivity analysis on all outcome measures to investigate differences in online information for webpages authored only by orthopaedic surgeons and webpages not authored by orthopaedic surgeons (this includes webpages where orthopaedic surgeons authored a webpage alongside other health professionals). Differences were analysed using χ^2 tests. All analyses were conducted using IBM SPSS Statistics Version 27.

4. Results

4.1. Search results and webpage characteristics

We identified 443 webpages from our online searches. After removing duplicates and applying our exclusion criteria, 115 webpages were included (Fig. 1). The included webpages came from a variety of sources including both non-for-profit and for-profit web-based consumer information companies, Wikipedia, government funded institutes, health insurers, professional societies, and hospitals or health services. Most webpages were authored by orthopaedic surgeons (n = 61, 53%), followed by general practitioners or physicians (n = 19, 17%), physiotherapists (n = 14, 12%), multiple health professionals (n = 8, 7%), pharmacists (n = 1, 1%) and sports medicine physicians (n = 1, 1%). We were unable to determine the webpage author on 11 webpages (10%).

Table 1
Outlines the outcomes and our justification for assessing them.

Primary Outcome	Justification
Whether each webpage suggests people can return to at least some form of sport with non-surgical management.	Two randomised controlled trials demonstrate that people who have rehabilitation alone or delay ACL reconstruction following an ACL rupture can achieve a similar level of sports participation compared to those who have early ACL reconstruction (Frobell et al., 2010; Reijman et al., 2021).
Secondary Outcomes	Justification
Suggests most people will return to some form of sport following an ACL reconstruction.	A systematic review of 7556 people following ACL reconstruction found that 81% return to some form of sport, 65% return to their pre-injury level of sports participation and 55% return to competitive level sport with a minimum follow up time of 12 months (Ardern et al., 2014).
Mentions approximately 2 in 3 people will return to their pre-injury level of sports participation following ACL reconstruction.	The above-mentioned systematic review found that approximately 2 in 3 people (65%) return to their pre-injury level of sports participation following ACL reconstruction (Ardern et al., 2014).
Suggests most people will return to sport within 9 months following an ACL reconstruction.	Guidelines recommend that athletes should not return to sport earlier than 9 months following ACL reconstruction (Filbay and Grindem, 2019). Those who return to sport at 8 months are twice as likely to have another ACL rupture compared to those who return at 9 months and re-injury risk is even higher when people return to sport earlier than 8 months (Grindem et al., 2016).
Mentions there is a risk of re-injury after returning to sport following an ACL reconstruction.	One in four people return to pivoting and cutting sports following ACL reconstruction will experience a subsequent ACL rupture (ipsilateral reinjury rate of 10% and a contralateral injury rate of 12%) (Wiggins et al., 2016).
Mentions benefits and harms of ACL reconstruction and non-surgical management	Providing information about benefits and harms of treatment options has been shown to facilitate active involvement of patients in treatment decisions and could reduce the use of unnecessary surgery (Stacey et al., 2017).
Suggests ACL reconstruction will reduce the risk (or non-surgical management will increase the risk) of knee osteoarthritis.	The risk of osteoarthritis is similar between people who have an ACL reocnstruction and those managed without ACL reconstruction (Bennell et al., 2016; Harris et al., 2017; Webster and Hewett, 2021).
Mentions activity modification as an approach to ACL rupture management.	Given that one in four people who have an ACL reconstruction experience a subsequent ACL rupture after returning to vigorous sports, some experts suggest people should consider modifying the sports they play or their activities to minimise the risk of further damage to the knee joint (Zadro and Pappas, 2019).

Of the webpages included, 38 (33%) had clear links to relevant information that were not on the landing webpage. Only 4 (3%) webpages disclosed conflicts of interest and 27 (23%) included references. Appendix C outlines all the included webpages.

4.2. *Return to sport following non-surgical management (primary outcome)*

Fifty-five webpages (48%) suggested people can return to at least some form of sport with non-surgical management (Table 2).

4.3. *Return to sport following ACL reconstruction*

Forty-seven (41%) webpages suggested most people will return to some form of sport following ACLR; 31 (27%) suggested most people will return to sport within 9 months following an ACLR and only 5 (4%) specifically mentioned that approximately 2 in 3 people will return to their pre-injury level of sports participation. Only 26 (23%) webpages mentioned there is a risk of re-injury after returning to sport following ACLR (Table 2).

4.4. *Benefits and harms of ACL reconstruction and non-surgical management*

Forty-nine (43%) webpages mentioned the benefits of ACLR while only 16 (14%) mentioned the benefits of non-surgical management. Forty-one (36%) webpages mentioned the harms of ACLR and 35 (30%) mentioned the harms of non-surgical management (Table 2).

4.5. *Risk of osteoarthritis*

Twenty-six (23%) webpages suggested ACLR will reduce the risk (or non-surgical management will increase the risk) of osteoarthritis (Table 2).

4.6. *Activity modification*

Twenty-three (20%) webpages mentioned activity modification as an approach to ACL rupture management (Table 2).

4.7. *Sensitivity analysis*

Webpages authored only by orthopaedic surgeons were less likely to suggest people can return to at least some form of sport with non-surgical management (39% vs. 57%, $p = 0.053$), suggest people will return to sport within 9 months following an ACLR (20% vs 35%, $p = 0.061$) or mention benefits of non-surgical management (7% vs 22%, $p = 0.015$). Webpages authored only by orthopaedic surgeons were more likely to mention the benefits of ACLR (64% vs. 19%, $p < 0.001$), mention the harms of ACLR (46% vs 24%, $p = 0.015$) and suggest ACLR will reduce the risk of osteoarthritis (33% vs 11%, $p = 0.006$) (Table 2).

5. Discussion

5.1. *Summary of main findings*

Most consumer webpages on the management of ACL ruptures are not aligned with the best available evidence and published guidelines. Less than half of webpages suggest people can return to at least some form of sport with non-surgical management, while activity modification as a management option is only mentioned in one-fifth of the webpages. Only one in four webpages acknowledge that there is a risk of re-injury when returning to sport following ACLR and only 4% mention that approximately two in three people will return to their pre-injury level of sports participation. The benefits of ACLR were mentioned more frequently than the benefits of non-surgical management, but harms were mentioned by a similar proportion of webpages. One positive was that less than a quarter of webpages claimed that ACLR will reduce the risk of osteoarthritis. Webpages authored only by surgeons were more likely to mention the benefits of ACLR and suggest surgery will reduce the risk of osteoarthritis.

5.2. *Strengths and limitations*

A strength of our study is that our search captured webpages providing information on the management of ACL ruptures that would mirror a Google search completed by people in Australia, including

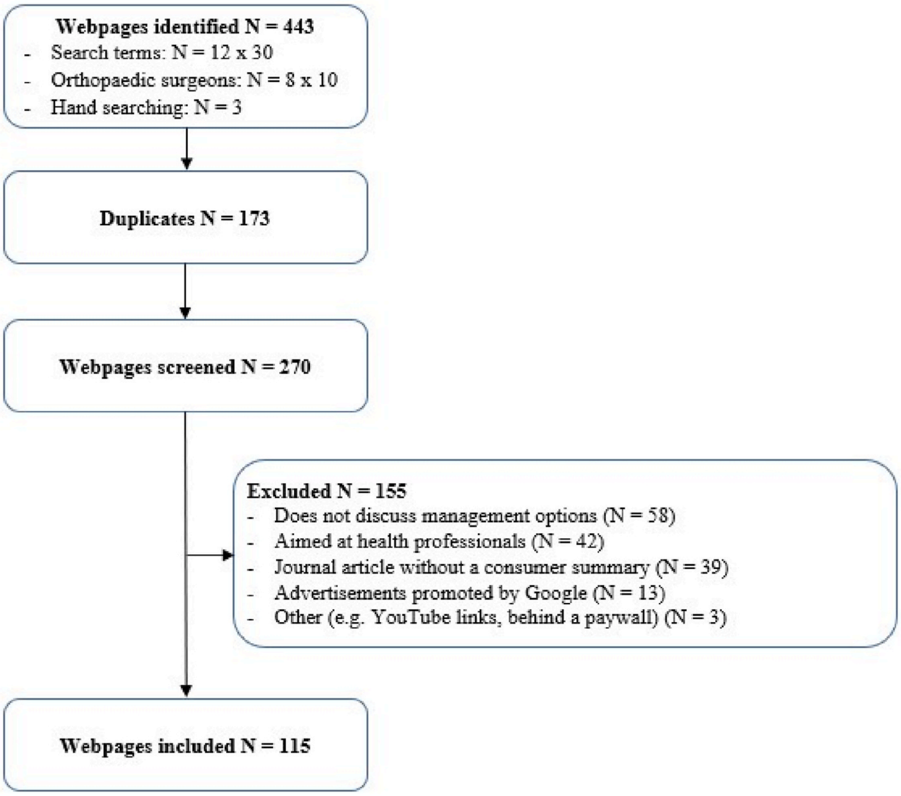

Fig. 1. Search results.

searching for knee surgeons in Australian capital cities that could be adapted globally. Furthermore, webpage selection and data extraction were done independently by two researchers, with all disagreements resolved by discussion or consultation with a third researcher. This study also has limitations. Some outcomes were subjective and may have been influenced by professional beliefs and bias. The authorship team includes people who have experienced an ACL rupture and physiotherapists working clinically and/or in research. Ideally, it would also include orthopaedic surgeons and sports physicians. Our study summarised individual components mentioned on each webpage but did not provide an interpretation of the overall message of the webpage or provide a summary score for the amount of misinformation (or "errors") present on the webpage. Another limitation could be limiting the search to knee surgeons, which may not capture people who search for non-surgical management options.

5.3. *Meaning of the study*

Only half of webpages on the management of ACL ruptures suggested that people can return to some form of sport with non-surgical management. The first randomised controlled trial showing that non-surgical management with an option for delayed ACLR is equally effective to early ACLR following ACL rupture was published in 2010 (Frobell et al., 2010) but the translation of this evidence to publicly available online information appears to be slow. Webpages that omit this information could leave people unaware that non-surgical management is a viable option - as presented in treatment guidelines (American Academy of Orthopaedic Surgeons Appropriate Use Criteria for ACL Prevention Programs) - and lead them to believe that surgery is the only way to return to some form of sport. In addition, some athletes can even return to vigorous sports that include pivoting and cutting if they do not have concomitant injuries, recurrent instability and follow a structured rehabilitation protocol (Grindem et al., 2018; Paterno, 2017). Webpages that omit this information could also be contributing to a delay in translating the evidence-based management of ACL ruptures into practice (Green and Seifert, 2005; Davis and Taylor-Vaisey, 1997).

Online information on return to sport following ACLR may be misleading people and creating false expectations. Strong evidence has shown that approximately two in three people will return to their pre-injury level of sports participation (Ardern et al., 2014) but almost none of the webpages included this information. Although half of webpages correctly stated that most ACLR patients will return to some form of sports, webpages were more likely to be vague and simply state that most people will return to sport following ACLR. However, if online information does not acknowledge that one in three people do not return to their pre-injury level of sports participation, people may have false expectations and believe a successful return to sport is practically guaranteed. This may be reflected by evidence that suggest that 84–91% of young adults expect to return to the same pre-injury level of sport prior to undergoing ACLR (Webster and Feller, 2019; Feucht et al., 2016).

Management decisions following ACL rupture may be heavily influenced by individual beliefs on how they can return to sport in the most timely manner. Our study showed one in four webpages indicated people will return to sport within 9 months following ACLR while guidelines suggest as the absolute minimum time a person should wait before returning to pivoting and cutting sports (Filbay and Grindem, 2019). However, most young competitive athletes expect to return to sport in 6 months or less following ACLR (86% in a survey of 57 athletes) (Armento et al., 2021). Webpages omitting important information on return to sport time frames may be contributing to unrealistic expectations, premature and risky return to sports and poor patient satisfaction after ACLR (Feucht et al., 2016).

A balanced understanding of the potential harms of different management strategies for ACL ruptures is important to assist people in making evidence-informed decisions. Worryingly, our study found that only one in four webpages mentioned the risk of re-injury when returning to sport following ACLR. Webpages omitting information on

Table 2
Characteristics of 115 consumer webpages on the management of ACL ruptures.

	Total sample of webpages N (%)	Webpages only authored by Orthopaedic surgeons (N, %)	Webpages not only authored by Orthopaedic surgeons (N, %)	Chi-squared P value
Primary outcome	N = 115	N = 61	N = 54	
Suggest people can return to at least some form of sport with non-surgical management	55 (48%)	24 (39%)	31 (57%)	0.053
Secondary outcomes	**N=115**	**N=61**	**N=54**	
Suggest most people will return to some form of sport following an ACL reconstruction	47 (41%)	29 (48%)	18 (33%)	0.122
Suggest most people will return to sport within 9 months following an ACL reconstruction	31 (27%)	12 (20%)	19 (35%)	0.061
Mention ~2/3 people will return to their pre-injury level of sports participation following ACL reconstruction	5 (4%)	1 (2%)	4 (7%)	0.130
Mention there is a risk of re-injury after returning to sport following an ACL reconstruction	26 (23%)	17 (28%)	9 (17%)	0.152
Mention benefits of ACL reconstruction	49 (43%)	39 (64%)	10 (19%)	<0.001
Mention benefits of non-surgical management	16 (14%)	4 (7%)	12 (22%)	0.015
Mention harms of ACL reconstruction	41 (36%)	28 (46%)	13 (24%)	0.015
Mention harms of non-surgical management	35 (30%)	23 (38%)	12 (22%)	0.072
Suggest ACL reconstruction will reduce the risk of osteoarthritis	26 (23%)	20 (33%)	6 (11%)	0.006
Mention activity modification as an approach to ACL injury management	23 (20%)	11 (18%)	12 (22%)	0.575
Webpage characteristics	**N=115**			
Links followed	38 (33%)			
Conflicts of interest disclosed	4 (3%)			
References included	27 (23%)			

ACL: anterior cruciate ligament; N: number of webpages.

injury rates for those people returning to sport following ACLR (25% will have a subsequent ACL rupture after returning to pivoting and cutting sports (Wiggins et al., 2016)) may provide athletes with a false sense of security and overconfidence. The benefits of ACLR (43% of webpages) were included in webpages more often than the benefits of non-surgical management (14% of webpages). If webpages don't present the benefits of treatment options in a balanced way, people may form strong beliefs that do not reflect the current best evidence-based recommendations prior to consulting a health professional (Hoffmann et al., 2020).

5.4. *Comparison to existing literature*

Limited research investigating whether webpages on the management of ACL ruptures are providing evidence-based information precludes us from making meaningful comparisons between studies. Nevertheless, some studies have investigated other aspects of online information on ACL ruptures that are worth discussing. For example, an analysis of internet resources on ACL injuries in females (n = 35 webpages) demonstrated that the readability of webpages was low and just one third of webpages cited references (Gosselin et al., 2013). Similarly, an evaluation of 140 YouTube videos on rehabilitation and return to sport following ACLR demonstrated that videos often offer inaccurate information (Springer et al., 2020).

Other studies assessing online information about musculoskeletal and orthopaedic conditions highlight that information rarely gives an accurate portrayal of the best available evidence. For example, a content analysis of 93 webpages on knee arthroscopy for osteoarthritis (Buchbinder and Bourne, 2018) found only eight webpages (9%) acknowledged the evidence that knee arthroscopy is not superior to sham surgery or non-surgical management (Moseley et al., 2002; Kirkley et al., 2008; Reichenbach et al., 2010; Laupattarakasem et al., 2008; Brignardello-Petersen et al., 2017). A content analysis of 'trustworthy' websites making treatment recommendations for low back pain (n = 79) found that less than half of websites made accurate recommendations (Ferreira et al., 2019). A content analysis of 155 webpages on shoulder surgery found that few webpages provided an accurate portrayal of the evidence for subacromial decompression surgery (18% of webpages) and rotator cuff repair surgery (4% of webpages) (Robertson et al., 2021).

5.5. *Unanswered questions and future research*

Studies of online information highlight the need to develop and disseminate evidence-based resources on the management of musculoskeletal and orthopaedic conditions. A good example is a recent study which described the development of a patient decision aid for the management of shoulder pain (Zadro et al., 2021) after consultation with experts and interviews with patients and health professionals. Patient decision aids are tools that support people to make more informed decisions by providing information about options (including their associated benefits and harms) (Stacey et al., 2017). Evidence suggests patient decision aids facilitate active involvement of patients in their treatment decisions and in some cases can reduce the use of unnecessary surgery (Cochrane review of 105 studies and 31,043 participants) (Stacey et al., 2017). A patient decision aid could assist people who have ruptured their ACL better understand the benefits and harms of ACLR and non-surgical management. Decision aids on the management of ACL ruptures do exist (Gleadhill & Barton,; Healthwise). However, these resources are missing key elements that are needed for patients with an ACL rupture to make informed treatment choices (e.g. numeric estimates of benefits and harms from randomised control trials (Frobell et al., 2010; Reijman et al., 2021), global summary of the benefits, harms and practice considerations of options) (Zadro et al., 2020). A comprehensive and user-friendly patient decision aid to facilitate a collaborative decision-making process could be very helpful.

Once evidence-based resources have been created, future research is needed to analyse how we can improve the accessibility and identification of reliable health information online. Webpages that provide consumer health information could be assessed using an evidence-based checklist to encourage authors to present balanced information that includes both the benefits and harms of management options, numeric estimates of benefits and harms where possible, and references. In addition, interventions aimed at improving health literacy could help patients make more informed decisions, and researchers could collaborate with web designer experts to promote ease of access to reliable online information found using search engines such as Google. There may also be a role for government agencies to intervene when websites consistently spread harmful information or for technology companies to fact check and mark webpages based on alignment with evidence-based information.

6. Conclusion

Most webpages providing information on management following ACL rupture are not aligned with the best available evidence, with less than half of webpages suggesting people can return to at least some form of sport with non-surgical management. Inaccurate and misleading online information about the management of ACL ruptures could create the false perception that surgery is the only viable treatment option. There is a need for better patient resources on the management of ACL ruptures, such as decision aids, to help patients understand the benefits and harms of options and make evidence-informed choices.

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Declaration of competing interest

Kieran Richardson runs face-to-face and online Professional Development programs for Healthcare Professionals that focus on the non-surgical management of patients with knee injuries (both privately and for the Australian Physiotherapy Association) and offers independent Specialist Physiotherapist reviews of patients wanting non-surgical opinion on knee pain and injury.

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Appendix A. Inclusion criteria and search strategy

Inclusion criteria

We included any online information that:

- Was written in English
- Targeted to consumers
- Discussed management options following an ACL rupture

This included links downloadable as Portable Document Format (PDFs) or videos featuring relevant information (e.g. resources routinely provided to patients by orthopaedic surgeons).

We excluded:

- Webpages that did not mention management options (e.g. only discussed anatomy, risk factors)
- Webpages that only mention partial ACL tears
- Journal articles without a consumer summary
- Post-operative rehabilitation protocols
- YouTube links
- Webpages aimed at health professionals
- Advertisements promoted by Google
- Duplicates

Search strategy (clear Browser history after each search)

Terms searched in Google (using Chrome browser); common descriptors of anterior cruciate ligament rupture and treatment (limited to first 30 webpages, excluding advertised links)

- Anterior cruciate ligament
- Anterior cruciate ligament rupture
- Anterior cruciate ligament injury
- Anterior cruciate ligament tear
- Anterior cruciate ligament treatment
- Anterior cruciate ligament management
- ACL
- ACL rupture
- ACL injury
- ACL tear
- ACL treatment

- ACL management

Terms searched in Google; orthopaedic surgeons linked to Australian capital cities (limited to first page of search results, excluding advertised links and Google Maps results due to geo-locating algorithms)

- knee surgeon Sydney
- knee surgeon Melbourne
- knee surgeon Canberra
- knee surgeon Hobart
- knee surgeon Adelaide
- knee surgeon Perth
- knee surgeon Brisbane
- knee surgeon Darwin

Association websites searched manually

- Australian Orthopaedic Association (AOA)
- Australian Physiotherapy Association (APA)
- Royal Australian College of General Practitioners (RACGP)
- Australian Rheumatological Association (ARA)
- Sports Medicine Australia (SMA)
- Ottawa Hospital Research Institute Patient Decision Aids

Appendix B
Coding framework

Code	Definition
Webpage characteristics	
ID	Unique identification number for webpage
Search term used	Search term used to retrieve the webpage (e.g. 'anterior cruciate ligament', 'ACL tear')
Owner	Owner of the webpage. Usually found at the top left corner of the webpage
Title	Title of the webpage (initial landing page)
URL	URL of the webpage (initial landing page)
Include	Webpage is eligible to be included (Yes/No)
Reason for exclusion	Reason for it being excluded if applicable
Type of health professional authoring the webpage	Type of health professional authoring the webpage (e.g. physiotherapists, orthopaedic surgeons, multidisciplinary, 'unable to determine')
Date published/updated/last reviewed	Date the webpage was published, updated, or last reviewed (whichever is latest)
Links followed to obtain relevant information	Links were followed from the initial landing page to obtain relevant information (Yes/No)
Any disclosed conflicts of interest, funding or sponsorship	The webpage mentions conflicts of interest, funding or sponsorship (Yes/No)
Reference list included	The webpage included a reference list (Yes/No)
Return to sport following non-surgical management	
Suggests people can return to at least some form of sport with non-surgical management [PRIMARY OUTCOME]	The webpage suggests people can return to at least some form of sport with non-surgical management (e.g. rehabilitation) following an ACL rupture (Yes/No)
Return to sport following ACL reconstruction	
Suggests most people will return to sport following an ACL reconstruction	The webpage suggests most people will return to sport following an ACL rupture (Yes/No)
Suggests most people will return to sport within 9 months following an ACL reconstruction	The webpage suggests most people will return to sport within 9 months following an ACL rupture (Yes/No)
Mentions that ~2/3 will return to their pre-injury level of sports participation following an ACL reconstruction	The webpage mentions that approximately 2/3 people (range 60–70%) will return to their pre-injury level of sports participation after ACL reconstruction (Yes/No)
Mentions risk of re-injury when returning to sport following an ACL reconstruction	The webpage mentions that there is a risk of re-injury when returning to sport following an ACL reconstruction (Yes/No)
Benefits and harms of ACL reconstruction and non-surgical management	
Mentions benefits of ACL reconstruction	The webpage mentions any benefits of ACL reconstruction (Yes/No)
Mentions harms/risks/complications of ACL reconstruction (e.g. knee pain or stiffness, poor healing of the graft, graft failure after returning to sport)	The webpage mentions any harms/risks/complications of ACL reconstruction (e.g. knee pain or stiffness, poor healing of the graft, graft failure after returning to sport) (Yes/No)
Mentions benefits of non-surgical management	The webpage mentions any benefits of non-surgical management (Yes/No)
Mentions harms/risks/complications of non-surgical management (e.g. increased risk of further damage to the knee, osteoarthritis)	The webpage mentions any harms/risks/complications of non-surgical management (e.g. increased risk of further damage to the knee, osteoarthritis) (Yes/No)
Risk of osteoarthritis	
Suggests ACL reconstruction will reduce the risk of osteoarthritis (or implies non-surgical management will increase it)	The webpage suggests that ACL reconstruction will reduce the risk of osteoarthritis (or implies non-surgical management will increase it) (Yes/No)
Activity modification	
Mentions activity modification as an approach to ACL rupture management	The webpage mentions activity modification as an approach to ACL rupture management (Yes/No)

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CHAPTER THREE

Development of a patient decision aid for children and adolescents following anterior cruciate ligament rupture: an international mixed-methods study

PREFACE

Chapter Three is a mixed methods study which describes the development and evaluates the acceptability of a patient decision aid for children adolescents who have an anterior cruciate ligament (ACL) rupture. The need for this study was identified due to Chapter Two demonstrating that most webpages providing information online on management following ACL rupture were not aligned with the best available evidence. Chapter Two identified the need for better patient resources on the management of ACL ruptures to improve patient understanding of the benefits and harms of patients' management options to reduce unnecessary surgery, such as a patient decision aid. A patient decision aid for children and adolescents with ACL rupture was needed due to the increasing rates of ACL ruptures, surgery and greater uncertainty of management recommendations compared to adults with an ACL rupture.

Citation

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Development of a patient decision aid for children and adolescents following anterior cruciate ligament rupture: an international mixed-methods study

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ABSTRACT

Aim To develop and user test an evidence-based patient decision aid for children and adolescents who are considering anterior cruciate ligament (ACL) reconstruction.

Design Mixed-methods study describing the development of a patient decision aid.

Setting A draft decision aid was developed by a multidisciplinary steering group (including various types of health professionals and researchers, and consumers) informed by the best available evidence and existing patient decision aids.

Participants People who ruptured their ACL when they were under 18 years old (ie, adolescents), their parents, and health professionals who manage these patients. Participants were recruited through social media and the network outreach of the steering group.

Primary and secondary outcomes Semistructured interviews and questionnaires were used to gather feedback on the decision aid. The feedback was used to refine the decision aid and assess acceptability. An iterative cycle of interviews, refining the aid according to feedback and further interviews, was used. Interviews were analysed using reflexive thematic analysis.

Results We conducted 32 interviews; 16 health professionals (12 physiotherapists, 4 orthopaedic surgeons) and 16 people who ruptured their ACL when they were under 18 years old (7 were adolescents and 9 were adults at the time of the interview). Parents participated in 8 interviews. Most health professionals, patients and parents rated the aid's acceptability as good-to-excellent. Health professionals and patients agreed on most aspects of the decision aid, but some health professionals had differing views on non-surgical management, risk of harms, treatment protocols and evidence on benefits and harms.

Conclusion Our patient decision aid is an acceptable tool to help children and adolescents choose an appropriate management option following ACL rupture with their parents and health professionals. A clinical trial evaluating the potential benefit of this tool for children and adolescents considering ACL reconstruction is warranted.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ We developed a decision aid that satisfies the International Patient Decision Aid Standards criteria and used mixed methods to evaluate acceptability of the decision aid.
- ⇒ One-on-one interviews conducted with participants from different countries allowed for in-depth feedback to be gathered on the decision aid, but the usability of the decision aid may be limited by the number of interviews with participants from each country.
- ⇒ We were able to interview health professionals who manage children who have ruptured their anterior cruciate ligament (ACL) but were unable to recruit children–participants to interview with their parents.
- ⇒ Our patient decision aid was limited by the lack of high-quality evidence comparing rehabilitation only to ACL reconstruction followed by rehabilitation in children and adolescents.
- ⇒ The systematic review used to inform estimates of benefits and harms included older studies that did not always report details of rehabilitation and may not reflect advances in treatment.

INTRODUCTION

The incidence of anterior cruciate ligament (ACL) ruptures continues to increase.[1] The total annual incidence of ACL ruptures in children and adolescents rose by 46% between 1994 and 2013 in the USA and the overall annual rate increased by 147.8% between 2005 and 2015 in Australia.[2 3] This increase has been linked to more children and adolescents participating in organised sport, increased intensity of training, and, potentially, a focus on single-sport specialisation at an earlier age.[4–6] The number of ACL reconstruction surgeries in children and adolescents is also increasing globally[1 6–8] despite non-surgical treatment (rehabilitation only) being an option.[9]

Recommended management options following ACL rupture include rehabilitation only, rehabilitation with the choice to undergo ACL reconstruction at a later time or early ACL reconstruction.[10 11] Research comparing these options is scarce, particularly in children and adolescents.[9] Two randomised control trials (RCT) (n=167[11]; n=121,[10]) have shown that early ACL reconstruction in adults does not result in superior knee function, sports participation and quality of life compared with rehabilitation only with the option for delayed ACL reconstruction. A third RCT (n=316[12]) found that ACL reconstruction was clinically superior to rehabilitation alone for adults with non-acute ACL injury and long-term knee instability. However, there are no RCTs directly comparing these treatment options in children or adolescents.[13]

All treatment options following ACL rupture have risks, with recent guidelines and systematic reviews highlighting uncertainty regarding which approach is superior for children and adolescents. International consensus guidelines state rehabilitation only is a viable and safe option following ACL rupture in skeletally immature children without associated injuries or major instability problems.[9 14] However, some guidelines also state 'repairable' injuries (eg, bucket-handle meniscal tear) associated with an ACL rupture should be considered an indication for early ACL reconstruction and meniscal repair.[9 15] Two recent systematic reviews[13 16] present conflicting evidence on the certainty of meniscus injury risk when choosing rehabilitation alone or considering the timing of a potential ACL reconstruction. Given this uncertainty and potential impact of poor management choices, there is a need for better evidence-based resources.

Patient decision aids are resources that present balanced information on the benefits and harms of different treatment options. They aim to improve the likelihood of informed choices and active participation of patients in healthcare decisions without negative patient outcomes.[17] Supporting shared decision-making in children and adolescents following ACL rupture is necessary given the possible consequences of poorly individualised treatment.[9 18 19] Currently, there is no patient decision aid for children and adolescents who have ruptured their ACL. A patient decision aid could help align expectations with evidence and improve patient satisfaction.

Our aim was to develop and user-test a patient decision aid for children and adolescents following ACL rupture to be used with parents and health professionals that presents evidence-based information on treatment options.

METHODS

Initial design of the decision aid

We developed a patient decision aid informed by the International Patient Decision Aid Standards (IPDAS) checklist and Collaboration Evidence Update 2.0.[20] A multidisciplinary steering group was assembled (study authors), including topic experts on ACL injury and physiotherapists with experience managing ACL ruptures (AG, JZ, MM, DA, EP, CM, SF and SM), people who have experienced an ACL rupture (SF, MM, EP and IAC) and one who was 18 years old when they ruptured their ACL (SF), an orthopaedic surgeon (IH) and patient decision aid and shared decision-making experts (KM, TH and RT). The first draft of the decision aid was informed by a template used for previous decision aids (for Achilles rupture,[21] shoulder pain,[22] antibiotics[23] and knee arthroscopy[24]) developed by some authors in the steering group (JZ, MM, KM, TH, RT, CM and IH). Key features adopted from these decision aids included questions to consider when talking to health professionals, icon arrays to present statistics, and a table comparing the potential benefits and harms of each management option. Decision science evidence suggests these features improve patient decision-making.[25–28] We also included statements of the quality of evidence, study participants demographic information and a reference list to give further context to statistics used in the decision aid.

We used evidence from a systematic review and meta-analysis on rehabilitation only and early or delayed ACL reconstruction in children and adolescents to inform the numeric estimates of benefits and harms.[13] We decided not to present benefits and harms data from the RCTs comparing rehabilitation only or delayed ACL reconstruction followed by rehabilitation to early ACL reconstruction followed by rehabilitation in adults.[10–12 19] The decision to exclude adult data was to avoid overloading children and adolescents with statistics that may not be relevant to them. Expert opinion and consensus from the multidisciplinary steering group were used to inform all information presented in the decision aid (eg, the benefits, harms and practical issues of each management option). The steering group provided feedback on the first draft of the decision aid before we began semistructured interviews.

Recruitment

All participant groups were recruited through social media, snowballing and using the steering group's collaboration network. Health professionals who participated in the study also assisted with recruitment of adolescent, adult and parent participants through referrals.

Using a preinterview questionnaire, we purposively sampled participants to achieve diversity in age, gender and ethnicity. For health professionals, we also purposively sampled to achieve diversity in profession, years of experience and country of practice. We adjusted our purposive sampling to recruit people with different characteristics from those already recruited. Before proceeding to the preinterview questionnaire, all participants provided consent by checking a box that confirmed they had read the participant information sheet and consent form and agreed to participate in the study.

Data collection

The data collection process involved a preinterview questionnaire (online supplemental files 1–4), semistructured interview (online supplemental files 5–7) and acceptability questionnaire (online supplemental files 8 and 9).

Preinterview questionnaires

For adolescent, adult and parent participants, we gathered data on demographics (eg, gender, age), country of birth, schooling/employment details, time since first ACL rupture, details about any other structures that were damaged, use of ACL reconstruction, rerupture, previous and current sports participation level, and factors related to treatment decision-making (online supplemental files 1–3).

For health professionals, we gathered data on demographics, profession and country of training/qualification, type of health professional, years of experience, clinical setting, average number of patients they manage with an ACL rupture per year and the percentage of patients they advise to have ACL reconstruction (online supplemental file 4).

Semistructured interviews

In accordance with IPDAS guidance,[29 30] semistructured interviews were used to gather feedback on participant's views of the decision aid and establish the best way to present different aspects such as treatment options, numeric estimates of benefits and harms, questions to ask health professionals, practical issues and visual layout. Interview guides were created to provide structure and group-specific prompts (online supplemental files 5–7). A trial interview was conducted as a test prior to beginning formal interviews. Interviews were conducted online via video conference (Zoom) by male researchers with experience in conducting qualitative interviews (AG and IAC), and lasted between 30 and 50 min. Four interviews were conducted by physiotherapy students who were under the supervision of the lead author.

Participants were informed of the reason for the study and provided a draft decision aid to view prior to the interview. However, not all participants viewed the decision aid before the interview. Changes to the decision aid were made throughout the interview process and participants were shown modifications against previous versions so they could provide input on whether changes were useful (online supplemental file 10). All interviews were recorded (with verbal consent obtained from participants). Participants were asked to 'think out loud' and encouraged to provide feedback as they viewed each page of the decision aid (eg, if they thought aspects of the decision aid could be improved or could be presented in a different way). During participant interviews, the interviewer took notes to highlight key concepts emerging from the interview and direct further questioning as needed. Following each interview, participants were sent an email thanking them for their time to participate; there was no incentive offered to participate in the study. All interviews were audiorecorded and transcribed verbatim for analysis and participants had the opportunity to review the transcript of their interview prior to data analysis if they wished.

Acceptability questionnaires

Following each interview, an acceptability questionnaire was completed by participants, either during the interview or via a questionnaire link sent via email following the interview. A separate acceptability questionnaire, adapted from The Ottawa Hospital Research Institute,[31] was created for adolescent, adult and parent participants (online supplemental file 8) and health professional participants (online supplemental file 9).

Data analysis

We reported the qualitative aspects of this study according to the 32-item Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist (online supplemental file 11).[32] The COREQ is a 32-item checklist that allows for reporting of important aspects of the research team, study methods, context of the study, findings, analysis and interpretation.

Preinterview and acceptability questionnaire responses were summarised using descriptive statistics (means and SDs, counts and percentages). Adolescent, adult and parent participant acceptability questionnaires (online supplemental file 10) involved rating sections of the decision aid as 'poor', 'fair', 'good' or 'excellent', the length of the decision aid, balance of information presented and its potential usefulness. The health professional participant acceptability questionnaire (online supplemental file 11) used a five-point Likert scale (strongly agree=5; strongly disagree=1) to assess agreement with various statements. We presented Likert scores as the percentage of responses for each category and as means (SD).

All interview data were analysed using thematic analysis; a method for identifying, analysing and reporting patterns within data.[33] Grounded theory using an inductive approach underpinned how data were collected and analysed. Two researchers (AG and SM) independently familiarised themselves with the interviews (via audio recordings or transcripts), recorded initial observations and identified concepts relevant to the questions asked. The two researchers developed a framework to organise concepts into broader themes and subthemes in Excel. Any disagreements in categorising concepts into themes and subthemes were discussed and resolved with a third author (JZ). The mapping of themes and subthemes (figure 1) was iterative as new data emerged so that the decision aid was continually updated before new interviews were conducted. Multiple iterative cycles of revisions were performed, and new versions of the decision aid were circulated to the steering group to reach consensus following changes from interviews. Consensus was reached by the majority of the steering group agreeing with proposed changes. In some cases, revisions were very minor changes (eg, correcting typos, rewording

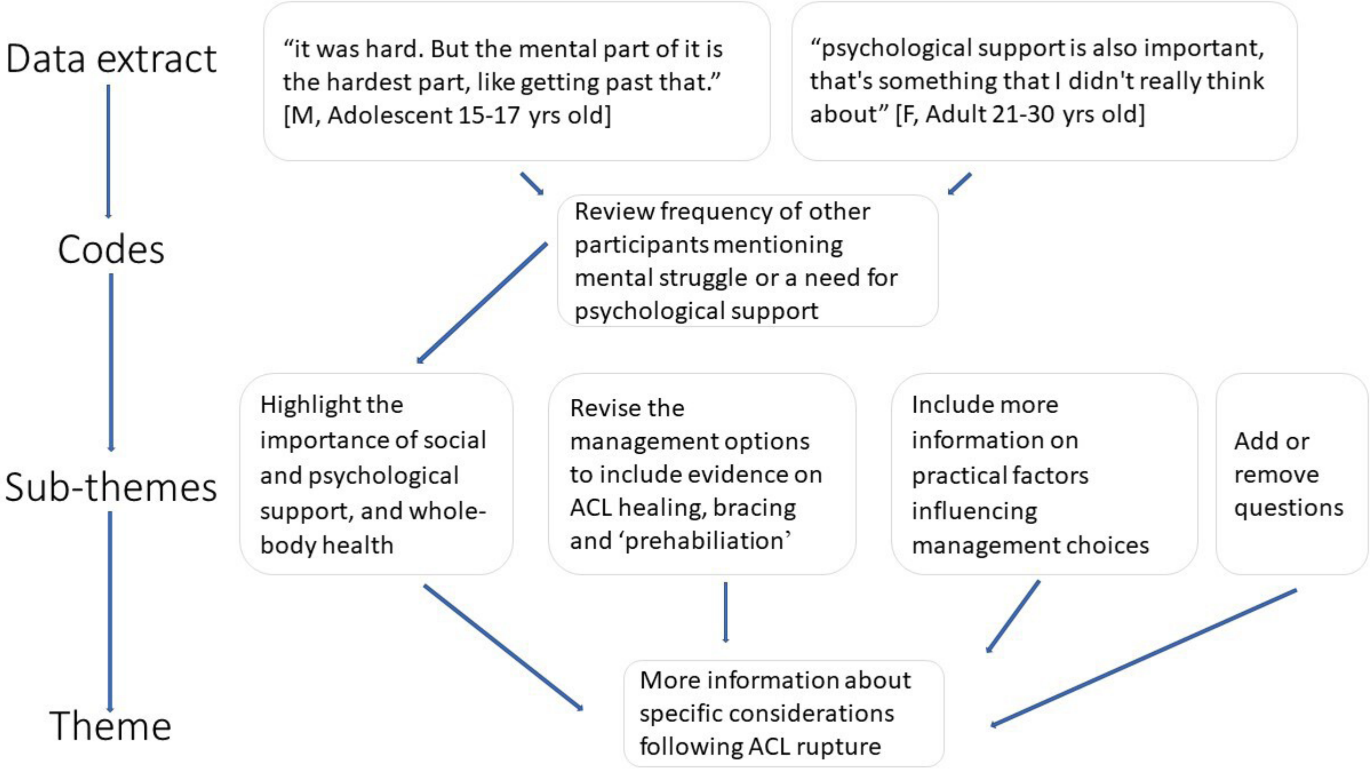

Figure 1 Formation of subthemes and themes.

a sentence). No further interviews were conducted once data saturation was achieved (no new feedback emerged) and participants had an overall positive impression of the decision aid.

Patient and public involvement

People who experienced an ACL rupture were part of the authorship group (SF, MM, EP and IAC). One was 18 years old when they ruptured their ACL (SF).

RESULTS

Adherence to the IPDAS criteria and user-centredness

The decision aid (online supplemental file 12) met all 6 of the criteria to be considered a decision aid, all 6 of the criteria to reduce the risk of harmful bias, and 21 of the 23 quality criteria according to the IPDASi checklist (V.4.0)[34] (online supplemental file 13). The two IPDASi criteria that were not met involved evaluating the decision aid. Readability was assessed including all the decision aid text (Grade 11.8) and without necessary complex words (Grade 9.7) using the SHeLL Editor (https://shell.techlab.works). Our decision aid also met 10 of the 11 criteria for user-centredness (online supplemental file 14) as assessed by the user-centred design 11-item measure.[35]

Participant characteristics and decision aid acceptability

A total of 32 initial interviews were completed; 16 health professionals who manage ACL ruptures (12 physiotherapists, 4 orthopaedic surgeons) and 16 people who had ruptured their ACL (7 adolescents and 9 who were now adults), 8 of these interviews were with a parent (1 parent was interviewed with 2 adolescents, 1 with an adult and 1 alone). Additional interviews were conducted with three health professionals (2 physiotherapists and 1 orthopaedic surgeon) who wanted to give further feedback but ran out of time in their initial interview. No participants withdrew from the study once their interview had commenced. One parent and adolescent did not participate in an arranged interview as they had not been offered rehabilitation only treatment and the parent did not want to potentially upset them. Participant characteristics are presented in tables 1 and 2. All participants completed the acceptability questionnaire except one adolescent participant (figure 2 and table 3).

Feedback for each section of the decision aid

Although most suggestions were implemented, some conflicted with others or were not possible to implement. Online supplemental file 15 outlines feedback we did not incorporate in the decision aid and our justification for this.

Thematic analysis of interviews

Summary of interview themes and subthemes:

Themes 1 and 2: positive and negative feedback

Most participants gave positive feedback about the design and usability of the decision aid, but health professionals expressed a range of views on the content.

> I wish I had something like this for either of my ACLs. Just to have it all in one place, is good (M, 21–30 years old, adult).

Table 1 Characteristics of participants who sustained an ACL rupture and parents of adolescent children who sustained an ACL rupture

Participant groups preinterview questionnaire responses (all statistics are reported as mean (SD) or N (%), unless specified otherwise)	Adolescents (n=7)	Adults (n=9)	Parents (n=8)
Age (years) range	16 (1) 15–17	26 (5.1) 18–33	46 (3.8) 41–51
Female	5 (71%)	3 (33%)	8 (100%)
Country of birth			
Australia	3 (43%)	7 (78%)	3 (38%)
Philippines	–	–	1 (13%)*
USA	2 (29%)	1 (11%)	2 (25%)
South Africa	2 (29%)	–	1 (13%)
Sri Lanka	–	1 (11%)*	–
Sweden	–	–	1 (13%)
Current grade at school			
Grade 10	4 (57%)	–	–
Grade 11	1 (14%)	–	–
Grade 12 or completed grade 12	2 (28%)	–	–
Highest level of education			
University graduate or postgraduate degree/s	–	6 (66%)	7 (88%)
TAFE/trade	–	1 (11%)	1 (13%)
High school (completed)	–	2 (22%)	–
Employment status			
Employed full time	–	5 (56%)	3 (38%)
Employed part time or casual	–	3 (33%)	3 (38%)
Student	–	1 (11%)	–
Other (eg, self-employed)	–	–	2 (25%)
Private health insurance	7 (100%)	7 (78%)	7 (88%)
Age at the time of ACL rupture (years) range	14.7 (1) 13–16	15.7 (1) 14–17	14.4 (1) 13–16‡
Concomitant injury at the time of ACL rupture§	4 (57%)	6 (67%)	6 (75%)‡
Lateral meniscus	2 (29%)	1 (11%)	2 (25%)‡
Medial meniscus	3 (43%)	4 (44%)	3 (38%)‡
MCL	–	1 (11%)	2 (25%)‡
PCL	1 (14%)	–	–
Cartilage damage	–	2 (22%)	–
Unsure of additional damaged structures	–	1 (11%)	–
Had ACL reconstruction	3 (43%)	9 (100%)	4 (50%)‡
Had a subsequent ACL rupture (ipsilateral or contralateral) at the time of the interview¶	0 (0%)	4 (44%)	0 (0%)‡
Had another ACL reconstruction¶	0 (0%)	3 (33%)	0 (0%)‡
Time since ACL reconstruction¶			
6–12 months	2 (66%)	–	1 (25%)‡
12–24 months	–	2 (22%)	3 (75%)‡
>24 months	1 (33%)	7 (78%)	–
Highest level of activity participation prior to ACL rupture† (Median score (IQR))	9 (1)	7 (2)	9 (1.75)‡
Highest current level of activity participation† (median score (IQR))	6 (6)	4 (3.5)	2 (7.5)‡
Which one factor most influenced the decision to have (or not have) an ACL reconstruction			
Someone you know (eg, a friend)	2 (29%)	–	–

Continued

Table 1 Continued

Participant groups preinterview questionnaire responses (all statistics are reported as mean (SD) or N (%), unless specified otherwise)	Adolescents (n=7)	Adults (n=9)	Parents (n=8)
Choice due to age (eg, being young)	1 (14%)	–	–
Wanting to return to sport	2 (29%)	4 (44%)	2 (25%)
Prevent further damage	–	2 (22%)	–
Recommendation from a health professional	2 (29%)	3 (33%)	4 (50%)
Other (eg, research and beliefs)	–	–	2 (25%)
Happiness with treatment choice			
Extremely happy	5 (71%)	6 (66%)	2 (25%)
Somewhat happy	–	1 (11%)	2 (25%)
Neither happy nor unhappy	1 (14%)	1 (11%)	1 (13%)
Somewhat unhappy	1 (14%)	–	1 (13%)
Extremely unhappy	–	1 (11%)	2 (25%)

One parent was interviewed without their adolescent; one parent was interviewed with an adult and one parent was interviewed with two adolescents.
*Management of ACL rupture were in Australia and not the country of birth.
†Scores are based on the Tegner Activity Scale (0–10), higher scores equal higher levels of patient-reported activity.
‡Refers to data reported by parents about their adolescent child.
§Some people had more than one concomitant injury to their ACL rupture.
¶Percentage of those who had ACL reconstruction.
ACL, anterior cruciate ligament; MCL, medial collateral ligament; N, number of adolescents and adults who ruptured their ACL and parents of adolescent children who ruptured their ACL; PCL, posterior cruciate ligament; TAFE, technical and further education.

> It would be wonderful to have this handed out (F, 41-50 years old, parent).
>
> It's well thought out, nice and balanced. It's good (M, 31-40 years old, orthopaedic surgeon).
>
> I really would suggest that you reconsider what you're doing (M, 51-60 years old, orthopaedic surgeon).
>
> I found the whole thing very wordy (M, 41-50 years old, orthopaedic surgeon).

Theme 3: how to use the decision aid in practice

Some health professionals suggested clarifying the influence of additional injuries (eg, meniscus tear) or instability on management decisions. Most participants suggested the decision aid should not replace professional advice and it should promote individual management.

> I also feel you have to have a health professional to guide you (F, 41-50 years old, parent).
>
> I think a lot of it just comes down to the individual's context, and their goals, and then also their present functional limitation (F, 21–30 years old, physiotherapist).

Theme 4: more information about specific considerations following ACL rupture

Adolescents frequently suggested including social and psychological support and whole-body health. Adolescents also suggested including information on planning for additional support and show fear of further injury or difficulties maintaining motivation is normal. Some health professionals suggested including ACL guidelines (eg, professionally endorsed ACL guidelines) and revising management options to include ACL healing, bracing and 'prehabilitation'. Some participants suggested including practical information on time needed to book ACL reconstruction, graft options, size of scars and loss of muscle strength and control. Modifying questions to ask health professionals were frequently suggested and some parents were particularly concerned about costs and pain relief.

> They don't talk about the psychological effects that it has on someone (F, 15-17 years old, adolescent).
>
> As far as this child is going to really need high care and nurturing, what have you got in place to ensure this person's needs are going to be met? (F, 41–50 years old, parent).
>
> The potential for the ACL to heal, I think parents and kids would be very interested in that (M, 31-40 years old, physiotherapist).

Theme 5: change or add information on rehabilitation, exercise and return to sport

Some health professionals suggested return to sport following ACL rupture is not guaranteed but most participants agreed rehabilitation timeframes gave realistic expectations. All participant groups mentioned rehabilitation testing should be included (eg, strength and hop tests) and to differentiate between restricted/unrestricted training and competition sport. Most participants also suggested including consideration for long-term goals and continuing to exercise beyond 12 months.

Table 2 Characteristics of health professionals that manage patients with ACL ruptures

Participant groups preinterview questionnaire responses (all statistics are reported as mean (SD) or N (%), unless specified otherwise)	Health professionals (n=16)
Age (years) range	39 (8.6) 23–54
Female	3 (19%)
Country of health professional training*	
Australia	11 (69%)
Germany	1 (6%)
Switzerland	1 (6%)
UK	1 (6%)
USA	2 (13%)
Role	
Physiotherapist	12 (75%)
Orthopaedic surgeon	4 (25%)
Years of experience	11.5 (7.3)
Work setting	
Private practice	11 (63%)
Private hospital	1 (6%)
Public hospital	4 (25%)
Other	1 (6%)
Average number of patients with ACL rupture managed per year	
5	1 (6%)
5–10	5 (31%)
10–20	2 (13%)
20–30	3 (19%)
>50	5 (31%)
The percentage of patients recommended to have ACL reconstruction following ACL rupture	67 (20.3)

*All health professional participants were practising in their country of training at the time of interviews.
ACL, anterior cruciate ligament; N, number of health professionals that manage patients with ACL ruptures.

> It's easy to get ahead of yourself and many times parents want to rush as well (F, 41-50 years old, parent).
>
> Some people may think once I finished my nine months of therapy, I'm done. But it's like, it's a lifelong journey (F, 41–50 years old, parent).
>
> You need a certain level of dedication (F, 15-17 years old, adolescent).

Theme 6: modify language and formatting used

Simple language, being concise and removing unnecessary text were frequently suggested. All participant groups suggested modifications to formatting such as layout, graphs, colour, pictures or icons and statistics (eg, most preferred icon array images to bar graphs or 'x in 100 people' to percentages).

Positive presentation of information, harms and return to sport was frequently suggested by all participant groups. Mixed views were expressed about risk of additional injury (eg, the relationship between meniscus damage and osteoarthritis), general surgery, paediatric specific risks and return to sport.

> I feel like the language is too academic. To me, I think it could be dumbed down more (M, 31-40 years old, physiotherapist).
>
> You want them to be finding the success stories and, yeah, have a positive outlook as well, rather than focusing on who didn't get back (F, 41–50 years old, parent).
>
> You could say potential harms and precautions (F, 41-50 years old, parent).

Theme 7: understanding the translation of research

Some health professionals suggested the decision aid should be seen before an appointment with a health professional (eg, before seeing an orthopaedic surgeon). Participants frequently suggested difficulty navigating the uncertainty of returning to sport with both treatment options. Participants more frequently had views to remove adult data, but some suggested providing context to adult statistics.

> When patients are overwhelmed, they, tend to just kind of they grasp for certainty (M, 31-40 years old, physiotherapist).
>
> You're using adult data in a decision aid for children, and you can't do that (M, 51-60 years old, orthopaedic surgeon).
>
> I would rather they have information that is relevant to their population and their category only, even if it is lower quality (M, 31–40 years old orthopaedic surgeon).

DISCUSSION

Summary of findings

Most adolescents, parents and adults rated all aspects of the decision aid as good-excellent (eg, presentation, comprehensibility, length, graphics, formatting and amount of information). Following interviews, we identified seven main themes with subthemes (online supplemental file 16). The interviews highlighted agreement with most of the decision aid content (eg, management options, questions to ask health professionals, summary of benefits and harms). Most health professionals selected 'strongly agree' or 'agree' when asked to rate statements about the decision aid but some health professionals had opposing views on components of the decision aid (eg, using statistics from studies including participants over 18 years old, potential risks and return to sport).

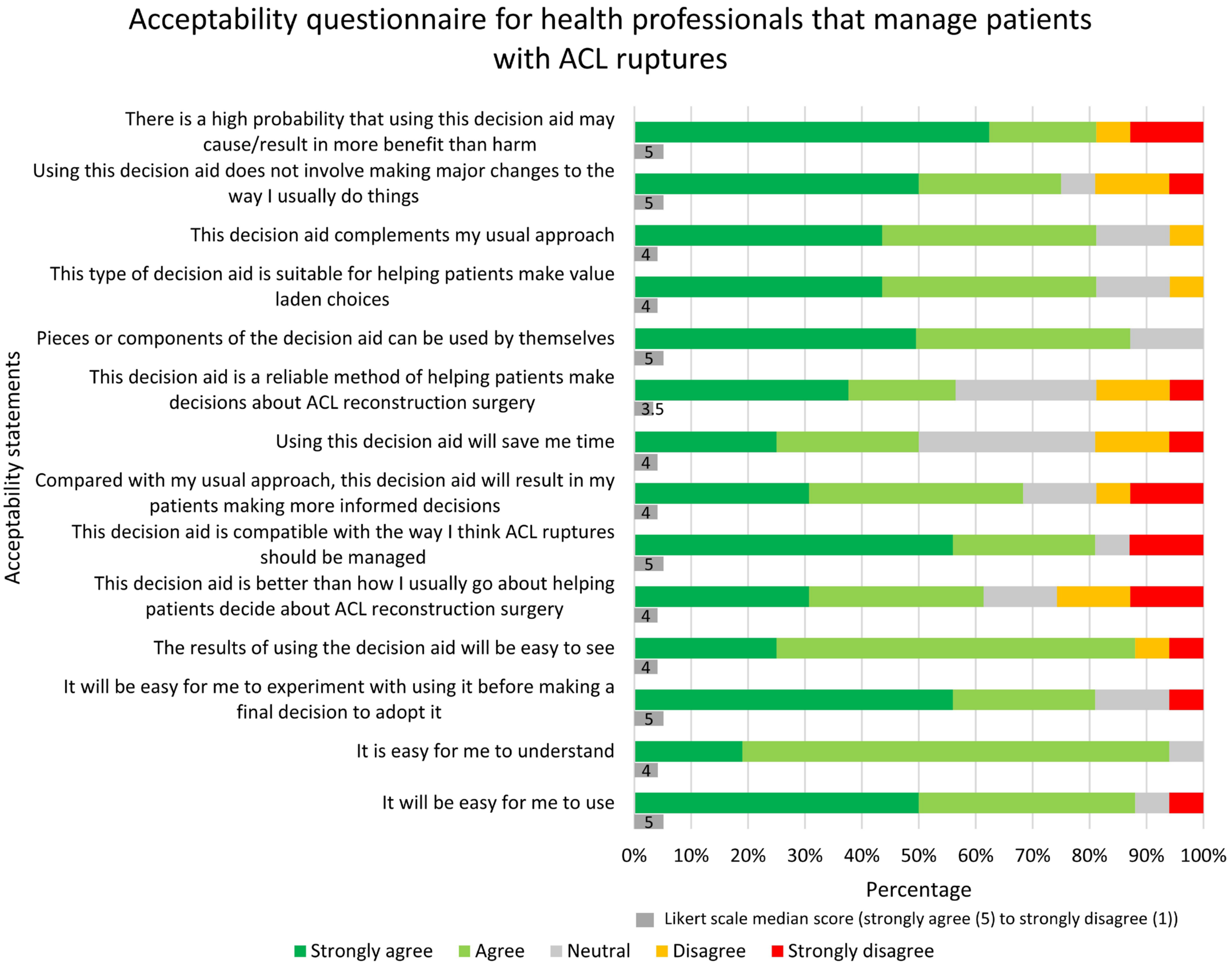

Figure 2 Acceptability questionnaire for health professionals that manage patients with ACL ruptures (n=16; 12 physiotherapists, 4 orthopaedic surgeons).

Meaning of the study

Analysis of the interviews revealed that most aspects of the decision aid were agreed on by participants despite suggestions for refinement. However, some health professionals had divided opinions on the evidence used to inform content and rehabilitation time frames. Feedback from all participant groups consistently highlighted the importance of positive messaging, social and psychological support and considering long-term goals. Most participant groups also gave positive feedback on 'questions to consider asking health professionals'.

Most participants agreed the decision aid clearly outlines its intended users and treatment options but there were mixed views on deciding optimal management. Some participants suggested bringing more attention to the impact of additional injury (eg, meniscus damage) to decision-making or adding other treatment options (eg, bracing, ACL healing and 'prehabilitation'). We decided to present only two management options side by side for ease of comparison, which is similar to other decision aids for musculoskeletal conditions.[21 22] Opinions of the optimal management for children and adolescents who have additional injuries to their ACL rupture were mixed and evidence remains uncertain.[13 16] The decision aid prompts patients to confirm their diagnosis with a team of health professionals to gain a balanced opinion on their individual circumstance and discuss multiple factors that may influence their choice (eg, presence of 'repairable' injuries, if their knee gives way and activity levels[9]).

Some physiotherapists and orthopaedic surgeons had conflicting views on using evidence from research that included participants over 18 years old. Given the decision aid is not for adults with an ACL rupture, we decided not to present data from studies on people over 18 years to avoid children and adolescents having to consider multiple data sources and potentially becoming confused.[36] The decision aid is designed for children and adolescents and includes prompts to encourage management that considers individual circumstances and different rates of child development (eg, questions to consider when talking to a health professional and key points).

Table 3 Acceptability questionnaire for people who sustained an ACL rupture (n=16) (adolescents (n=7)*, adults (n=9)) and parents of adolescent children who sustained an ACL rupture (n=8)

Acceptability items **(All statistics are reported as N (%))**	**Adolescents, adults and parents (n=23)**
Section of decision aid rated as excellent or good	
Who should read this decision aid?	23 (100%)
Diagram of management options following ACL rupture	23 (100%)
The treatment options covered in this decision aid	23 (100%)
Comparing benefits and harms of each management option for those aged under 18 years old	22 (96%)
Summary of benefits and harms of each management option for those aged under 18 years old	23 (100%)
The length of the decision aid was	
Just right	23 (100%)
The amount of information was	
Just right	21 (91%)
Too little	1 (4%)
Too much	1 (4%)
I found the decision aid	
Balanced	18 (78%)
Slanted towards rehab only (or delayed ACL surgery)	2 (9%)
Slanted towards ACL reconstruction surgery (early ACL surgery)	3 (13%)
Agreed they would have found this decision aid ‘extremely useful’ or ‘very useful’ when making the decision about ACL reconstruction surgery	18 (78%)
Agreed this decision aid would have made their decision easier	20 (87%)

*One adolescent participant did not complete the acceptability questionnaire.
ACL, anterior cruciate ligament; N, number of adolescents and adults who have sustained an ACL rupture and parents of adolescent children who sustained an ACL rupture.

Although children and adolescents should be encouraged to take an active role in the decision-making process, interviews with parents suggested that individual circumstances may dictate how the decision aid is best used. Some parents suggested the decision aid would save them time when researching information to help with making treatment choices (eg, *getting this handout instead of me having to go home and Google, I Googled many, many nights trying to find you know, something like this’* (F, 41–50 years old, parent)). One parent withdrew their adolescent child before the interview due to concerns that discussion of potential harms could disrupt their child’s focus on rehabilitation. This adolescent recently had ACL reconstruction and was not given the option to have non-surgical management based on their injuries. Overall, parents and health professionals should consider encouraging children and adolescents to be involved in shared decision-making[9 37 38] and consider that the decision aid is designed to be used before making the management decision. Once a decision is made, particularly an irreversible decision, parents and health professionals may have an important role in guiding focus and promoting optimism.

The decision aid can facilitate parents discussing their child’s treatment preference, sport choice and potential harms of participation. Parents and health professionals should acknowledge their supporting role in treatment decisions (eg, ‘*it’s important that we listen to the kids and what they have to say, it’s their body’* (F, 41–50 years old, parent)). Discussions of sporting choice may solidify a decision or lead to diversifying sporting participation that has been shown to encourage the development of resilient self-identities.[36] Parental anxiety or pain catastrophising has been shown to negatively influence children’s anxiety, postoperative pain and ability to perform rehabilitation.[39] While potential harms and uncertainty of returning to sport can be a sensitive topic, their acknowledgement could also provide reassurance to children and adolescences if something goes wrong (eg, ‘*as a parent you’re trying to make sure they understand the decision they’re making’* (F, 41–50 years old, parent)).

Avoiding unrealistic expectations and including children and adolescents in decision-making was frequently mentioned by all participant groups. Using the decision aid could prevent decisions being made based on unrealistic expectations and help improve treatment satisfaction. It is accepted that patient satisfaction has been closely linked to expectations,[40] the decision aid may help improve the mismatch between expectations and evidence. Many young athletes (86%) expect to return to sport following ACL reconstruction by 6 months which is much sooner than is recommended in accepted professional guidelines.[41 42] While return to sport rates may be higher in children who have ACL reconstruction followed by rehabilitation compared with rehabilitation only,[13] subsequent ipsilateral or contralateral ACL rupture following ACL reconstruction followed by rehabilitation can be as high as 32% in paediatric athletes.[39] The reality is that despite anatomical surgical success or well-designed rehabilitation programmes, many athletes may never return to their preinjury athletic performance level or their primary sport.[43]

Interviews frequently highlighted that information regarding psychological and social support should be included in the decision aid. Sudden changes to sport participation can affect self-identity in children and adolescents who particularly mentioned the mental struggle of recovering post ACL rupture (eg, '*the point that stands out to me, that was probably the stay positive one. Because the other year, it was hard. But the mental part of it is the hardest part, like getting past that*' (M, 15–17 years old, adolescent)). Children and adolescent self-identities can be fragile and absence from participating in a sport they depend on can be psychologically traumatising.[39] Therefore, we decided to include messages to encourage the discussion and planning for psychological support. Health professionals should give early recognition to psychosocial factors that have been shown to affect mental well-being and ability to recover from injury.[43] The decision aid incorporates reassurance and encourages monitoring physical and psychological recovery.

Strengths and limitations

Our development process (online supplemental file 17) had several strengths. The steering group includes people who experienced an ACL rupture and one who was 18 years old when they ruptured their ACL, the manuscript is transparent about the authors' professional backgrounds, the design, conduct and reporting of this study were guided by the IPDAS criteria, we conducted one-on-one interviews with participants which allowed for in-depth feedback to be gathered on the decision aid, and used mixed methods to evaluate acceptability of the decision aid. The readability of our tool measured higher (grades 9–11) than recommendations (grade 8) but contains multiple features to support understanding and readability that align with best practice[44] including bullet points, white space, images and subheaders. The tool, therefore, performs well relative to existing decision aids in terms of its attention to health literacy.[44] We also included justification of the evidence used to inform numeric estimates of benefits and harms in the decision aid and used the highest quality evidence available comparing rehabilitation only and ACL reconstruction followed by rehabilitation for children and adolescents.[13]

Our patient decision aid was limited by the lack of high-quality evidence comparing rehabilitation only to ACL reconstruction followed by rehabilitation in children and adolescents. Emergence of future studies related to this topic will likely warrant an update of the evidence used in the decision aid. Another limitation is that evidence from older studies did not always report details of rehabilitation or consider advances in treatment to know if they reflect current recommended practice. We were unable to recruit any children participants to interview and adolescent participants were aged between 15 and 17 years old. We did interview health professionals who treat children and younger adolescents, but not being able to recruit children participants means the decision aid was not directly influenced by children's feedback. Most authors are physiotherapists, and most health professional participants were physiotherapists (75%), trained in Australia (69%) and worked in private practice (63%) which may impact the themes that emerged from interviews (eg, views on costs and waiting time for ACL reconstruction). Recruitment of participants was difficult which was expected without offering incentives for their time. We did not directly involve children or adolescents in all stages of the study as consumers, and stakeholder involvement heavily influenced the design of the decision aid via feedback during online interviews and questionnaires on the acceptability of the decision aid. Our aim was to interview participants until we achieved data saturation, but we acknowledged that the majority of participants were Australian (60%). Including participants from several different countries may have made the decision aid more globally acceptable (eg, feedback was influenced by different cultures and healthcare systems) but the sample size of participants from each country may limit the usability of the decision aid for use in different countries. Future work includes adapting this decision aid for culturally and linguistically diverse populations as it is only presented in English.

Conclusion

Our patient decision aid appears to be an acceptable tool to help children and adolescents following ACL rupture choose between surgical and non-surgical management, with support from their parents and health professionals. Feedback from adolescents frequently suggested the importance of planning to include psychological and social support during rehabilitation. Feedback also suggested that health professionals should use positive messaging despite uncertainty of outcomes while avoiding the creation of unrealistic expectations. Our patient decision aid is a user-friendly tool that could improve decision-making in children and adolescents following ACL rupture. A randomised controlled trial evaluating its impact is the next important step.

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Contributors All authors critically revised the manuscript for important intellectual content and approved the final manuscript. Please find below a detailed description of the role of each author. ARG: developed and designed data collection tools, conducted data collection, analysed, and interpreted data, drafted and revised the manuscript and approved the final version to be published. MJM: developed and designed data collection tools, interpreted data and approved the final version to be published. DBA: developed and designed data collection tools, interpreted data and approved the final version to be published. EP: developed and designed data collection tools, interpreted data and approved the final version to be published IAC: developed and designed data collection tools, conducted data collection, analysed, and interpreted data and approved the final version to be published. SM: developed and designed data collection tools, analysed and interpreted data and approved the final version to be published. IAH: developed and designed data collection tools, interpreted data and approved the final version to published. SRF: developed and designed data collection tools, interpreted data and approved the final version to be published. KM: developed and designed data collection tools, interpreted data and approved the final version to be published. TCH: developed and designed data collection tools, interpreted data and approved the final version to be published. RT: developed and designed data collection tools, interpreted data and approved the final version to be published. CGM: developed and designed data collection tools, interpreted data and approved the final version to be published. JRZ: developed and designed data collection tools, conducted data collection, analysed, and interpreted data, drafted, and revised the manuscript and approved the final version to be published. The corresponding author (ARG) attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted. As the guarantor, the corresponding author (ARG) accepts full responsibility for the work and/or the conduct of the study, had access to the data and controlled the decision to publish. Artificial intelligence (AI) was only used to transcribe audio recordings of interviews for analysis.

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Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by the University of Sydney Human Research Ethics Committee (HREC) (project number: 2022/008). Participants gave informed consent to participate in the study before taking part.

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CHAPTER FOUR

Development and acceptability of a patient decision aid for people with degenerative cervical myelopathy: an international mixed-methods study

PREFACE

Chapter Four is a mixed methods study which describes the development of a patient decision aid for adults with degenerative cervical myelopathy (DCM) and evaluates decision aid acceptability. The need for this study was identified due to previous research suggesting most webpages providing information on degenerative cervical myelopathy were not aligned with the best available evidence. Misleading online information may result in adults with degenerative cervical myelopathy undergoing unnecessary surgery. Chapter Three found a patient decision aid for children and adolescents with anterior cruciate ligament (ACL) rupture was rated as acceptable to help them decide between surgical and non-surgical management alongside their parents and health professionals. Chapter Three described the development of a patient decision aid for children and adolescents with an acute sporting injury which commonly has a clear mechanism of injury (ACL rupture). In contrast, we identified the need to develop a patient decision aid for adults with a chronic or degenerative musculoskeletal condition (degenerative cervical myelopathy) and assess its acceptability to reduce potentially unnecessary surgery.

Citation

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Development and acceptability of a patient decision aid for people with degenerative cervical myelopathy: an international mixed-methods study

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ABSTRACT

Aim: To develop and user-test a patient decision aid for people diagnosed with degenerative cervical myelopathy and who are considering surgery.

Design: Mixed-methods study describing the development of a patient decision aid.

Setting: A draft decision aid was developed by a multidisciplinary steering group (including people with degenerative cervical myelopathy, health professionals and researchers) informed by the best available evidence, authorship consensus, and existing patient decision aids.

Participants: People with degenerative cervical myelopathy and health professionals who manage people with degenerative cervical myelopathy. Participants were recruited through social media and the steering group's research and practice network.

Primary and secondary outcomes: Semi-structured interviews and questionnaires were used to gather feedback, refine the decision aid, and assess its acceptability. An iterative cycle of interviews, refining the aid according to feedback and further interviews, was used. Interviews were analysed using reflexive thematic analysis.

Results: We conducted 32 interviews; 19 people with lived experience of degenerative cervical myelopathy and 13 health professionals who manage people with degenerative cervical myelopathy (neurosurgeons, neurologists, physiotherapists, orthopaedic surgeon, general practitioner, chiropractor/researcher, rehabilitation specialist and occupational physician). Participants were from 10 countries (Australia, Canada, Cyprus, Germany, Ireland, New Zealand, Sweden, Switzerland, United Kingdom and USA). Most participants rated the decision aid's acceptability as good-to-excellent and agreed with most aspects of the decision aid (e.g., defining degenerative cervical myelopathy, management recommendations, potential benefits and harms, questions to consider asking a health professional).

Conclusion: Our patient decision aid was rated as an acceptable tool by both health professionals who treat degenerative cervical myelopathy and people with lived experience of degenerative cervical myelopathy. This decision aid can be used by clinicians and patients to help with shared decision making following a diagnosis of degenerative cervical myelopathy. A study testing the potential benefits of this decision aid in a clinical setting is recommended.

Keywords: decision aids; orthopedics; shared decision making; spinal cord compression; spine; degenerative cervical myelopathy; neck pain

Strengths and limitations of this study:

- We developed a decision aid that satisfies the International Patient Decision Aid Standards criteria and used mixed methods to evaluate acceptability of the decision aid.
- One-on-one interviews with people with DCM from diverse education levels and employment status, and health professionals from various professions allowed for in-depth feedback to be gathered on the decision aid.
- Acceptability of the decision aid in different countries may be limited by the number of interviews with participants from each country and being presented in English only.
- Most participants with DCM who volunteered to participate were female and most health professionals interviewed were male.
- Data on benefits and harms in the decision aid were based on the only randomised controlled trial comparing non-surgical and surgical management for people with DCM which was conducted at a single centre.

Degenerative cervical myelopathy: development and acceptability of a patient decision aid for informed management decisions

1. Introduction

Degenerative cervical myelopathy (DCM) is the most common cause of spinal cord dysfunction in adults, with an estimated prevalence of 2.2% in the general population and up to 5% in people over the age of 40.[1-4] DCM can lead to a wide range of symptoms including upper and lower extremity sensory changes, gait impairment, clumsiness of the hands, and bladder/bowel dysfunction.[5-7] Subtle[8] and diverse symptoms of DCM can mimic other conditions and may contribute to misdiagnosis.[1,9] The quality of life of people living with DCM is worse than people living with other diseases such as diabetes or some cancers.[10]

Diagnostic criteria for DCM include clinical examination findings indicating upper motor neuron disturbance (e.g., hyperreflexia) and radiological evidence of spinal cord compression (e.g., degenerative changes found on MRI).[1] People with DCM often experience long delays before receiving a diagnosis which can impact management recommendations and their quality of life.[11] A diagnosis of DCM takes on average 2.2 years, but can take up to 9 years after an initial visit with a health professional.[1] Delayed diagnosis is likely due to a lack of awareness of the condition amongst clinicians and the community.[12,13] Earlier diagnosis and treatment models have been associated with improved quality of life and cost effectiveness.[14]

Clinical practice guidelines use the modified Japanese Orthopaedic Association (mJOA) scale to categorise DCM severity and guide management.[15] The mJOA is an 18-point scale categorising the severity of DCM into non-myelopathic (18), mild (15-17), moderate (12-14) or severe (0-11).[15,16] Guidelines suggest non-surgical management for people who are non-myelopathic (on the mJOA scale) and surgical management for people with moderate and severe DCM, but there is uncertainty about management for people with mild DCM.[17] Only one randomised controlled trial (RCT) has been conducted comparing non-surgical and surgical management of people with mild to-moderate DCM.[18] The ten year follow up showed on average, no significant between-group differences in neurological function using mJOA scores at a single centre.[19] Although outcomes following surgical decompression in this study differ from some other studies which may be due to surgical technique.[17]

An evidence-based resource is needed to align patient management decisions with best evidence and their values, particularly given the uncertainty of evidence to guide the decision to have surgery among people with mild DCM. One potential solution is a patient decision aid for people with mild DCM comparing non-surgical and surgical management.[20] Patient decision aids outline expected benefits and risks of management options by providing evidence-based information to better align treatment choices with evidence and personal values. A patient decision aid could promote shared decision making for people with DCM and increase awareness of the condition for timely diagnosis and intervention.[13]

The aim of this study was to develop and user-test a patient decision aid for people with DCM to guide appropriate management.

2. Methods

2.1 Initial design of the decision aid

We developed a patient decision aid informed by the International Patient Decision Aid Standards (IPDAS) checklist and Collaboration Evidence Update 2.0 [21] (supplementary file 1). A multidisciplinary steering group (study authors) was assembled, including physiotherapists, physicians and a surgeon who are topic experts on DCM (AG, DA, BD, SS and JVG), as well as patient decision aid and shared decision-making experts (AG, JZ, DA, MM, TH, KM). The first draft of the decision aid was informed by the design of previous decision aids[22-24] developed by some authors in the steering group (AG, JZ, DA, MM, CM, SM, TH, KM). Key features adapted from these decision aids included outlining the condition and management options, using icon arrays to present potential benefits and harms, and providing questions to consider when talking to a health professional. Decision science evidence suggests these features can improve patient decision-making.[25-28]

To inform the content in the decision aid, a literature search (supplementary file 2) was conducted based upon a search strategy of a previous Cochrane review.[29] Author consensus informed by the evidence hierarchy[30-31] determined the information included. Diagnosis and management recommendations were informed by the most recent clinical practice guidelines for people with mild, moderate, and severe DCM.[17] Benefits and harms statistics were informed by various sources of evidence, including ten year follow-up data[19] from the only RCT comparing non-surgical and surgical management[18] for people with mild-moderate mJOA scores, recent systematic reviews,[32-34] a large observational study[35] and the only study examining physiotherapy management for people with mild DCM via a web based survey.[4] We included additional statistics to the RCT to provide more information and context to aid decision making.[4,32-35] The study authors provided feedback on the first draft of the decision aid before we began semi-structured interviews.

2.2 Recruitment

Participants were recruited through social media (Myelopathy.org), snowballing, and via the steering group's research and clinical practice network. All participants provided consent to participate in the study by checking a box confirming they read the participant information sheet and consent form.

2.3 Data collection

The data collection process involved pre-interview questionnaires (supplementary files 3 and 4), semi-structured interviews (supplementary file 5 and 6), and acceptability questionnaires (supplementary file 7 and 8) for people with DCM and health professionals.

2.31 Pre interview questionnaires

Pre interview questionnaires were completed electronically by people with DCM and health professionals who manage people with DCM to gather baseline information. We collected data on demographics (e.g., age, gender, education), clinical information and professional background (table 1 and 2). Pre-interview questionnaires were used to purposively sample participants to ensure a balance of demographic, clinical backgrounds and professional experiences where possible.

2.32 Semi structured interviews

Semi-structured interviews were conducted in accordance with IPDAS guidance[36,37] to gather feedback on the design and content of the decision aid. A pilot interview was conducted to standardise the interview style between interviewers. All interviews were conducted online via video conference (Zoom) – minus one conducted in-person - by a male (AG) or female (SM) researcher experienced in qualitative interviewing. Interviewers utilised interview guides and took notes to highlight key concepts or direct further questioning.

All participants provided written and verbal consent for interviews to be audio recorded and transcribed verbatim for analysis. A draft decision aid was provided to participants prior to their interview. A 'think out loud' method was used to gain feedback from participants as they viewed each page of the decision aid. New versions of the decision aid were created following interviews and were contrasted to previous versions in subsequent interviews (supplementary file 9). Interviews lasted between 18-59 minutes. All participants had the opportunity to review their interview transcript prior to data analysis. No financial incentive was provided for participation.

2.33 Acceptability questionnaires

Following each interview, an acceptability questionnaire was provided electronically to participants during or after the interview. The acceptability questionnaires were adapted from The Ottawa Hospital Research Institute.[38] People with DCM rated sections of the decision aid ('poor', 'fair', 'good' or 'excellent'), the length of the decision aid, and balance and usefulness of the information presented. Health professionals used a five-point Likert scale (strongly agree=5; strongly disagree=1) to assess agreement with various statements.

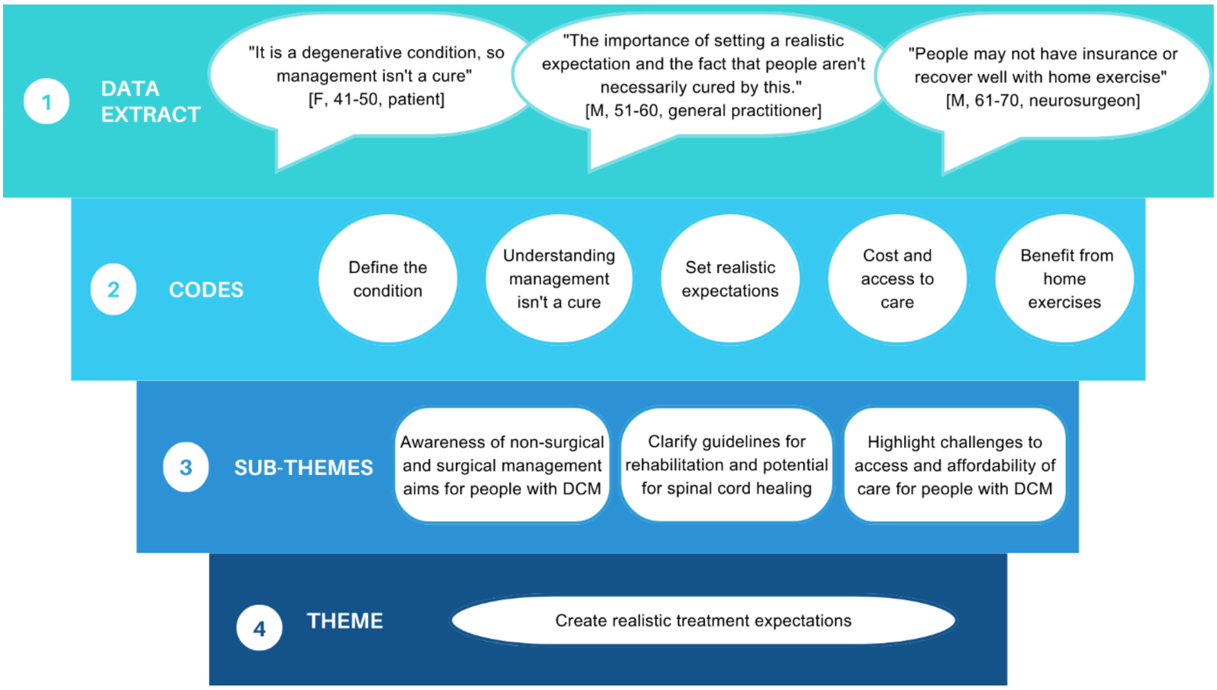
2.4 Data analysis

Pre-interview and acceptability questionnaire responses were summarised using descriptive statistics (means and standard deviations (SD), medians and interquartile ranges (IQR) or counts and percentages as appropriate).

All qualitative aspect of this study were reported according to the 32-item Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist (supplementary file 10).[39]

All interview data were analysed using thematic analysis; a method for identifying, analysing and reporting patterns within data.[40] Grounded theory using an inductive approach underpinned how data were collected and analysed.[41] Two researchers (AG and SM) independently recorded initial themes, familiarised themselves with the interviews via audio recordings or transcripts and developed a framework to organise concepts into broader themes and subthemes in Microsoft Excel. The mapping of themes and subthemes (figure 1) was achieved through multiple iterative cycles as new data emerged. Any disagreements were discussed and resolved with a third author (JZ). The decision aid was continually updated before new interviews and circulated to the study authors to reach consensus. Consensus was determined by the majority of the study authors agreeing with proposed changes. No further interviews were conducted once data saturation was achieved (i.e., no new feedback emerged from three consecutive participants) and participants had an overall positive impression of the decision aid.

Figure 1: Process of the formation of subthemes and themes from participant interviews



2.5 Patient and Public involvement:

People with DCM and health professionals provided feedback on the decision aid throughout development and the manuscript.

3. Results:

3.1 Adherence to the International Patient Decision Aid Standards (IPDAS) criteria and user-centredness

Our decision aid (supplementary file 11) met all six criteria to be classified as a decision aid which reduces the risk of harmful bias. 21 of the 23 quality criteria of the IPDASi checklist (V.4.0)[42] (supplementary file 12) were met and the criteria not met involved evaluating the effectiveness of the decision aid (e.g. in a clinical trial). Readability was assessed including all the decision aid text (Grade 11.8) and without necessary complex words (Grade 8.7) using the SHeLL Editor (https://shell.techlab.works). Our decision aid met 10 of the 11 criteria for user-centredness (supplementary file 13) as assessed by the User-Centred Design 11-item measure.[43]

3.2 Participant characteristics and decision aid acceptability

A total of 32 initial interviews were completed; 19 people with DCM and 13 health professionals who manage people with DCM (table 1 and 2). We had two male participants attend an interview but withdraw before the interview began because we were unable to offer any compensation for their time. The results from the acceptability questionnaires are presented in table 3 and figure 2.

Table 1: Characteristics of participants with Degenerative Cervical Myelopathy

Characteristics All statistics are reported as N (%) unless specified otherwise		**Participants with DCM (n=19)**
Age in years, mean (SD)		55 (10)
Female		17 (89%)
Country of residence	United Kingdom	11 (58%)
	Australia	2 (11%)
	USA	2 (11%)
	Canada	1 (5%)
	Cyprus	1 (5%)
	Ireland	1 (5%)
	Sweden	1 (5%)
Highest level of education	University graduate or postgraduate degree/s	11 (58%)
	TAFE/Trade	4 (21%)
	High school (completed)	4 (21%)
Employment status	Employed full-time	3 (1%)
	Employed part-time or casual	4 (21%)
	Retired	5 (26%)
	Sick/disability leave	2 (11%)
	Other (e.g., self-employed)	5 (26%)
Time from noticing symptoms until diagnosis of DCM	<1 month	1 (5%)
	1-3 months	3 (16%)
	4-6 months	2 (11%)
	7-12 months	2 (11%)
	13-24 months	0 (0%)
	>24 months	11 (58%)
Heard of mJOA scale		12 (63%)
Had surgery for DCM		15 (79%)
Satisfaction with treatment choice	Extremely unsatisfied	5 (26%)
	Somewhat unsatisfied	4 (21%)
	Neither satisfied nor unsatisfied	5 (26%)
	Somewhat satisfied	3 (16%)
	Extremely satisfied	2 (11%)

N, number of participants. DCM, Degenerative Cervical Myelopathy. SD, Standard Deviation. USA, United States of America. TAFE, Technical and Further Education. mJOA, Modified Japanese Orthopaedic Association.

Table 2: Characteristics of health professional-participants who manage people with degenerative cervical myelopathy

Characteristics		**Health professional-participants (n=13)**
Age in years, mean (SD)		49 (12)
Female		2 (15%)
Country of health professional training[a]	Australia	4 (27%)
	United Kingdom	3 (20%)
	Canada	2 (13%)
	USA	2 (13%)
	Germany	1 (7%)
	India	1 (7%)
	New Zealand	1 (7%)
	Switzerland	1 (7%)
Professional background	Neurosurgeon	4 (31%)
	Neurologist	2 (15%)
	Physiotherapist	2 (15%)
	Orthopaedic surgeon	1 (8%)
	General practitioner	1 (8%)
	Rehabilitation specialist	1 (8%)
	Occupational physician	1 (8%)
	Chiropractor/researcher	1 (8%)
Years of experience, mean (SD)		18 (11)
Work setting	Private practice	4 (31%)
	Private hospital	0 (0%)
	Public hospital	7 (54%)
	Other	2 (15%)
Average number of people with DCM managed per year	5-10	3 (23%)
	11-20	1 (8%)
	21-30	3 (23%)
	31-40	1 (8%)
	>40	5 (38%)
The average percentage of people diagnosed with DCM they would advise to have surgery		57%
The average percentage of people diagnosed with mild DCM they would advise to have surgery		26%

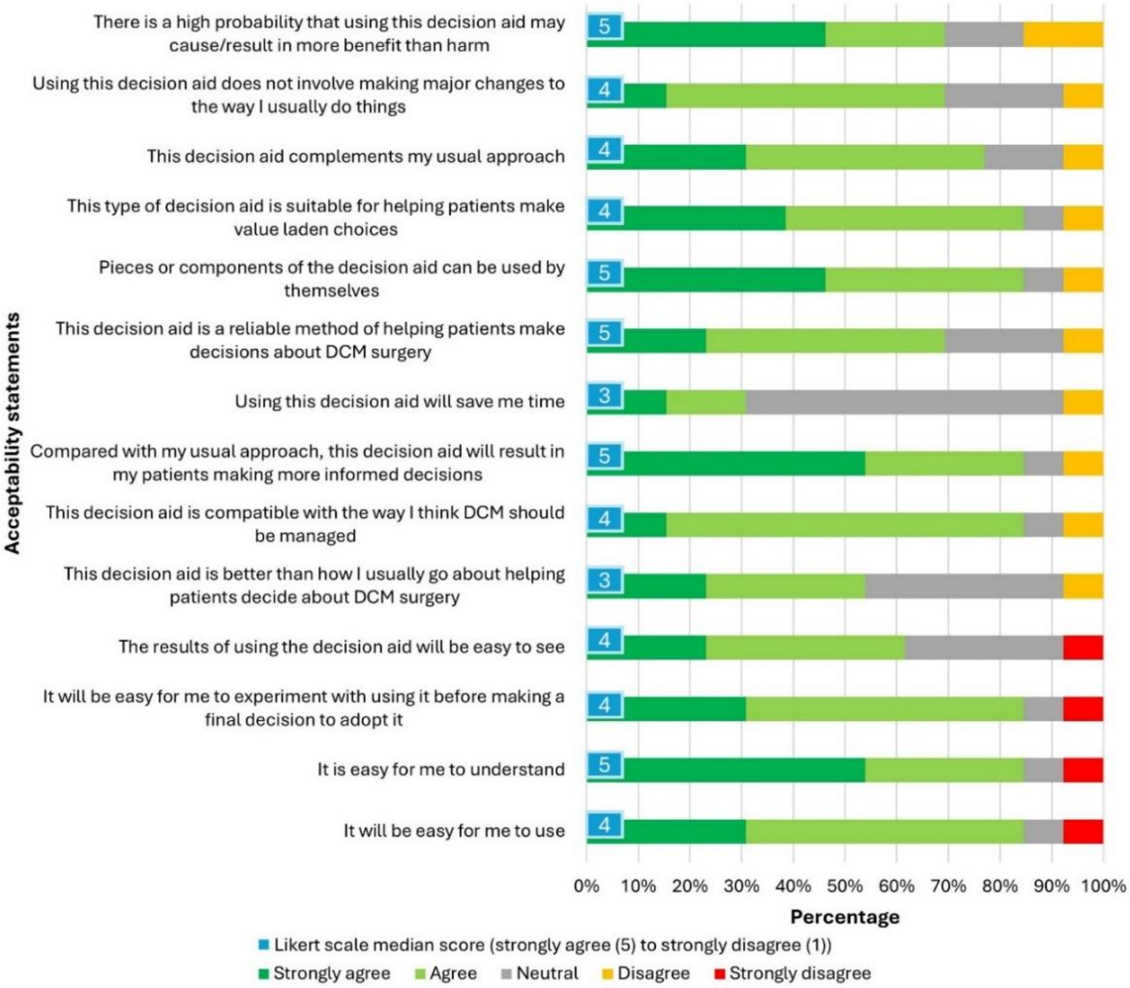
N, number of participants. DCM, Degenerative Cervical Myelopathy. SD, Standard Deviation. USA, United States of America. [a]All health professional-participants were practicing in their country of training at the time of interviews. One health professional-participant practicing in Australia also trained in India and the United Kingdom.

Table 3: Acceptability questionnaire for participants with Degenerative Cervical Myelopathy (n=18)[a]

Acceptability questionnaire items		N (%)
Section of decision aid rated as ‘excellent’ or ‘good’		
	Degenerative Cervical Myelopathy: Should I have surgery?	15 (83%)
	What is DCM? How is DCM diagnosed?	16 (89%)
	What are the categories of DCM?	16 (89%)
	Which DCM category are you in when using the mJOA tool?	11 (61%)
	What is recommended?	12 (67%)
	Description of non-surgical management and DCM surgery	15 (75%)
	Potential harms and benefits of non-surgical management and DCM surgery	12 (67%)
	Questions for when you talk with a health professional	5 (83%)[b]
The length of the decision aid was just right		16 (89%)
The amount of information was just right		15 (83%)
I found the decision aid	Balanced	13 (72%)
	Slanted towards surgery	3 (17%)
	Slanted towards the non-surgical option	2 (11%)
Would have found the decision aid ‘extremely’ or ‘very’ useful when making the decision about DCM surgery		12 (67%)
Agreed that the decision aid would have made their decision easier		16 (89%)
Enough information is provided to help people with DCM decide on whether to have surgery		13 (72%)

N, number of participants with Degenerative Cervical Myelopathy. DCM, Degenerative Cervical Myelopathy. mJOA, modified Japanese Orthopaedic Association. [a]One patient-participant did not complete the anonymous acceptability questionnaire. [b]Only six participants completed this question as it was added later in the development process.

Figure 2: Acceptability questionnaire for health professional-participants that manage people with Degenerative Cervical Myelopathy (n=11)[a]



[a]Two health professional-participants did not complete the anonymous acceptability questionnaire.

3.3 Feedback for each section of the decision aid

Most suggestions from participants were incorporated into the decision aid but some were not possible to implement as they conflicted with the best available evidence or other participants' feedback. Online supplementary file 14 outlines the feedback we did not incorporate in the decision aid and our justification for this.

3.4 Thematic analysis of interviews

Themes 1 and 2: Positive and constructive feedback

Most participants gave positive feedback on the content and design of the decision aid. All participants identified potential changes and most provided suggestions to simplify the decision aid.

"I like the graphics that you've got on there. And I like the fact that it's putting the decision-making back with the patient but giving them information." (F, 51-60, patient)

"If neurologists had access to data like this...we would be better suited to help them or help triage them appropriately." (F, 31-40, neurologist)

"I think it could be simplified, maybe more visual." (F, 51-60, patient)

"The document itself is dense with a lot of material but there are ways to simplify it."

(M, 61-70, neurosurgeon)

Theme 3: Modify the decision aid to enhance understanding for people with DCM

All participants suggested modifying wording to make the decision aid more patient friendly. People with DCM and health professionals suggested using more practical examples (e.g. difficulty buttoning up a shirt), considering colours appropriate for people with colour blindness, and modifying some graphics. One health professional suggested the decision aid could be presented in languages other than English.

"I did wonder like whether a QR code would be helpful, that could take them through to either a website or an option for larger texts or different languages."

(F, 41-50, physiotherapist)

"Be careful with language - is it a slowly progressing spinal cord injury [not a] scary slow motion spinal cord injury" (M, 21-30, physiotherapist)

Theme 4: Improving awareness of DCM and acceptability of the decision aid

People with DCM frequently suggested their diagnosis was delayed. Health professionals suggested some primary practitioners may not be aware of DCM, clarify who the decision aid is targeting and had mixed views on the most appropriate format. Most participants agreed that the wording used is appropriate to encourage timely action without people with DCM feeling panic, but some had conflicting views on using the mJOA or how it is incorporated.

"Awareness is an issue in primary care." (M, 21-30, physiotherapist)

"I didn't know what it was until I found out I had it, and I even have trouble explaining it to friends now, so I just say I have a spinal cord injury." (F, 41-50, patient)

"I think what potentially we should have, is a better explanation of the mJOA. And also explain how it's determined." (F, 51-60, patient)

Theme 5: Highlight variations in symptoms and promote individual management

All people with DCM highlighted the impact of their symptoms which were variable. Primary care health professionals highlighted the difficulties of early diagnosis of DCM due to the diversity of symptoms. Most health professionals agreed management should involve shared decision making but some surgeons suggested aspects of care are more appropriate for a specialist to decide (e.g. the surgical approach). Some health professionals suggested including quality of life measures or other surveys to guide treatment alongside the mJOA.

"The clumsiness and tripping over were the main symptoms for me." (F, 51-60, patient)

"This should be an individualised discussion specific to that patient…thresholds can be subjective, and people need to get the right information." (M, 21-30, physiotherapist)

"I talk to them about symptoms worsening or the impact of their life, but the score is just where they stand." (M, 41-50, neurosurgeon)

Theme 6: Create realistic treatment expectations

People with DCM and health professionals frequently highlighted that DCM is a progressive condition needing tailored management. They also agreed with descriptions of non-surgical management and suggested including perioperative recommendations. Some people with DCM mentioned they were unaware of rehabilitation requirements while others felt post-surgical care was beneficial. Some health professionals had different views on how to explain surgery, but most suggested surgery aims to slow DCM progression. Some health professionals suggested focusing on acute healing times while people with DCM highlighted the time to adapt to life post-surgery.

"The importance of setting a realistic expectation and the fact that people aren't necessarily cured by this."

(M, 51-60, general practitioner)

“Post op care and rehab makes a huge difference – persistence with exercises and recommendations from OT.” (F, 41-50, patient)

"Rehabilitation is important post-surgery, but type and timing should be personalised. People may not have insurance or recover well with home exercise." (M, 61-70, neurosurgeon)

Theme 7: Facilitate equitable access to care and active management strategies

People with DCM and health professionals suggested timely access to care varies between public and private healthcare settings and countries. Both suggested incorporating prompts to monitor symptoms with a health professional within the decision aid (e.g. note key changes). Health professionals suggested monitoring at 6-month intervals and considering individual circumstances. People with DCM frequently suggested that social groups are helpful.

“So, in the NHS, no rehabilitation is provided, nothing. Yeah. After my first operation, I was so traumatised... I was so traumatised after surgery. And adapting can take time.”

(F, 71-80, patient)

"They may not need to see anyone, but they need to know the risk factors and when to come back.” (M, 41-50, neurosurgeon)

4. Discussion:

4.1 Summary of findings

People with DCM and health professionals involved in the management of DCM highlighted a need to increase awareness of the condition, early diagnosis and effective monitoring. Seven themes were developed from interviews (Supplementary file 15). Themes covered feedback on the decision aid, symptom diversity, outcome expectations and active management participation. Most people with DCM rated the decision aid as good-to-excellent and 89% said it would have made their management decision easier. Most health professionals strongly agreed or agreed the decision aid is acceptable and suggested the aid could better align treatment expectations with evidence.

4.2 Meaning of the study

This is the first patient decision aid for people with DCM. It is designed to facilitate shared decision making, particularly for those with mild DCM where it is unclear if surgical or non-surgical management is best. It includes prompts for monitoring DCM with health professionals and consideration for its implementation. It was suggested that the decision aid could increase awareness of DCM which is prioritised in the literature.[13]

Most people with DCM interviewed (58%) received their diagnosis over twenty-four months after noticing symptoms and only one person (5%) was diagnosed within one month. Interviews suggested presenting the decision aid in different media (e.g. video) and electronically distribution via multi-disciplinary teams (i.e. health professionals and non-clinical staff such as administration staff) may increase engagement. The decision aid will be available online via the Institute for Musculoskeletal Health webpage and Myelopathy.org. Myelopathy.org is the first global charity dedicated to improving the quality of life of people with DCM and was recognised in a Lancet Neurology editorial as pivotal to driving future change.[44]

Future use of our decision aid may be facilitated by visual appeal, simplicity of design and ease of use. For example, 89% of people with DCM who completed the acceptability questionnaire said our decision aid would have made their decision easier (table 2) and all health professionals ‘strongly agreed’ or ‘agreed’ it would be easy to use and understand. Actioning feedback to facilitate shared decision-making and reduce complexity (e.g. an external link to the mJOA) may mean the aid is more likely to be integrated into routine care than other more complex educational tools.[45] Incorporating plain language, bullet points, and appropriate visuals could also facilitate user understanding and reduce cognitive load.[46] Dot point questions about quality of life and pain included take into account the ‘ceiling-effect’ of the mJOA for people with mild DCM.[47]

Health professionals interviewed frequently suggested the decision aid should only focus on people with mild DCM but people with lived experience of DCM advocated that people with moderate DCM could also be managed without surgery in some instances. To address this discussion point, the decision aid includes the only known RCT that had compared surgical and non-surgical management for people with mild-moderate DCM. This RCT reported no significant between-group differences in outcomes at 10 years.[19] To separate mild and moderate DCM, we used the most recent clinical guidelines that recommend people with moderate DCM undergo surgery. The majority of the authorship group agreed the decision aid is most useful to help people with mild DCM decide if they need surgery or non-surgical management plus monitoring.[48] A recent systematic review and meta-analysis presents estimates of people with mild DCM who experience neurological decline without surgery (9%

at 1 year, 16% at 2 years, 21% at 3 years, 27% at 5 years, 36% at 15 years and 37% at 20 years).[32] Encouraging appropriate screening could further encourage earlier detection of DCM and facilitate appropriate management.[49]

Interviews frequently highlighted non-surgical management and perioperative rehabilitation for people with DCM is necessary but inconsistently provided. Limited research guides the type of rehabilitation patients should receive.[50] A recent retrospective cohort study (n=116) demonstrated that people with DCM participating in a comprehensive rehabilitation can achieve considerable functional improvement following spinal surgery.[50] People with DCM reported benefits from several allied health services like physiotherapy or occupational therapy (*"Through ongoing activity, particularly focused on addressing the symptoms of myelopathy, I've been able to behave in pretty much a normal way. I'm active, I run again." - F, 61-70, patient*). However, early management is important as people with mild DCM managed without surgery (n= 167) are more likely to report benefits from physiotherapy than those with moderate or severe DCM.[4] People with moderate or severe DCM should consult a surgeon but may benefit from support from non-surgical clinicians before, after or in the absence of available surgical management options.[50]

Affordable care is a barrier to optimal management but facilitating social connection could improve quality of life for people with DCM. Affordability and waiting times for surgery in the public sector can be substantial in many countries. People with DCM of various severity can become increasingly anxious as they wait for a diagnosis. Health professionals suggested strategies to empower people with DCM to manage and monitor their own symptoms (e.g. recording symptom changes). The decision aid includes numeric estimates of benefits and harms, links to social groups and that research on neural plasticity and rehabilitation is ongoing.

Including these features may reduce potential anxiety and improve quality of life (e.g. mood and motivation) for people living with DCM irrespective of their situation.[50]

4.3 Strengths and Limitations

The development process has several strengths. We developed a decision aid that satisfies the IPDAS criteria, used mixed methods to evaluate acceptability of the decision aid, used data saturation to guide the number of interviews conducted and used triangulation to improve the rigour of the coding process.[51] The study authors include a multidisciplinary team of health professionals and people with lived experience of DCM. People with DCM involved in the development process were from diverse backgrounds across the world and provided feedback at multiple stages (e.g. interviews, review of the final manuscript and decision aid). One-on-one interviews conducted with participants also allowed for in-depth feedback. The readability of the decision aid was measured and improved during development. The decision aid includes key elements to address low health literacy such as subheadings, bullet points and white space for ease of use.[46] We also provide justification of the evidence used to inform the benefits and harms presented.

Limitations include challenges with recruitment. For example, most people with DCM interviewed were females (89%), most health professionals were males (85%) and most people with DCM had undergone surgery (79%). As most people with DCM rated the decision aid's acceptability after having surgery, future evaluation is needed to evaluate the acceptability of the tool with patients prior to having surgery. Health professionals interviewed were from eight different professions and eight different countries of training which has advantages and disadvantages. Recruiting from diverse settings increases the generalisability of our study results at the cost of reducing region-specificity. Nonetheless, we prioritised developing an acceptable decision aid for use in different countries to increase reach, promote earlier diagnosis and encourage evidence-based management for people with DCM globally. The decision aid and other future resources (e.g. supplementary video) will need to be translated to other languages for people from non-English speaking backgrounds. Use of the decision aid should consider uncertainty in the existing evidence and the need for individualised management.

5. Conclusion

Our decision aid for people with DCM was rated as an acceptable tool by people with DCM and health professionals involved in their management. This decision aid can be used by clinicians and people diagnosed with DCM to improve knowledge of the benefits and harms of management options via shared decision making. The tool could be of particular benefit for those people with mild DCM, given surgical management may not yet be required, and a variety of non-surgical management options are still available. During the study, our interviews reinforced the need to increase awareness of DCM, improve monitoring and ensure ease of access to the decision aid to optimise global impact. We encourage the use of the decision aid in daily clinical practice, while a larger study evaluating the potential benefits of the decision aid is being planned.

Supplementary files:

Supplementary file 1: Flow chart of the development process

Supplementary file 2: Literature search strategy

Supplementary file 3: People with DCM pre-interview questionnaire

Supplementary file 4: Health professional pre-interview questionnaire

Supplementary file 5: People with DCM interview guide

Supplementary file 6: Health professional interview guide

Supplementary file 7: Acceptability questionnaire for people with DCM

Supplementary file 8: Acceptability questionnaire for health professionals

Supplementary file 9: Decision aid version from PowerPoint

Supplementary file 10: 32-item Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist

Supplementary file 11: Final decision aid

Supplementary file 12: International Patient Decision Aid Standards Checklist (IPDASi v4.0)

Supplementary file 13: User-Centred Design 11-item measure (UCD-11)

Supplementary file 14: Reasons for not implementing feedback for each section of the decision aid

Supplementary file 15: Interview themes and subthemes, and example quotes

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Contributors:

All authors critically revised the manuscript for important intellectual content and approved the final manuscript. Please find below a detailed description of the role of each author. ARG: Developed and designed data collection tools, conducted data collection, analysed, and interpreted data, drafted, and revised the manuscript and approved the final version to be published. DBA: Developed and designed data collection tools, interpreted data and approved the final version to be published. MJM: Developed and designed data collection tools, interpreted data and approved the final version to be published. BD: Developed and designed data collection tools, interpreted data and approved the final version to be published. SM: Developed and designed data collection tools, analysed and interpreted data and approved the final version to be published. JVG: Developed and designed data collection tools, interpreted data and approved the final version to be published. TCH: Developed and designed data collection tools, interpreted data and approved the final version to be published. KM: Developed and designed data collection tools, interpreted data and approved the final version to be published. SS: Developed and designed data collection tools, interpreted data and approved the final version to be published. CA: Revised the manuscript and approved the final version to be published. RC: Assisted participant recruitment, revised the manuscript and approved the final version to be published. CZ: Revised the manuscript and approved the final version to be published. TFB: Revised the manuscript and approved the final version to be published. LAT: Revised the manuscript and approved the final version to be published. MGF Revised the manuscript and approved the final version to be published. ED: Revised the manuscript and approved the final version to be published. CN Revised the manuscript and approved the final version to be published. HH: Revised the manuscript and approved the final version to be published. AKD: Revised the manuscript and approved the final version to be published. CGM: Developed and designed data collection tools, interpreted data and approved the final version to be published. JML Revised the manuscript and approved the final version to be published. RD: Revised the manuscript and approved the final version to be published. JRZ: Developed and designed data collection tools, conducted data collection, analysed, and interpreted data, drafted, and revised the manuscript and approved the final version to be published. The corresponding author (ARG) attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted. As the guarantor, the corresponding author (ARG) accepts full responsibility for the work and/or the conduct of the study, had access to the data, and controlled the decision to publish.

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Data availability statement: Data are available upon reasonable request. All data relevant to the study are available upon reasonable request to the corresponding author, Mr Andrew R Gamble at andrew.gamble@sydney.edu.au.

Conflicts of interest statement:

TCH and KM are unpaid members of the International Patient Decision Aid Standards (IPDAS) Collaboration Steering Committee.

Ethics approval:

Sydney Local Health District Human Research Ethics Committee, Concord Repatriation General Hospital (CRGH) approval 2023/ETH01021

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CHAPTER FIVE

The development and early evaluation of a model of care to reduce waiting times in outpatient musculoskeletal clinics: a mixed-methods study

PREFACE

Chapter Five is a mixed methods study which describes the three-stage development of an innovative model of care for people with musculoskeletal conditions that aims to reduce waiting times in public hospital outpatient clinics. The need for this study was identified due to Chapter Two demonstrating online information may mislead people to want to have unnecessary surgery and Chapter Three and Four demonstrating the acceptability of patient decision aids to provide evidence-based information for acute and chronic musculoskeletal conditions. There is poor uptake of evidence-based care among people with musculoskeletal conditions due to the overuse of unnecessary surgery and long waiting times preventing people getting the right care at the right time. Chapters Two, Three and Four identified potential strategies to help reduce the overuse of unnecessary surgery. Chapters Five and Six focused on strategies to reduce long waiting times which prevent many people with musculoskeletal conditions from receiving evidence-based care.

Citation

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The development and early evaluation of a model of care to reduce waiting times in outpatient musculoskeletal clinics: a mixed-methods study

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ABSTRACT

Aim: Develop a model of care to reduce waiting times for adults with musculoskeletal conditions referred to outpatient musculoskeletal clinics in Australian public hospitals.

Methods: Mixed-methods development involving three stages: Stage 1: designing a preliminary model based on existing research and input from a multidisciplinary steering group; Stage 2: a feasibility randomised controlled trial (RCT) with nested qualitative interviews evaluating our model in an outpatient back pain clinic; Stage 3: refining the model based on findings from the feasibility RCT and further qualitative interviews to ensure the model of care is ready to evaluate in a fully powered RCT including people with various musculoskeletal conditions (WAIT-less trial).

Results: Stage 1: our preliminary model involved matching the mode and type of care to patients' risk of persistent disabling pain (Keele STarT MSK tool) and presence of potential radiculopathy (if applicable). Stage 2: our feasibility RCT found our model was largely feasible to deliver in an outpatient public hospital setting and feasible to evaluate in a future trial including people with various musculoskeletal conditions (WAIT-less trial). Stage 2 and 3: Findings from the feasibility RCT and qualitative interviews with 24 participants (11 patients with musculoskeletal conditions, 13 health professionals and key stakeholders) helped refine the model to be tested in the WAIT-less trial.

Conclusion: We developed a model of care that can identify patients with musculoskeletal conditions who could be effectively managed with less resources (e.g. brief telephone call, App-based exercises), thereby allowing patients with complex symptoms to be seen in-person sooner.

Key words: Musculoskeletal pain; stratified care; telehealth; feasibility; mixed methods; qualitative.

Ethics and trial registration: This study received approval from the Ethics Review Committee (RPAH Zone: X21-0221).

Social media abstract:

We developed a model of care that identifies patients with musculoskeletal conditions who could be managed with less resources (e.g. a brief call, App-based exercises) so patients with complex symptoms can be seen in-person sooner.

Introduction

Musculoskeletal conditions are the second leading cause of disease burden in Australia and globally.[1,2] Many adults with musculoskeletal conditions in Australia experience long waiting times to access care in public hospitals,[3] which leads some patients to develop symptoms that are difficult and costly to manage.[4-6] Over half of Australians cannot afford private physiotherapy[7] and rely on outpatient physiotherapy clinics in the public system where waiting times for an appointment can be as high as 12 months.[3] One potential solution to reduce waiting times is to use a triage-based screening approach to match the mode and type of care provided based on prognostic factors. This could help identify patients with musculoskeletal conditions who could be managed with less resources (e.g. a brief telephone call, App-based exercises) and allow patients with more complex symptoms to be seen in-person sooner.

To improve access to musculoskeletal clinics in Australia we drew inspiration from a physiotherapist-led telephone-assessment and advice service (PhysioDirect) evaluated in a large UK trial (n=2249 people with musculoskeletal conditions).[8] PhysioDirect involved a telephone call with a physiotherapist to determine those needing simple telephone advice, education and exercise instructions before being discharged and those who required clinic-based physiotherapy. Compared to usual clinic-based care, PhysioDirect reduced median waiting times by 27 days (7 days vs. 34 days) and the mean number of clinic-based appointments by an incidence rate ratio of 0.59 appointments (2 vs. 3), without adversely affecting physical health outcomes.[8] PhysioDirect was also acceptable to patients and physiotherapists involved in the trial[9] and inspired us to develop a similar model of care to reduce waiting times for musculoskeletal clinics in Australia.

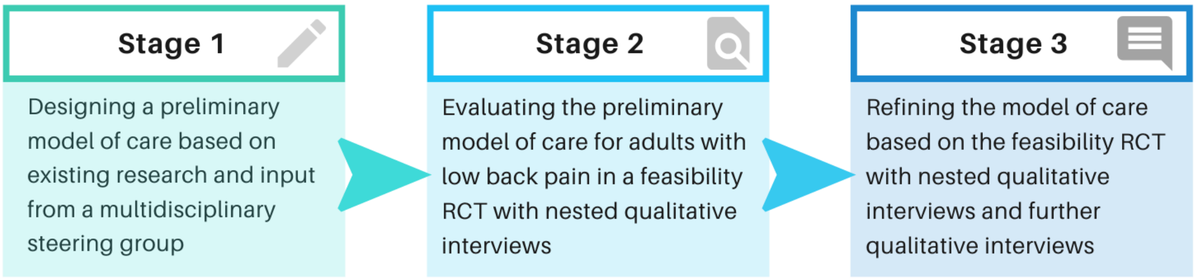
This study aims to describe how we developed, feasibility-tested and refined a triage and management service to reduce waiting times for adults with musculoskeletal conditions referred to outpatient musculoskeletal clinics in Australian public hospitals. The final model of care is being evaluated in an adequately powered, multi-site randomised control trial (RCT) in Australia (WAIT-less trial).

Methods:

Study design

A three-stage mixed-method design (Figure 1) informed the development of our model of care to reduce waiting times for adults with a musculoskeletal condition referred to outpatient musculoskeletal clinics.

Figure 1: Stages used to develop a model of care to reduce waiting times in outpatient musculoskeletal clinics.



Stage 1: Designing a preliminary model of care based on existing research and input from a multidisciplinary steering group.

We assembled a multidisciplinary steering group to support the development of our preliminary model of care (Figure 2). The steering group included health professionals from public hospitals (CN – rheumatologist, JH, MH - physiotherapist), health policy (SM), and research experts in the fields of musculoskeletal pain (AG,JZ,CM, MM, DA, TD, CH, NF), telehealth (LH, NF, JZ), stratified care (NF), health service research (CM, NF, JZ), and model of care development (JZ, NF, LH, JC).

The model of care aimed to reduce waiting times by improving the existing system for triaging new referrals to public hospital outpatient clinics in Australia. Currently, adults with musculoskeletal pain referred to public hospital outpatient musculoskeletal clinics from primary care (e.g., a general practitioner) or within the hospital (e.g., emergency departments or post-surgery) are prioritised based on possible presence of red flags (e.g. serious pathology) and concerning neurological features, as well as the severity and duration of their symptoms. For example, patients with acute symptoms (0-6 weeks) and those who are post-surgery are categorised as 'priority 1' can wait for 2-8 weeks to be seen. Patients with sub-acute symptoms (longer than 6 weeks and less than 3 months) are categorised as 'priority 2' and can wait for 3 months to be seen. Patients with a longer duration of chronic symptoms (greater than 3 months) are categorised as 'priority 3' can wait up to 12 months or longer to be seen.[3] However, there are several challenges with this approach. First, long waiting times for people with chronic musculoskeletal conditions can lead to their symptoms becoming more complex and costly to manage.[10] Second, many patients with acute conditions have a good prognosis (e.g. acute low back pain)[11,12] and can be supported to self-manage at home without the need for clinic-based treatment.[13,14] Third, postoperative rehabilitation can be just as effective if it is performed at home or with minimal supervision.[13,15-20] Finally, early physiotherapist-led care for musculoskeletal conditions is associated with subsequent reductions in opioid use in people with low back, shoulder and knee pain.[6]

For these reasons, we considered that prioritising new referrals to musculoskeletal clinics based on patients' risk of persistent disabling pain would be more appropriate than prioritising based on acuity, and this was the basis for us developing our model of care. We hypothesised that if we limited clinic-based treatment for adults with a good prognosis (i.e. at low risk of persistent disabling pain), we may be able to reduce waiting times for adults with more complex presentations that require clinic-based care. As such, we chose the 10-item Keele STarT MSK tool[21] to assess risk of persistent disabling pain (categorised as low, medium, or high) as part of the model of care because it is quick and simple to use and has good validity for determining risk profiles in adults with some of the most common musculoskeletal pain presentations (back, neck, knee, shoulder or multisite pain).[21,22] The Keele STarT MSK tool was chosen due to its validity to identify patients with musculoskeletal conditions at low, medium or high risk of persistent disabling pain which was demonstrated in a previous feasibility and pilot trial conducted in the UK (n=524).[22,23] The tool includes a numeric pain scale rating (0-10) and nine ('agree' or 'disagree') statements about patients beliefs on how to manage their condition, expected recovery, activity and exercise limitations, presence of other health conditions, mood, and duration of symptoms.

For our model of care, we considered that providing simple advice and education about self-management over the telephone would be appropriate for adults at low risk of persistent disabling pain given they have a favourable prognosis. This assumption was based on the PhysioDirect trial in the UK, described above, where a telephone call with a physiotherapist was used to determine the treatment needs of people with musculoskeletal conditions.[8] A telephone call was used to provide advice, education and exercise instructions before patients were discharged without adversely affecting their physical health outcomes.[8] For adults at medium risk of persistent disabling pain, we considered telehealth appointments (with or without an App-based exercise program) would be appropriate. This assumption was based on numerous high-quality systematic reviews and RCTs that suggest telehealth provides similar outcomes to clinic-based care for various musculoskeletal conditions (e.g., back pain,[24] shoulder pain,[25] knee osteoarthritis[26] and following total knee and hip arthroplasty[25-27]) and supervised physiotherapist-led exercise provides similar outcomes to home-based exercise programs following many orthopaedic surgeries[14] (e.g. following ACL surgery,[13] total knee[15] and hip replacement[16] and lumbar disc surgery[17]). The recent REFORM trial (n=210 participants with musculoskeletal conditions) further strengthened these assumptions as it demonstrated that remotely delivered physiotherapist-led care for people with a range of musculoskeletal conditions was as effective as clinic-based physiotherapist-led care.[28] Treating patients at low- and medium-risk of persistent disabling pain with less resources would therefore reduce the waiting time for clinic-based care for those at high-risk of persistent disabling pain. See Table 1 for a more detailed description of the preliminary model of care.

Table 1: Preliminary model of care

Treatment group and subgroup	Intervention protocol
All patients	All patients with musculoskeletal conditions referred to public hospital outpatient clinics are assessed for their risk of persistent disabling pain (via STarT MSK tool).
Low risk of persistent disabling pain (Keele STarT MSK tool score 0–4)	Patients at low risk of persistent disabling pain are provided with one telephone appointment. During this call they are informed they do not need further treatment as they have a good prognosis. They are also given advice to temporarily modify painful activities, take simple pain medications if required, and then work towards gradually increasing their activities (e.g., walking) as pain permits. They are told to call back if their condition doesn't improve over the following 6 weeks.
Medium risk of persistent disabling pain (Keele STarT MSK tool score 5–8)	Patients at medium risk of persistent disabling pain are offered physiotherapist-led telehealth. The number of telehealth consultations and length of time between appointments is determined by the treating physiotherapist. Physiotherapist-led telehealth includes advice and education to support self-management (e.g., advice to exercise, modify activities, lose weight, or take simple pain medications if needed), and an exercise program prescribed using the app-based program PhysiTrack. PhysiTrack is a program that has over 5000 exercises. The physiotherapist tailors the exercise program to participants' activity goals and level of function. Exercise type,

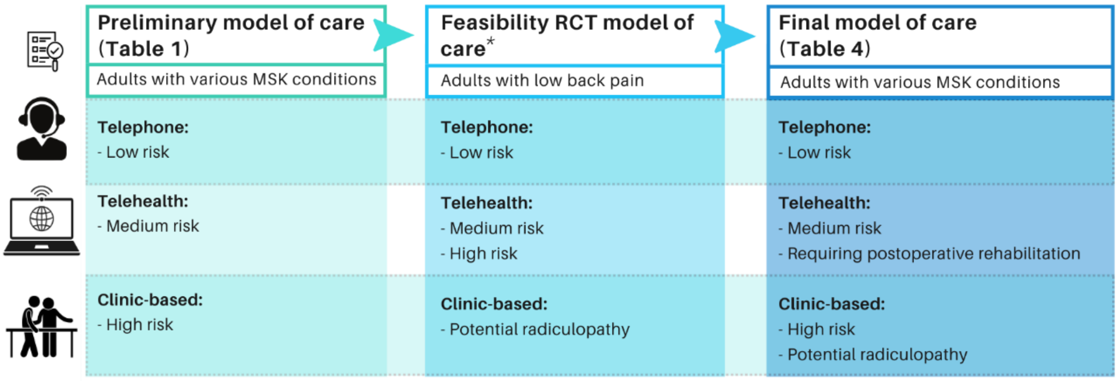
	dosage and progression is at the discretion of the treating physiotherapist. All physiotherapists complete online training modules developed by the Sydney Local Health District and Agency for Clinical Innovation to facilitate the use of the PhysiTrack App.
High risk of persistent disabling pain (Keele STarT MSK tool score 9–12)	Patients at high risk of persistent disabling pain are offered clinic-based physiotherapist-led consultations. The number of clinic-based consultations is determined by the treating physiotherapist. The physiotherapist provides advice and education to support self-management (e.g., advice to exercise, modify activities, lose weight or take simple pain medications if needed), and may provide interventions to address psychological barriers to recovery (e.g., pacing, graded exposure), and an App-based exercise programme (PhysiTrack; as described for patients at medium risk of persistent disabling pain). The physiotherapist also directs patients to complete an online self-directed pain education programme developed by the Agency for Clinical Innovation. The programme (Pain Management: For Everyone https://www.aci.health.nsw.gov.au/chronicpain/for-everyone) is publicly available and includes seven modules: (1) Introduction to pain (6:47 min); (2) Getting help from your healthcare team (5:56 min); (3) Pain and physical activity (12:43 min); (4) Pain: Lifestyle and nutrition (8:41 min); (5) Pain and role of medications (9:57 min); (6) Pain and thoughts (10:27 min); (7) Pain and sleep (11:08 min). Patients are encouraged to go through the programme at their own pace and bring any questions to their

	next consultation. Patients in this subgroup can be referred to see a psychologist if the physiotherapist believes it would be valuable.

Stage 2: Evaluating the preliminary model of care for adults with low back pain in a feasibility RCT with nested qualitative interviews

The next stage was to evaluate the feasibility of delivering and evaluating our preliminary model of care in a pilot and feasibility RCT (hereafter referred to as a feasibility RCT) with nested qualitative interviews. The preliminary model of care was designed for adults with a range of musculoskeletal pain presentations. However, rheumatologists and physiotherapists working at a small back pain clinic at Royal Prince Alfred (RPA) Hospital were interested in ways to reduce their clinic's waiting time, so we decided to conduct our feasibility RCT in their back pain clinic. Details of the feasibility RCT methods can be found in the published protocol[29] and results, in the published trial.[30] In brief, forty participants were randomised to usual care (n=14) or our new model of care (intervention group) (n=26). Participants in the intervention were offered care according to their subgroup (low-, medium- or high risk of persistent disabling pain or those with potential radiculopathy) as described in Table 1, with some modifications shown in Figure 2.

Figure 2: Changes to the mode and type of treatment provided during the development and early evaluation process



Preliminary model of care (Table 1) Adults with various MSK conditions	Feasibility RCT model of care* Adults with low back pain	Final model of care (Table 4) Adults with various MSK conditions
Telephone: - Low risk	**Telephone:** - Low risk	**Telephone:** - Low risk
Telehealth: - Medium risk	**Telehealth:** - Medium risk - High risk	**Telehealth:** - Medium risk - Requiring postoperative rehabilitation
Clinic-based: - High risk	**Clinic-based:** - Potential radiculopathy	**Clinic-based:** - High risk - Potential radiculopathy

MSK, Musculoskeletal. RCT, Randomised controlled trial. Low-, medium- and high-risk refers to patients' risk of persistent disabling pain determined using the STarT MSK tool. Potential radiculopathy was defined as the presence of pain that starts from the back and travels below their knee or pain that started from the neck and travels below the shoulder. *Results of the feasibility RCT are reported in a separate publication.[30]

We made several modifications to our preliminary model of care as we developed the protocol for the feasibility RCT. First, we added a screening question to identify participants with 'potential radiculopathy' at baseline so we could offer these participants clinic-based care. This was based on feedback from clinicians involved in the trial who reported they would not be comfortable ruling out radiculopathy via telephone. Second, participants at high-risk of persistent disabling pain (without potential radiculopathy) were offered physiotherapy via telehealth to ensure people with potential radiculopathy were prioritised for clinic-based care. People at high-risk of persistent disabling pain also received an online self-directed pain education program from the Agency for Clinical Innovation on pain management (https://www.aci.health.nsw.gov.au/chronic-pain/for-everyone).

Clinicians and participants involved in the trial were contacted for qualitative interviews after the intervention period had begun to investigate the acceptability of the model of care. Nested qualitative interviews exploring acceptability of the trial and model are reported in the feasibility RCT.[30] Interview questions that focused on using the model for other musculoskeletal conditions were analysed alongside the additional qualitative interviews conducted in Stage 3 (see below).

Stage 3: Refining the model based on findings from the feasibility RCT and further qualitative interviews.

To further refine the model of care we evaluated in our feasibility trial, we used an implementation framework (Figure 3) to the inform nested qualitative interviews and further qualitative interviews. Nested qualitative interviews were with clinicians involved in the trial and participants in the trial who had low back pain and other musculoskeletal conditions. Further interviews were conducted with other health professionals who were interested in being involved in the larger trial and key stakeholders with an interest in the model of care (e.g., heads of physiotherapy departments at hospital sites in NSW, individuals from professional bodies). All interviews gathered feedback on the model of care evaluated in our feasibility RCT and a proposed final model of care that could be used for people with a range of musculoskeletal conditions and evaluated in a large multi-site trial in outpatient physiotherapy clinics. Interview questions largely focused on understanding the barriers and facilitators to implementation, views and experiences of using telehealth for patients with musculoskeletal conditions, suggestions for future trial processes, and refining our model of care. Participants were recruited via the network of the steering group and via snowball sampling from patients and clinicians involved in the feasibility RCT.

All interviews were conducted one-on-one via telephone or video conference (e.g., Zoom). One male researcher with experience in conducting interviews and qualitative research methods conducted all the interviews (AG). Additional verbal consent was gained from all participants before each interview was recorded. Interviews were conducted using a semi-structured interview guide (Supplementary file 1) and notes were taken during the interviews to highlight key themes that emerged and direct further questioning. Transcription of interviews was completed by a second researcher (SM) using Otter AI transcribing software. Participants had the opportunity to review transcripts following their interview, but prior to data analysis. Two researchers (AG and CH) independently familiarised themselves with interviews (via audio-recordings and transcripts), recorded initial observations, identified concepts relevant to the questions asked and developed a framework to organise concepts into broader themes and sub-themes in Microsoft Excel. Any disagreements in categorising concepts into themes and sub-themes were discussed and resolved with a third researcher (JZ). Qualitative results are reported according to the 32-item Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist (Supplementary file 2).

All qualitative interview data from Stage 2 and 3 was combined for analysis. The mapping of themes and subthemes was an iterative process as new data emerged, and interviews were stopped once no new themes emerged (data saturation). Interview themes and subthemes were matched to the five determinants (intervention, inner setting, outer setting, individuals, and implementation process) of our Implementation Research Logic Model (IRLM)[31] (Figure 3).

The IRLM provides a visual representation of the development plan to enhance the transparency of our development process and was used to guide interviews.[31] The IRLM determinants are drawn from the Consolidated Framework for Implementation Research (CFIR)[32] and provide a comprehensive list of factors that can impact implementation (i.e., barriers and facilitators). Mapping themes to the IRLM determinants allowed connections to be drawn between implementation strategies, mechanisms of action, and planned clinical outcomes.

Results:

Stage 1: Designing a preliminary model of care based on existing research and input from a multidisciplinary steering group.

Figure 2 summarises the preliminary model of care and how it was modified for the feasibility RCT.

Stage 2: Evaluating the preliminary model of care for adults with low back pain in a feasibility RCT with nested qualitative interviews

The feasibility RCT and nested qualitative interviews provided important information to guide modifications to our preliminary model of care. Over half of the feasibility targets were met, including treatment fidelity, treatment adherence, and qualitative interviews suggesting the model was acceptable. The full results of the feasibility RCT, plus qualitative interviews focusing on acceptability, are described elsewhere.[30]

Stage 2 and 3: Refinement of the model based on findings from the feasibility RCT and further qualitative interviews.

A total of twenty-four interviews were conducted across Stages 2 and 3 (patients n=11, health professionals, and key stakeholder n=13; Table 2). Twenty-four patients and three clinicians from the feasibility RCT were approached for nested qualitative interviews. All patients interviewed were from the feasibility RCT and had various musculoskeletal conditions; Intervention (n=7) and Usual Care (n=4). One patient interviewed had been lost to follow up in the trial. One patient did not attend an arranged interview, and no patient interviewed was classified as low risk in the intervention group as none were recruited. An additional thirty-four health professionals and key stakeholders were invited for further qualitative interviews.

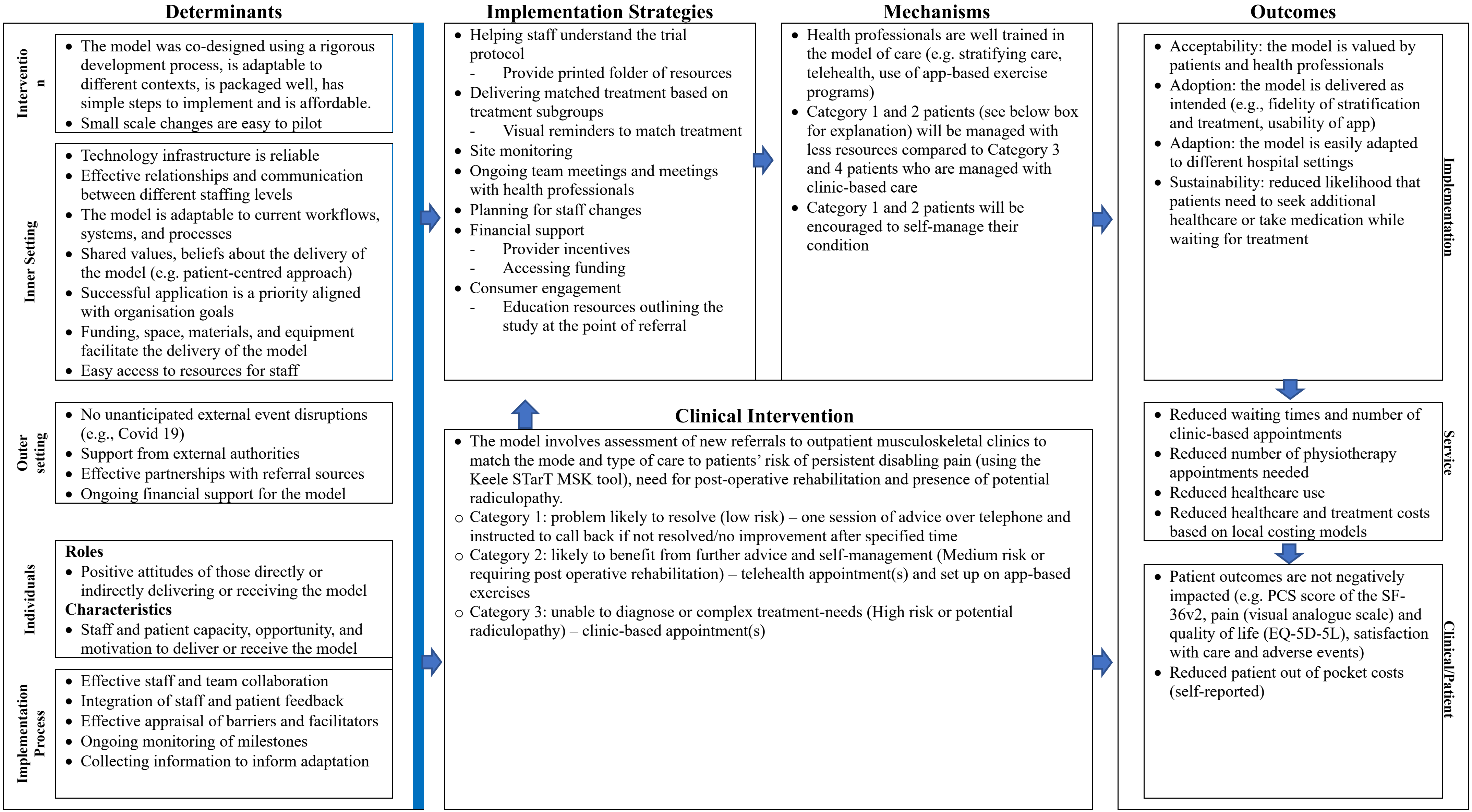
Demographic data and key characteristics for all participants interviewed are presented together (Table 2). Interviews lasted an average of 42 minutes (range, 28 to 60 minutes). Slightly more than half of the patients interviewed were female (64%) and had a median age of 60 (IQR 50 to 66). Health professionals and key stakeholders interviewed were from six hospital sites across NSW, Australia, had a median age of 50 (IQR, 40 to 60) and 20 years' experience (IQR, 13 to 28), and 7 were female (54%). Key stakeholders included individuals from the Australian Physiotherapy Association (APA) and Sydney Health Partners (SHP). All qualitative interviews were organised into eleven themes using inductive thematic analysis and refined into seven key themes (Supplementary 3). The themes include 1. Factors impacting the acceptability of our preliminary model of care, 2. Barriers and facilitators to telehealth, 3. Communication and providing quality care, 4. Access to care and utilisation of health resources, 5. Potential impact of external factors, 6. Characteristics of staff and patients, 7. Future implementation and delivery of care.

Table 2. Characteristics of patients, health professionals and key stakeholders who participated in a qualitative interview

Patients	Total sample (n=11)	Intervention (n=7)	Usual care (n=4)
Age, median (IQR)[a]	60 (50 to 66) [b]	63 (59 to 66)[d]	50 (25 to 70) [c]
Female, n (%)	7 (64)	4 (57)	3 (75)
Language other than English spoken at home, n (%)	4 (36)	3 (43)	1 (25)
Employment, n (%)			
Currently employed	3 (27)	3 (43)	2 (50)
Not currently employed	6 (55)	4 (57)	0 (0)
Student	2 (18)	0 (0)	2 (5)
Unpaid carer	0 (0)	0 (0)	0 (0)
Education, n (%)			
High school (not completed)	2 (18)	2 (29)	0 (0)
High school (completed)	1 (9)	0 (0)	1 (25)
TAFE/Trade	3 (27)	1 (14)	2 (50)
University – postgraduate degree	1 (9)	1 (14)	0 (0)
University – undergraduate degree	4 (36)	3 (43)	1 (25)
Other	0 (0)	0 (0)	0 (0)
Symptom duration of 12 weeks or longer, n (%)	11 (100)	7 (100)	4 (100)
Taken sick leave, n (%)	6 (55)	5 (71)	1 (25)
Risk subgroup, n (%)			
Low risk	1 (9)	0 (0)	1 (25)
Medium risk	2 (18)	1 (14)	1 (25)
High risk	2 (29)	2 (29)	0 (0)
Keele STarT MSK score (0-12), median (IQR)	9 (7 to 10)	10 (9 to 11)	5 (3 to 7)
Potential radiculopathy*	6 (55)	4 (57)	2 (50)
Health professionals and Key stakeholders	**Total (n=13)**		
Age, median (IQR)	50 (40 to 60)		
Female, n (%)	7 (54%)		
NSW public hospital site, n (%)			
Hospital 1	4 (30)		
Hospital 2	1 (8)		

Hospital 3	2 (16)
Hospital 4	1 (8)
Hospital 5	2 (16)
Hospital 6	1 (8)
Not applicable	2 (16)
Type of Health profession, n (%)	
Physiotherapist	11 (85)
Rheumatologist	1 (8)
Psychologist	1 (8)
Years experience, median (IQR)	20 (13 to 28)
Position, n (%)	
HOD/Assistant HOD	2 (16)
Team leader/senior/outpatient (physiotherapist or rheumatologist)	9 (70)
APA Board member	1 (8)
Sydney Health Partner member	1 (8)
Years in current position, median (IQR)	5 (3 to 6)

[a,b,c] Data missing for two patient participants age (one from each group). N, Number of participants; IQR, interquartile range; TAFE, Technical and Further Education, MSK, Musculoskeletal. NSW, New South Wales, HOD, head of department. *Pain that started from their back and went below their knee.



Determinants

Intervention

- The model was co-designed using a rigorous development process, is adaptable to different contexts, is packaged well, has simple steps to implement and is affordable.
- Small scale changes are easy to pilot

Inner Setting

- Technology infrastructure is reliable
- Effective relationships and communication between different staffing levels
- The model is adaptable to current workflows, systems, and processes
- Shared values, beliefs about the delivery of the model (e.g. patient-centred approach)
- Successful application is a priority aligned with organisation goals
- Funding, space, materials, and equipment facilitate the delivery of the model
- Easy access to resources for staff

Outer setting

- No unanticipated external event disruptions (e.g., Covid 19)
- Support from external authorities
- Effective partnerships with referral sources
- Ongoing financial support for the model

Individuals

Roles

- Positive attitudes of those directly or indirectly delivering or receiving the model

Characteristics

- Staff and patient capacity, opportunity, and motivation to deliver or receive the model

Implementation Process

- Effective staff and team collaboration
- Integration of staff and patient feedback
- Effective appraisal of barriers and facilitators
- Ongoing monitoring of milestones
- Collecting information to inform adaptation

Implementation Strategies

- Helping staff understand the trial protocol
  - Provide printed folder of resources
- Delivering matched treatment based on treatment subgroups
  - Visual reminders to match treatment
- Site monitoring
- Ongoing team meetings and meetings with health professionals
- Planning for staff changes
- Financial support
  - Provider incentives
  - Accessing funding
- Consumer engagement
  - Education resources outlining the study at the point of referral

Mechanisms

- Health professionals are well trained in the model of care (e.g. stratifying care, telehealth, use of app-based exercise programs)
- Category 1 and 2 patients (see below box for explanation) will be managed with less resources compared to Category 3 and 4 patients who are managed with clinic-based care
- Category 1 and 2 patients will be encouraged to self-manage their condition

Outcomes

Implementation

- Acceptability: the model is valued by patients and health professionals
- Adoption: the model is delivered as intended (e.g., fidelity of stratification and treatment, usability of app)
- Adaption: the model is easily adapted to different hospital settings
- Sustainability: reduced likelihood that patients need to seek additional healthcare or take medication while waiting for treatment

Service

- Reduced waiting times and number of clinic-based appointments
- Reduced number of physiotherapy appointments needed
- Reduced healthcare use
- Reduced healthcare and treatment costs based on local costing models

Clinical/Patient

- Patient outcomes are not negatively impacted (e.g. PCS score of the SF-36v2, pain (visual analogue scale) and quality of life (EQ-5D-5L), satisfaction with care and adverse events)
- Reduced patient out of pocket costs (self-reported)

Clinical Intervention

- The model involves assessment of new referrals to outpatient musculoskeletal clinics to match the mode and type of care to patients' risk of persistent disabling pain (using the Keele STarT MSK tool), need for post-operative rehabilitation and presence of potential radiculopathy.
  - Category 1: problem likely to resolve (low risk) – one session of advice over telephone and instructed to call back if not resolved/no improvement after specified time
  - Category 2: likely to benefit from further advice and self-management (Medium risk or requiring post operative rehabilitation) – telehealth appointment(s) and set up on app-based exercises
  - Category 3: unable to diagnose or complex treatment-needs (High risk or potential radiculopathy) – clinic-based appointment(s)

Figure 3: Implementation research logic model (IRLM) for our triage and treatment service.

Final model of care 'Physiotherapist-led triage and treatment service'

The three-stage development process led to creating a final model of care for evaluation in an adequately powered multi-site RCT, which we called the 'Physiotherapist-led triage and treatment service'. Table 3 describes the model of care and key changes from the feasibility RCT.

Table 3: Physiotherapist-led triage and treatment service[33] and key changes to the model of care evaluated in the feasibility RCT.[30]

Treatment group and subgroup	Intervention protocol
All participants	All patients with musculoskeletal conditions referred to public hospital outpatient clinics are assessed for their risk of persistent disabling pain (via STarT MSK tool), need for postoperative rehabilitation or presence of potential radiculopathy.
Low risk of persistent disabling pain (Keele STarT MSK tool score 0–4)	Participants at low risk of persistent disabling pain will be offered brief advice and education (via one telephone call with a physiotherapist) including advice on activity modification and analgesia if necessary, and education that their condition has a good prognosis. Participants in this treatment subgroup will be asked to call the screening physiotherapist back if their symptoms have not improved in 6 weeks. If nil contact is received after 6 weeks, participants will be discharged from the physiotherapy service.
Medium risk of persistent disabling	Participants at medium risk of persistent disabling pain or requiring postoperative rehabilitation will be offered physiotherapist-led

pain or requiring postoperative rehabilitation (Keele STarT MSK tool score 5-8)	telehealth. Physiotherapist-led telehealth will consist of assessment, advice on modifying activities, weight loss, or taking simple pain medications if needed, education to support self-management and a tailored home-exercise programme delivered via the PhysioTherapy Exercise App (freely available online exercise prescribing software created by some of the study authors: www.physiotherapyexercises.com). The number of appointments offered will be at the discretion of the treating physiotherapist.
High risk of persistent disabling pain (Keele STarT MSK tool score 9-12) or potential radiculopathy	Participants at high risk of persistent disabling pain and/or with potential radiculopathy will be offered a course of clinic-based physiotherapist-led consultations as is usually provided in Australian public hospitals. Participants will be offered clinic-based care but will not be told they are at high risk of poor outcomes (according to the Keele STarT MSK tool). Clinic-based physiotherapist-led consultations may include a combination of any advice and education to support self-management (e.g., advice to exercise, modify activities, lose weight or take simple pain medications if needed), exercise tailored to patients' activity goals and level of function, graded activity, graded exposure and manual therapy. The number of appointments offered will be at the discretion of the treating physiotherapist.
Key changes from the feasibility RCT	• Participants requiring postoperative rehabilitation will receive Telehealth (as per participants at medium risk of persistent disabling pain).

	- App-based exercises will be delivered via The PhysioTherapy Exercise App instead of PhysiTrack App. - Participants at high risk of persistent disabling pain and/or those with potential radiculopathy will be offered clinic-based care.

MSK, musculoskeletal. Potential radiculopathy was determined by patient reported pain that started from their back and went below their knee or pain that started from the neck and went below the shoulder.

Discussion

A three-staged process was used to develop, conduct early evaluation and refine a model of care that may reduce waiting times for adults with musculoskeletal pain referred to outpatient musculoskeletal clinics in Australian public hospitals. Our development process began with creating a preliminary model of care combining stratified care and telehealth from previous research and input by our multidisciplinary steering group. This model was then refined and evaluated in a feasibility RCT with nested qualitative interviews. The feasibility RCT found that over half of the feasibility targets were met indicating our model of care was largely feasible to deliver to patients with low back pain and feasible to evaluate in a larger multi-site RCT. It also showed promise for reducing waiting times and guided key changes to refine the model before proper evaluation.[30] Interviews with patients suffering from musculoskeletal conditions, health professionals who treat these conditions, and key stakeholders identified key modifications needed before our model of care was evaluated in an adequately-powered trial for people with various musculoskeletal conditions referred to outpatient musculoskeletal clinics in Australian public hospitals.

Refining the model of care:

Adapting models of care that have been successful in other healthcare settings can been challenging.[35] For example, the use of screening tools to stratify care for patients with low back pain (e.g., STarT Back tool) improved disability compared to non-stratified current best practice care in a UK trial.[36] However, using the STarT Back tool to match treatment for patients with low back pain in the United States (US) had no significant effect on patient outcomes or healthcare use.[37] Different studies aiming to answer the same question are typically not direct replicas and there is complexity to producing positive outcomes in new health care contexts.[38-40] The US study example[37] found a lack of feedback audits to check adherence to matching treatment to patient subgroups, high patient disability at baseline and complex treatment pathways not familiar to clinicians were barriers despite high levels of clinical engagement in the study. Our model will simplify treatment pathways, include audits of clinical notes to encourage health professionals to monitor the matching of patients to the appropriate treatment (implementation fidelity) and include sites that will allow recruitment of participants with various baseline disability levels based on our feasibility RCT findings.[30]

Evaluation challenges:

Communication via telehealth relies on suitable technological infrastructure and individual proficiency with equipment which can present potential challenges. Physiotherapists delivering PhysioDirect in the large UK RCT were senior staff who received training on enhanced communication.[8] Our interviews suggested that communication via telehealth can be equally effective as clinic-based care, and its effectiveness is not always determined by clinical experience. Health professionals we interviewed suggested that clinical experience was important to help with communication during telehealth appointments, but understanding the model of care by all staffing levels was suggested to better increase health professionals' confidence in delivering telehealth. Interviews with health professionals also suggested that following COVID-19 most staff were familiar with telehealth and on-going support of staff would further facilitate implementing the new model of care.

Qualitative interviews prompted us to consider who the model of care is suitable for and if we allow health professionals the flexibility to offer additional clinic-based appointments to patients. Health professionals had mixed views about patients' appropriateness for telehealth (e.g., due to issues related to access to equipment or the type of musculoskeletal condition). Evidence shows that telehealth can achieve similar health outcomes (e.g., function) compared to usual care for a variety of musculoskeletal conditions[26] and particularly for adults with low back pain,[41] osteoarthritis[26] and those needing rehabilitation following total knee and hip arthroscopy.[25] Given the available evidence and feedback we received, it was decided the type of musculoskeletal condition or pain region would not determine the mode of treatment, other than patients with potential radiculopathy who will receive clinic-based care. Our steering group also decided that having a more stringent stratification algorithm will allow us to better interpret results (i.e., rather than allowing too much flexibility for clinicians to manage patients as they wish).

Including patients from non-English speaking backgrounds and providing individualised care also required careful consideration. Health professionals and key stakeholders suggested that the use of translators during a telehealth appointment has become much easier with advances in software (e.g., My Virtual care) and online technology (e.g., Google translate and MediBabble).[42] However, we decided to not include non-English speaking participants in the

WAIT-less trial because of the cost and feasibility of using translation services at the point of referrals (i.e. before people are booked for an appointment). Additionally, our selected outcome measures had not been validated in the most common non-English languages spoken in participating hospitals. As such we decided excluding non-English speaking participants is the first necessary step to improving access for a more diverse range of patients in different health districts in Australia in the future.

Implementation challenges:

Adoption of telehealth was accelerated by the COVID-19 pandemic but there is still a lack of awareness of the benefits of telehealth and potential benefits it could have on health service delivery (e.g. reducing wait times). Changes in government regulations during COVID-19 were made due to necessity[43] but have not been sustained.[44] Highlighting the safety precautions and potential benefits of our model such as increased convenience, savings in time and costs, and advantages of teaching exercises at home may alter preferences of some health professionals and patients for only clinic-based care. Future collaboration with health professionals is vital to improving the uptake of our final model of care. Based on interview feedback we plan to use existing online links to support health professionals and patients with the use of telehealth[45-48] and develop resources to increase awareness of the trial among primary practitioners and the public. Multidisciplinary awareness of our model of care could further help overcome barriers and facilitate implementation aiming to improve efficiency of care pathways.

Strengths and limitations:

This study had several strengths. We used a three-stage mixed-methods design which involved developing, evaluating and refining the model of care with a multidisciplinary steering group, health professionals, patients and key stakeholders, a pilot and feasibility RCT method was used to evaluate the model, and one-on-one qualitative interviews provided in-depth feedback on our new model. Qualitative data was analysed by two researchers, with any disagreements resolved by a third researcher. The results were reported according to the COREQ checklist, and an Implementation Research Logic Model (IRLM) was used to identify factors which may impact implementation of the new model of care.

The development process was not without its limitations. The COVID-19 pandemic significantly impacted the number of staff able to work on our pilot and feasibility RCT trial and clinic opening hours which negatively impacted the recruitment rates. We interviewed participants and clinicians from the pilot and feasibility trial but did not interview patients external to the trial. However, participants interviewed were asked to provide feedback on the model of care based on their experiences within the trial and with previous musculoskeletal conditions they reported. We did not include participants from non-English speaking backgrounds in the pilot and feasibility RCT or in qualitative interviews as we did not have the resources to include these patients in the planned adequate-powered evaluation. However, qualitative interviews identified the need to plan how to best include people form non-English speaking backgrounds in future evaluations of the model of care to promote greater equality in patient access to care.

Conclusion

We used a three-stage process to develop a physiotherapist-led triage and treatment service that can identify patients with musculoskeletal conditions who could be effectively managed with less resources (e.g. brief telephone call, App-based exercises), thereby allowing patients with complex symptoms to be seen in-person sooner. This model of care is currently being investigated in a large multi-site clinic trial (WAIT-less) across several public hospital outpatient physiotherapy departments in Sydney, Australia. If successful, implementation of this model of care could help adults with musculoskeletal conditions receive care sooner and achieve better clinical outcomes.

Supplementary files:

Supplementary file 1: Semi-structured interview guides

Supplementary file 2: 32-item Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist

Supplementary file 3: Qualitative interview themes and subthemes, example quotes and key changes

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Declaration of Generative AI and AI-assisted technologies in the writing process:

During the preparation of this work the author(s) did not use generative AI or AI-assisted technologies in the writing process and take full responsibility for the content in the publication.

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CHAPTER SIX

The feasibility of delivering and evaluating stratified care integrated with telehealth (‘Rapid Stratified Telehealth’) for patients with low back pain: a feasibility and pilot randomised controlled trial

PREFACE

Chapter Six presents a single-blinded, single site, two arm parallel feasibility and pilot randomised controlled trial (RCT) with nested qualitative interviews which evaluated if an innovative new model of care is feasible to deliver and evaluate for adults with low back pain referred to an outpatient back pain clinic in Australia. Chapter Five identified the need to evaluate an innovative new model of care to reduce waiting times for people with musculoskeletal conditions referred to public hospital outpatient musculoskeletal clinics. The preliminary model of care was designed for adults with a range of musculoskeletal pain presentations. However, rheumatologists and physiotherapists working at a small back pain clinic at Royal Prince Alfred (RPA) Hospital in Sydney, Australia were interested in ways to reduce their clinic's waiting time. This collaboration presented an excellent opportunity to evaluate the feasibility of our new model of care in a pilot RCT for people with a common musculoskeletal condition.

Citation

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The feasibility of delivering and evaluating stratified care integrated with telehealth ('Rapid Stratified Telehealth') for patients with low back pain: a feasibility and pilot randomised controlled trial

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ABSTRACT

Objectives: Establish the feasibility of delivering and evaluating stratified care integrated with telehealth (‘Rapid Stratified Telehealth’) to reduce waiting times for people with low back pain seeking care in the Australian public hospital system.

Methods: We conducted a single-blinded, single site, 2:1 ratio, two-arm parallel feasibility and pilot randomised controlled trial (RCT) with nested qualitative interviews. Usual clinic-based care was compared to Rapid Stratified Telehealth which matched the mode and type of care to participant’s risk of persistent disabling pain based on the Keele STarT MSK Tool or potential radiculopathy. Key process outcomes include acceptability of the model, intervention fidelity and adherence, appointment details, response, recruitment and consent rates, and missing data. Additional outcomes included waiting time to access care, clinical outcomes, healthcare utilisation and adverse events. Quantitative outcomes were summarised descriptively. Qualitative data were analysed using thematic analysis.

Results: Of 133 people screened, 101 were eligible (76%), and 40 (30%) were randomised (26 in intervention, 14 in control). Feasibility targets were met for acceptability, fidelity (80%), adherence (88-100%) and missing data (5%). Intervention participants waited a median of 13 days less for their first appointment compared the usual care participants (16 days vs. 29 days) but additional outcomes should be interpreted with caution. Feasibility targets were not met for recruitment and consent rates, largely owing to clinic disruptions due to COVID-19.

Conclusion: This study provides important information to guide modifications to our Rapid Stratified Telehealth model of care and planning of a large multi-site RCT across hospital outpatient clinics.

Key words: low back pain; stratified care; telehealth; randomised controlled trial; pilot; feasibility.

Ethics and trial registration: This study was approved by the Ethics Review Committee (RPAH Zone: X21-0221). ANZCTR Trial Registration: ACTRN12621001104842.

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1. Introduction

Long waiting times in many Australian public hospitals prevent timely access to care for people with low back pain (LBP) – the leading cause of disability in Australia and globally[1] –and other musculoskeletal conditions. Over half of Australians (55%) do not have private health insurance which can increase reliance on public care.[2] Delayed access to care for people with LBP can contribute to symptoms becoming more disabling, complex and costly to manage.[3-5] A potential solution to reduce waiting times for people with LBP is a model of care that identifies LBP cases that can be managed with less resources (e.g., brief telephone appointments, self-management advice, App-based home exercise programmes), thereby freeing up clinic-based resources for more complex LBP cases.

'PhysioDirect' is a UK model of care that supported physiotherapists to triage patients with musculoskeletal conditions into needing simple telephone advice, education and exercises instructions or clinic-based physiotherapist-led care.[6] PhysioDirect was compared to usual care where patients joined the usual waiting list for the next clinic-based appointment in a non-inferiority RCT across four physiotherapy services in England (n=2249).[6] PhysioDirect reduced waiting times (median of 7 days vs 34 days in usual care) and the need for clinic-based appointments (40% relative reduction) compared to usual care, without compromising physical health outcomes. Qualitative interviews also found that PhysioDirect was acceptable to patients and physiotherapists in the trial.[7] This innovative overseas model of care inspired us to develop a similar one for the Australian context that could reduce long waiting times for musculoskeletal care.

In Australia, many public health outpatient clinics caring for patients with musculoskeletal conditions prioritise referrals based on the acuity of their presentation. For example, patients referred to outpatient physiotherapy clinics in New South Wales (NSW) are seen much sooner if they have acute musculoskeletal conditions (defined as symptoms less than 4 weeks) or require rehabilitation after surgery. Those with chronic musculoskeletal pain (defined as symptoms longer than 12 weeks) are usually not prioritised and often wait a long time to be seen in clinic. Unfortunately, acuity alone is not a good indicator of prognosis for many patients with musculoskeletal conditions (e.g. LBP)[8] and a shift to using validated prognostic tools could improve the way treatment is matched to patients.[9]

As such, we proposed a new model of care for people with LBP. Our model integrates stratified care with telehealth (‘Rapid Stratified Telehealth’) and involves matching the mode and type of care patients are offered to their risk of persistent disabling LBP (based on the Keele STarT MSK Tool; low-, medium- or high risk)[10] and presence of potential radiculopathy. The development of the model of care is detailed elsewhere.[11] In brief, we designed a preliminary model of care with a multidisciplinary steering group guided by research evidence.[6,7] We then wanted to test the feasibility of the model of care with patients with LBP before considering broadening to other musculoskeletal conditions.

Key process aims of this feasibility and pilot RCT were to determine the: (1) feasibility of delivering stratified care integrated with telehealth (‘Rapid Stratified Telehealth’) for patients with LBP referred to a public hospital outpatient clinic and (2) feasibility of a future multicentre RCT to compare the clinical and cost-effectiveness of this new model to usual care for patients with various musculoskeletal conditions. Additional aims were to explore differences in waiting times, number of appointments, clinical outcomes (pain, function, quality of life, satisfaction), healthcare use and adverse events between those who were managed with our 'Rapid Stratified Telehealth' model of care compared with usual care.

2. Methods:

2.1 Study design

We conducted a single-blinded, single site, two-arm parallel feasibility and pilot RCT with nested qualitative interviews. The trial is reported in accordance with the CONSORT extension for randomised pilot and feasibility trials[12] (Supplementary file 1). The nested qualitative interviews of clinician and patient acceptability of Rapid Stratified Telehealth are reported below according to the COREQ (Consolidated Criteria for Reporting Qualitative Research)[13] (Supplementary file 2).

2.2 Participants and recruitment

The full methods are detailed in the feasibility and pilot RCT protocol.[14] In brief, participants were recruited from referrals to a multidisciplinary outpatient 'Back Clinic' at Royal Prince Alfred Hospital in Sydney, Australia, where rheumatologists assess patients and refer them to an outpatient physiotherapist if needed. The Back Clinic was open for two and a half days per week with four medical staff (one rheumatologist, one physiotherapist and to registrars). For our trial, the head rheumatologist working at the Back Clinic screened new LBP referrals from primary care (e.g. general practitioners) according to our inclusion criteria (Box 1). Potentially eligible patients were then contacted by a physiotherapist researcher and informed they were on the waiting list for an appointment as per usual care. At the end of the routine call, the physiotherapist researcher mentioned the trial, screened the patient for eligibility, and if they agreed to participate, they were sent further information with the baseline questionnaires via email or post to provide consent (Supplementary file 3 and 4). All participants were informed that participation was voluntary, and non-consent to participate or withdraw from the trial would not affect their care.

Box 1: Inclusion and Exclusion criteria

Inclusion criteria:

- ► 18 years or older
- ► LBP (acute and chronic non-specific LBP or radicular LBP/sciatica of any duration)
- ► New referral to the Back Clinic from primary care (i.e. have not been on the waiting list prior to enrolment)
- ► Willing to participate for up to 6 months and provide follow-up data at 6 weeks, 3 months and 6 months

Exclusion criteria:

- ► Suspected serious underlying pathology (e.g., cancer, fracture, infection, inflammatory arthritis, cauda equina syndrome)
- ► Referral strongly suggestive of concerning neurological features (e.g., progressive radiculopathy)
- ► Pregnant

LBP, low back pain.

2.3 Data collection

Baseline questionnaires collected data on demographic and clinical information prior to randomisation (Table 1). Participants completed baseline questionnaires via return paid envelopes or electronically in Research Electronic Data Capture (REDCap) via email, SMS or telephone. Data entered into REDCap from hard copy questionnaires were double checked for accuracy. The Keele STarT MSK tool[10] was completed by all participants as part of the baseline questionnaire to identify the risk subgroup of each participant (low-, medium- or high-risk of persistent disabling pain). We used the Keele STarT MSK tool instead of the Keele STarT Back tool[15] because we planned to include people with LBP and other musculoskeletal conditions in our future trial[16]. Due to clinician feedback, the protocol was modified before recruitment so participants who reported pain that started from their back and went below their knee in the baseline questionnaire were classified as having 'potential radiculopathy' and offered clinic-based appointments. A single item question at baseline was used to identify participants with potential radiculopathy instead of a clinician developed screening tool (as per our published protocol) as it enabled a more conservative approach aligning with clinician input on the model of care.

2.4 Interventions and procedures

2.41 Randomisation procedure

Consenting participants were randomised (2:1 ratio) to either the Rapid Stratified Telehealth model of care (intervention) or usual care. The random allocation sequence was independently generated in Stata statistical software and uploaded to REDCap. Allocation was concealed and the physiotherapy researcher did not know the participant's allocation until their baseline data were entered into REDCap. The allocation sequence was also concealed from participants and all staff associated with the trial. A secure computer-generated blocked random allocation sequence was generated using block sizes of 3, 6 or 9. Risk subgroup, as assessed by the Keele STarT MSK tool (low, medium, high risk), and the presence of potential radiculopathy (single item question in the baseline questionnaire) were used as stratification variables.

2.42 Rapid Stratified Telehealth and usual care

Rapid Stratified Telehealth (intervention) - subgroup allocation:

Participants in the intervention group had their mode and type of care matched to their risk of persistent disabling pain; categorised as low, medium or high (based on their baseline Keele STarT MSK score) or having potential radiculopathy (based on having pain that started from their back and went below their knee).[14] The Keele STarT MSK tool was chosen due to its validity to identify patients with musculoskeletal conditions at low, medium or high risk of persistent disabling pain which was demonstrated in a previous feasibility and pilot trial conducted in the UK (n=524).[10,17]

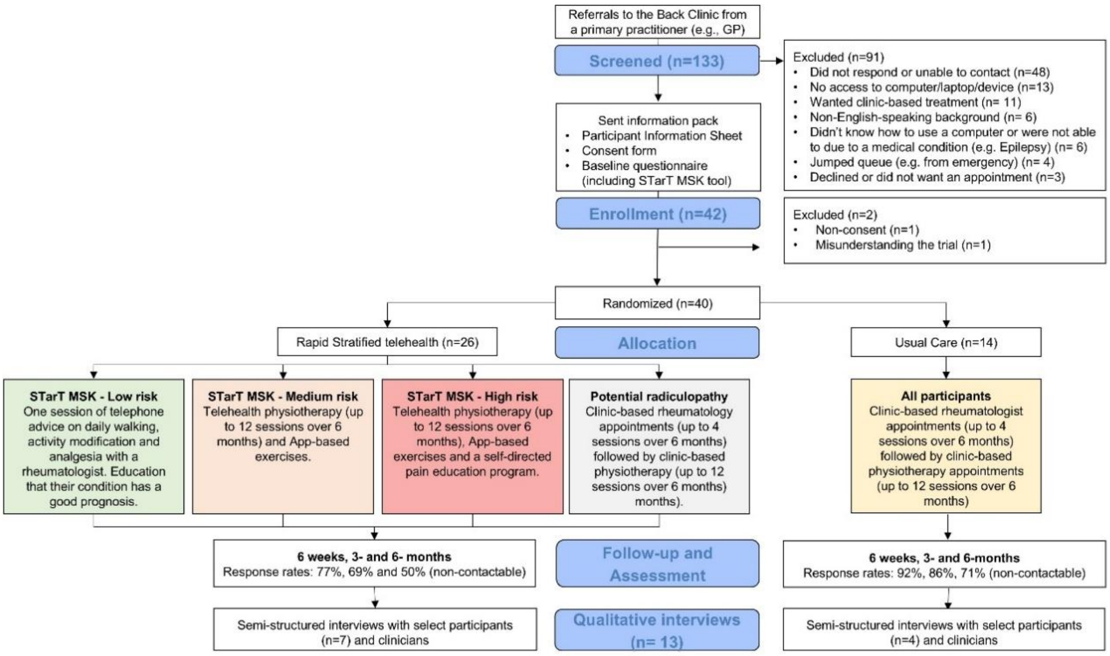
Rapid Stratified Telehealth (intervention) - matched treatment:

All participants without potential radiculopathy in the intervention group received an initial call with the rheumatologist. Participants at low risk of persistent disabling pain were told they did not need further treatment as they were very likely to have a good prognosis and were given advice to gradually increase their daily walking (or other activities) as pain permitted, temporarily modify painful activities, and take a regular dose of paracetamol if required. They were also given written education material produced by the Agency for Clinical Innovation on managing low back pain (https://bit.ly/3iGfGrX). These participants were told to call back if their condition did not improve over the next 6 weeks. Participants at medium- or high-risk of persistent disabling pain were referred by the rheumatologist to physiotherapist-led telehealth (videoconference). The number of sessions was determined by the treating physiotherapist (maximum of 12 sessions over 6 months; reflecting usual care in public hospitals). Physiotherapist-led telehealth included advice to support self-management, and an exercise program prescribed using the app-based program PhysiTrack. Those in the high-risk group were additionally directed to complete an online self-directed pain education program developed by the Agency for Clinical Innovation (https://www.aci.health.nsw.gov.au/chronic-pain/for-everyone). Participants with potential radiculopathy had clinic-based sessions with a rheumatologist who took further medical history, conducted a physical and neurological examination, reviewed any previous investigations (e.g., imaging, pathology tests), formulated a management plan, monitored progress. The rheumatologist determined the number of appointments they needed with a rheumatologist (maximum of 4 over 6 months; reflecting usual care). Participants with potential radiculopathy were also referred by the rheumatologist to clinic-based physiotherapist-led care (if needed) which included advice and education to support self-management, exercise therapy, graded activity, graded exposure and/or spinal manipulative therapy. Treating physiotherapists ensured that participants with potential radiculopathy who were also at high risk of persistent disabling pain were offered interventions to address psychological barriers to recovery (e.g. psychologically informed physiotherapy)[18] and were referred to see a psychologist if necessary. The number of clinic-based physiotherapy appointments was determined by the treating physiotherapist (maximum of 12 over 6 months; reflecting usual care). Treatment recording forms and clinician notes were used to record the treatment provided.

Usual care:

Participants in the usual care group were offered a clinic-based appointment with a rheumatologist. The rheumatologist took participants' medical history, conducted a physical and neurological examination, reviewed any previously undertaken investigations (e.g., imaging, pathology tests), formulated a management plan, and monitored progress. The rheumatologist determined the number of appointments they needed (maximum of 4 over 6 months; reflecting usual care). If required, the rheumatologist referred participants to a physiotherapist, specialised pain clinic or psychologist, consisted with usual care in the Back Clinic. If referred to a physiotherapist, management was determined by the treating physiotherapist and may have consisted of further advice and education to support self-management, exercise therapy, graded activity, graded exposure and/or spinal manipulative therapy. The number of clinic-based appointments was determined by the treating physiotherapist (maximum of 12 over 6 months; reflecting usual care). Treatment recording forms and clinician notes were used to record the treatment provided.

Figure 1: Consort flow diagram



GP, General Practitioner; N, number of potential participants and participants; MSK, musculoskeletal.

2.5 Outcomes

Feasibility measures (key process outcomes), feasibility targets, and additional outcomes are described in Box 2.

Box 2. Feasibility measures (primary outcomes), feasibility targets, and secondary outcomes

Outcome measures	A priori feasibility targets
Key process outcomes: 1. Feasibility outcomes for ‘delivering’ Rapid Stratified Telehealth:	
Clinician and patient acceptability of the intervention, determined using semi-structured interviews (see section 3.3)	Acceptable to clinicians and patients
Percentage of participants who are provided care that matches the protocol for their subgroup (‘intervention fidelity’), assessed via treatment recording forms	>75%
Patient adherence to App based exercises (PhysiTrack) in the medium- and high-risk subgroups and accessing the online pain education in the high-risk subgroup, assessed via treatment recording forms	>75%
Number of appointments, median appointment times and attendance	No target
2. Feasibility outcomes for ‘evaluating’ Rapid Stratified Telehealth in a future multi-centred randomised controlled trial:	
Number of participants recruited per week over 6 months (recruitment rate)	≥ 3 participants per week
Number of eligible participants per week	No target
Percentage of participants who consent to be part of the study from those who were eligible (consent rate), similar to the PhysioDirect trial.[6]	50% or more over 6 months
Response rate at 6 weeks, 3- and 6-months	≥ 75%
Percentage of missing data for key outcome measures	<15%

Additional outcomes:
Treatment waiting time (i.e., time in days from the Back Clinic receiving a referral to first clinic-based or telehealth appointment)
Clinical outcomes at 6 weeks, 3- and 6-months including: Quality of life (PROMIS-29 Profile V.2.0 questionnaire), pain (0-10 Numeric Rating Scale; 0 being no pain, 10 being the worst pain imaginable), RMDQ; (0-24 scale; higher scores indicate greater disability), and patient satisfaction (0-10 Numeric Rating Scale; 0 being the worst possible care, 10 the best care possible)
Healthcare service and medication use at 6 weeks, 3- and 6-months.
Adverse events (AEs) at 6 weeks, 3- and 6-months
Intervention and health care costs at 6 weeks, 3- and 6-months*

No., number, PROMIS: Patient-Reported Outcomes Measurement Information System, RMDQ; Roland and Morris Disability Questionnaire. *Intervention and health care cost outcomes will be reported in a separate paper.

2.6 Statistical analysis

The main analysis focused on the feasibility (process) of delivering Rapid Stratified Telehealth (acceptability, fidelity, adherence and appointment details) and evaluating the model of care in a future multi-centre RCT (recruitment rates, consent rates, response rate and percentage missing data). Quantitative feasibility data were summarised using descriptive statistics (means and SD, median and IQR and counts and percentages, as appropriate). Qualitative feasibility data (acceptability) was analysed using Microsoft Excel (see section 2.7).

The additional outcomes (see Box 2) were explored, comparing the Rapid Stratified Telehealth and usual care arms of the trial using descriptive statistics (median, IQRs and counts and percentages, as appropriate). All quantitative analyses were conducted in STATA V.16.0. No statistical inference testing was performed as this was a feasibility and pilot RCT.[19]

2.7 Qualitative interviews

2.71 Participants and recruitment

Semi-structured interviews were conducted to investigate the acceptability of Rapid Stratified Telehealth. Interview participants were recruited via telephone or email using purposive sampling of patients and clinicians involved in the trial. Participants provided consent electronically in REDCap using a separate Participant Information Statement (Supplementary file 5) and Participant Consent Form (Supplementary file 6).

2.72 Data collection and analysis

One-on-one interviews were conducted via telephone or videoconference (e.g., Zoom) by one male physiotherapist researcher experienced in conducting semi-structured interviews and in qualitative research methods (AG). Additional verbal consent was gained from all participants before interviews were audio- or video-recorded. Semi-structured interview guides (Supplementary file 7) informed questioning on the pros and cons of stratification, telehealth, and barriers and facilitators to adapting our model of care for treating various musculoskeletal conditions in a larger multi-site trial. Notes were taken during the interviews to highlight key themes that emerged and direct further questioning. Each interview was transcribed verbatim. Participants had the opportunity to review transcripts prior to data analysis.

All interview data were analysed using inductive thematic analysis, a method for identifying, analysing and reporting patterns within data.[20] Two male researchers (AG and CH) independently familiarised themselves with interviews (via audio-recordings and transcripts), recorded initial observations, and identified concepts relevant to the questions asked. The two researchers (AG and CH) developed a framework to organise concepts into broader themes and sub-themes in Microsoft Excel. Any disagreements in categorising concepts into themes and sub-themes was discussed and resolved with a third researcher (JZ). The mapping of themes and subthemes was an iterative process as the new data emerged, and interviews were stopped once no new themes were being identified in three consecutive interviews (data saturation).

3. Results:

3.1 Participant flow and recruitment

Of the 133 screened, 101 patients eligible to participate, 40 consented and were randomised (30% consent rate; Figure 1, Table 2), between July 2021 and March 2024. The overall recruitment rate was 0.4 participants per week (recruited over 95 weeks) and, if converted to reflect a clinic that was open 5 days a week from 9-5pm, the recruitment rate was 4 participants per week (Table 2). All participants were referred to the hospital clinic by their general practitioner.

3.2 Characteristics of trial participants

Participants median age (Interquartile Range, IQR) was 51 (39 to 66) years and 56% were female. Participants in the Rapid Stratified Telehealth group were slightly older (median age 55 vs 51 years old), more frequently reported speaking a language other than English at home (20% vs. 5%), and were almost twice as likely to have taken sick leave due to their LBP (64% vs. 36%). All participants had symptoms for 12 weeks or longer.

Table 1: Characteristics of participants

Demographics	**Total sample (n=40)**	**Intervention (n=26)**	**Usual care (n=14)**
Age, median (IQR)[a^]	51 (39 to 66) [a]	55 (42 to 67) [c]	51 (29 to 59) [b]
Female, n (%)*	22 (56)	13 (52)	9 (64)
Language other than English spoken at home, n (%)*	6 (15)	5 (20)	1 (7)
Employment, n (%)*			
Currently employed	17 (44)	12 (48)	5 (36)
Not currently employed	17 (44)	11 (44)	6 (43)
Student	4 (10)	1 (4)	3 (21)
Unpaid carer	1 (3)	1 (4)	0 (0)
Education, n (%)*			
High school (not completed)	4 (10)	4 (16)	0 (0)
High school (completed)	6 (15)	4 (16)	2 (14)
TAFE/Trade	12 (31)	5 (20)	7 (50)
University – undergraduate degree	8 (21)	5 (20)	3 (21)

University – postgraduate degree	7 (18)	6 (24)	1 (7)
Other	2 (5)	1 (4)	1 (7)
Symptom duration of 12 weeks or longer, n (%)*	39 (100)	25 (100)	14 (100)
Taken sick leave due to LBP, n (%)*	21 (54)	16 (64)	5 (36)
Keele STarT MSK Tool risk subgroup, n (%)			
Low risk	1 (3)	0 (0)	1 (7)
Medium risk	8 (20)	5 (19)	3 (21)
High risk	7 (18)	5 (19)	2 (14)
Keele STarT MSK Tool score (0-12), median (IQR)	9 (7 to 10)	9 (8 to 10)	9 (7 to 11)
Potential radiculopathy**	24 (60)	16 (62)	8 (57)

N= number of participants who were randomised, IQR = Interquartile range, TAFE, Technical and Further Education, MSK, Musculoskeletal.

[a] n=37, [b] n=13, [c] n=24, ^Data on age were missing for two participants, *Data on gender, employment, education and symptom duration and sick leave were missing for one participant from the intervention group. **Pain that started from their back and went below their knee.

3.21 Primary outcomes and feasibility targets

Four out of seven pre-defined feasibility targets were met (Table 2).

Table 2: Key feasibility outcomes

Outcome measures	Feasibility target met: Yes/No
1. Feasibility outcomes for ‘delivering’ Rapid Stratified Telehealth (intervention):	
Qualitative interviews: Patients and clinicians suggested the model of care and trial were acceptable (see section 3.3).	Yes
Intervention fidelity: *Percentage who received matched physiotherapist-led care in the intervention group:* • Overall; 10 (80%) • Medium-risk; 2 (50%) • High-risk; 1 (100%) • Potential radiculopathy; 7 (86%)	Yes
Adherence: *Median percentage of those who adhered to aspects of the model of care (as a percentage of those reporting data):* • App based exercises; 1 88% • Online pain education program; 1 (100%)	Yes
Number of appointments:	-

Median (IQR) number of rheumatology appointments: • Intervention 1 (1 to 2) vs. usual care 1 (1 to 2) *Total number of rheumatology appointments:* • Intervention 21 vs. usual care 16 *Median (IQR) number of physiotherapy appointments:* • Intervention 3 (1 to 8) vs. usual care 7 (5 to 8) *Total number of physiotherapy appointments:* • Intervention 44 vs. usual care 45 **Appointment times for all participants:** *Median (IQR) appointment times*: • Rheumatology appointments 60 minutes (60 vs 60) • Physiotherapy appointments 60 minutes (60 vs 60) **Attendance:** *Number of participants referred for physiotherapy*: • Overall, 26; 17 of these participants attended at least one appointment (65%) • Intervention 10 (63%) vs. usual care 7 (70%).	
2. Feasibility outcomes for ‘evaluating’ Rapid Stratified Telehealth (intervention) in a future multi-centred RCT:	
Recruitment rate: *Participants per week:* • 0.4 recruited over 95 weeks *The criterion was met if the recruitment rate was converted to reflect a clinic that was open 5 days a week from 9-5pm (4 participants per week).	No*

Consent rate: *Percentage:* • 39% (40 participants from 103 eligible)	No
Response rate: *Percentage:* • 82% at 6 weeks, 75% at 3- and 57% at 6-months	No
Missing data: *Percentage at baseline:* • 2 participants for age (5%), 1 participant for gender, employment, education, symptom duration and sick leave (3%).	Yes

3.22 Additional outcomes

Treatment waiting time

Median (IQR) waiting time from randomisation to first appointment with a rheumatologist was 16 days (7 to 30) in the intervention group and 29 days in the usual care group (7 to 89; Table 3).

Health service and medication use

Health service use outside the trial was similar between the intervention and usual care groups at 6 weeks, and 3 months, and higher in the intervention group at 6 months. Over half of the trial participants reported seeking health care that was ongoing. The number of participants using medications for their LBP was similar between the intervention and usual care groups at 6 weeks, lower in the intervention group at 3 months and similar at 6 months. (Table 3)

Clinical outcomes, patient satisfaction and adverse events

Median pain intensity and satisfaction ratings were similar between participants in the intervention and usual care groups at 6 weeks, 3 months, and 6 months. Median physical function (PROMIS-29) was lower in the intervention group compared to the usual care group at 6 weeks and 3 months, and similar between groups at 6 months. Median disability (RMDQ) was higher in the intervention compared to usual care groups at 6 weeks, similar at 3 months and higher in the intervention group at 6 months. Adverse event rates were similar between the intervention and usual care groups at 6 weeks, higher in the intervention group at 3 months and similar at 6 months. No serious adverse events occurred during the study. (Table 3)

Table 3: Additional feasibility RCT outcomes

Outcome	Total		Intervention		Usual care	
	Median (IQR)	No. of participants	Median (IQR)	No. of participants	Median (IQR)	No. of participants
PROMIS-29						
Physical function (0-20)						
Baseline	13 (11 to 17)	40	12 (8 to 15)	26	13 (11 to 17)	14
6 weeks	14 (10-16)	33	12 (10 to 16)	20	15 (11 to 18)	13
3 months	13(10 to 16)	30	12 (10 to 15)	18	16 (12 to 18)	12
6 months	13 (11 to 16)	23	13 (9 to 14)	13	15 (11 to 17)	10
Anxiety (0-20)						
Baseline	12 (7 to 14)	40	11 (7 to 13)	26	11 (4 to 15)	14
6 weeks	11 (6 to 12)	33	11 (8 to 13)	20	11 (5 to 12)	13
3 months	10 (5 to 12)	30	11 (5 to 14)	18	10 (5 to 11)	12
6 months	9 (5 to 12)	23	9 (4 to 12)	13	9 (6 to 12)	10

Depression (0-20)						
Baseline	10 (5 to 13)	40	9 (5 to 13)	26	11 (5 to 13)	14
6 weeks	10 (6 to 12)	33	10 (6 to 12)	20	11 (6 to 12)	13
3 months	10 (4 to 12)	30	10 (4 to 12)	18	10 (5 to 12)	12
6 months	8 (4 to 12)	23	8 (4 to 12)	13	7 (4 to 11)	10
Fatigue (0-20)						
Baseline	12 (10 to 17)	40	13 (10 to 17)	26	11 (9 to 17)	14
6 weeks	12 (9 to 16)	33	12 (9 to 17)	20	11 (8 to 16)	13
3 months	13 (9 to 16)	30	13 (12 to 17)	18	10 (9 to 12)	12
6 months	11 (7 to 15)	23	14 (9 to 16)	13	9 (7 to 11)	10
Sleep disturbance (0-20)						
Baseline	13 (10 to 16)	40	13 (10 to 16)	26	12 (10 to 15)	14
6 weeks	11 (9 to 16)	33	12 (10 to 16)	20	11 (9 to 16)	13
3 months	12 (9 to 16)	30	12 (10 to 16)	18	13 (9 to 16)	12
6 months	11 (8 to 14)	23	11 (9 to 14)	13	11 (7 to 14)	10

Social participation (0-20)						
Baseline	9 (3 to 12)	40	7 (3 to 13)	26	10 (3 to 12)	14
6 weeks	9 (4 to 14)	33	9 (1 to 15)	20	12 (4 to 13)	13
3 months	12 (3 to 15)	30	11 (3 to 14)	18	12 (5 to 16)	12
6 months	12 (3 to 15)	23	10 (3 to 12)	13	13 (7 to 15)	10
Pain interference (0-20)						
Baseline	14 (12 to 16)	40	14 (12 to 16)	26	13 (12 to 16)	14
6 weeks	14 (9 to 16)	33	16 (9 to 16)	20	9 (8 to 16)	13
3 months	13 (8 to 15)	30	14 (8 to 15)	18	11 (7 to 14)	12
6 months	14 (8 to 15)	23	15 (12 to 15)	13	10 (8 to 14)	10
RMDQ total (0-24)						
Baseline	12 (7 to 14)	40	12 (9 to 14)	26	12 (4 to 14)	14
6 weeks	10 (5 to 14)	33	12 (5 to 15)	20	8 (5 to 14)	13
3 months	9 (6 to 13)	29	10 (6 to 11)	17	9 (6 to 16)	12
6 months	12 (3 to 16)	23	12 (8 to 14)	13	9 (3 to 16)	10

Pain in the past 7 days (0-10)						
Baseline	6 (5 to 7)	40	6 (5 to 7)	26	6 (4 to 6)	14
6 weeks	5 (4 to 6)	33	6 (5 to 6)	20	5 (3 to 6)	13
3 months	5 (4 to 6)	29	5 (4 to 6)	17	5 (3 to 5)	12
6 months	6 (5 to 7)	22	6 (6 to 7)	12	6 (4 to 7)	10
Satisfaction with care (0-10)						
Baseline	Not assessed	Not assessed	Not assessed	Not assessed	Not assessed	Not assessed
6 weeks	5 (2 to 7)	33	5 (2 to 8)	20	5 (1 to 7)	13
3 months	5 (2 to 8)	29	5 (1 to 6)	17	6 (4 to 9)	12
6 months	6 (3 to 8)	22	5 (0 to 6)	12	8 (6 to 8)	10
	Yes (%)	No. of participants	Yes (%)	No. of participants	Yes (%)	No. of participants
Health service use						
Baseline	36 (90)	40	23 (89)	26	13 (93)	14

6 weeks	27 (82)	33	16 (80)	20	11 (85)	13
3 months	24 (83)	29	14 (82)	17	10 (83)	12
6 months	19 (86)	22	11 (92)	12	8 (80)	10
Ongoing health service use						
Baseline	19 (48)	40	15 (58)	26	4 (29)	14
6 weeks	19 (58)	33	13 (65)	20	6 (46)	13
3 months	18 (62)	29	10 (59)	17	8 (67)	12
6 months	16 (73)	22	8 (67)	12	8 (80)	10
Medication use	Yes (%)		Yes (%)		Yes (%)	
Baseline	31 (78)	40	21 (81)	26	10 (71)	14
6 weeks	23 (70)	33	15 (75)	20	8 (62)	13
3 months	19 (66)	29	12 (71)	17	7 (58)	12
6 months	17 (77)	22	9 (75)	12	8 (80)	10
Adverse events*						
Baseline	Not assessed	Not assessed	Not assessed	Not assessed	Not assessed	Not assessed

6 weeks	8 (24)	33	5 (25)	20	3 (23)	13
3 months	6 (21)	29	5 (29)	17	1 (8)	12
6 months	12 (55)	22	6 (50)	12	6 (60)	10

IQR, Interquartile range; No., Number; Quality of life (PROMIS-29 Profile V.2.0 questionnaire; Patient-Reported Outcomes Measurement Information System: 0-10 pain score and a 5-point Likert Scale for seven other health domains), pain (measured using a 0-10 Numeric Rating Scale; 0 being no pain to 10 being the worst pain imaginable), RMDQ; Roland and Morris Disability Questionnaire (scale 0-24; high scores indicate severe disability), and patient satisfaction (11-point numerical scale; 0 being the worst possible care and 10 the best care possible).

*Adverse events included musculoskeletal pain (e.g., knee or Achilles injury), hernia, fractures (e.g., ankle), worsened pain intensity, location or frequency of pain (e.g., shoulder, upper back or radiating pain), nausea, dizziness, COVID-19, infection, vascular problems in the lower limb or planned surgery.

3.3 Qualitative interview outcomes:

We conducted 13 interviews with 11 patients (n=7 in the intervention group, n=4 usual care) and 2 clinicians involved in the trial (n=1 Rheumatologist, n=1 Physiotherapist), lasting between 30-50 minutes. Characteristics of interviewed participants are outlined in Supplementary file 8. Qualitative interviews were summarised in seven key themes and described in more detail in another paper.[11]

3.31 Feasibility of delivering the Rapid Stratified Telehealth model

Management of patients using the new model of care was seen as a safe solution to reducing waiting times in a currently overloaded system by clinicians. Clinicians suggested that all patients would benefit from an initial telephone assessment to build relationships between the clinician and patient and empower self-management aligned with evidence-based care. Clinicians suggested it can be time consuming to review a referral, call and assess a patient, and make a booking but if there are sufficient staff and support there is potential to see patients sooner and provide clinic-based care to those who need it most. Some patients were apprehensive about not having physical touch via telehealth or trusting the accuracy of a remote assessment compared to clinic-based appointments, but all participants acknowledged the convenience of the intervention. Those who were managed via telehealth suggested their overall experience was acceptable and using the App-based exercise program PhysiTrack improved their ability to learn exercises and track progress. The ease of access and knowledge to use necessary equipment and technology was suggested to influence acceptability of the new model of care.

"They appreciated being contacted as they can often wait for a year and so they felt like they hadn't been forgotten" (Clinician, M, 60-70 years old).

"It was quite strange initially, but then I got used to it and looked forward to it"

(Patient, F, unknown years old).

"The convenience outweighs the need for personal touch" (Patient, M, 50-60 years old)

"Sometimes the technological issues could be one of the barriers"

(Clinician, F, 20-30 years old).

3.32 Potential to adapt the Rapid Stratified Telehealth for other musculoskeletal conditions.

The intervention was frequently suggested to be acceptable by patients and clinicians involved in the trial to manage other musculoskeletal conditions. Beliefs about anatomical complexity, pain characteristics and the ability to adapt specific exercises for various conditions influenced perceived adaptability. All participants agreed patients whose mobility was impacted would be appropriate for remote care irrespective of their diagnosis. Clinicians suggested that patients with any musculoskeletal conditions managed with evidence-based advice and exercise would be suited to remote care.

"If I was at home and house bound, I definitely think I would benefit from that opportunity" (Patient, M, 50-60 years old)

" There is potential for osteoarthritis to be managed using virtual care."

(Clinician, M, 60-70 years old).

"The ankle seems more complex and could be difficult to assess online"

(Patient, F, unknown years old).

4. Discussion

4.1 Summary of findings

Over half of the feasibility targets we set a priori were met and there was evidence from the qualitative interviews suggesting the model was acceptable and offered convenience to access advice and treatment sooner. The a priori targets not met included recruitment and consent rates, and response rates, which should be interpreted with caution due to reduction in staff and operating days of the Back Clinic following the COVID-19 pandemic. Participants in the intervention group waited 13 days less for their first appointment with the rheumatologist compared to the usual care group although no participant in the intervention group received the low-risk treatment pathway (i.e. a single telephone appointment). Participants in both groups had poor attendance to allocated physiotherapy appointments and largely similar clinical outcomes (i.e., pain, satisfaction). Participants in the intervention had less appointments compared to the usual care group but showed higher disability ratings.

4.2 Comparison to existing research

Our findings align with previous qualitative studies indicating the acceptability of remote care[21,22] and high-quality RCTs in Australia showing that delivering physiotherapist-led telehealth is as effective as usual clinic-based care for people with a variety of musculoskeletal conditions[23] including osteoarthritis.[24] Participants we interviewed provided positive feedback about the convenience of telehealth and using App-based exercises within our model. Clinicians suggested a telephone call or telehealth appointment was acceptable to provide advice and support for self-management and could be used for patients with a variety of musculoskeletal conditions. A recent systematic review of patients with various musculoskeletal conditions (n=845) also strengthens the argument that mobile Apps can improve clinical outcomes.[25]

4.3 Implications for future evaluation

Our findings suggest that modifications to the model of care and analysis of the single site processes could enhance future evaluation. A multidisciplinary Back Clinic was selected as the single site for this trial due to the limited capacity for new appointments, long waiting times for referred patients, and enthusiasm from the rheumatologist and physiotherapist at this site to test a model of care that addressed these issues. We found waiting times until first appointment with a rheumatologist were reduced for participants in the Rapid Stratified group compared to usual care. Our model was designed to use a single telephone call for patients at low risk of persistent disabling pain to provide reassurance and support for self-management, without further treatment. Discharging low risk patients remotely after one session would allow the next patient on the waiting list to be contacted sooner. No participant in the intervention group was classified as at low risk of persistent disabling pain, meaning we were unable to realise the benefit of a single telephone call to provide advice and support for self-management to these participants. Including participants at low risk of developing persistent disabling symptoms in future evaluation may better determine between-group differences in waiting and clinical outcomes. Nevertheless, we suspect the reduction in waiting time we found was due to medium- and high-risk participants who were encouraged to self-manage via an exercise App and use less staffing resources.

Our future adequately-powered trial evaluating this model of care will be conducted at multiple sites with more health professionals, longer operating hours and we have funding to follow up patients in the trial who will also be offered gift vouchers for completion of questionnaires. Consideration of sites that are likely to include participants who would be stratified into all risk subgroups may reduce the number of participants classified as having potential radiculopathy and lead to a larger reduction in waiting times by utilising the low-risk management pathway. Future evaluation should also consider including sites which include participants who have had symptoms for various durations and using duration of symptoms as a stratification variable. Another approach could be investigating how the STarT MSK tool can be used during primary care before referral to hospital outpatient musculoskeletal clinics.[26] Future implementation success of our model will likely depend on factors such as individual patient characteristics, complexity of different musculoskeletal conditions and acceptability of telehealth by clinicians and patients.

4.4 Strengths and limitations

Our study had several strengths. We conducted a feasibility and pilot RCT with concealed allocation and reported it according to Consolidated Standards of Reporting Trials extension for randomised pilot and feasibility RCTs.[12] The nested qualitative interviews of patient and clinician acceptability of our new model of care were reported according to the COREQ (Consolidated Criteria for Reporting Qualitative Research).[13] The model of care protocol was refined prior to recruitment with patients with LBP and clinicians involved in managing these patients and is described in more detail elsewhere.[11]

The study has several important limitations. It was conducted at a single site with a complex patient population which provided challenges in terms of recruitment, risk stratification, and response rate, but also provided valuable learnings to modify the protocol for evaluation in the future large multisite trial.[16] For example, post-COVID the Back Clinic staff was reduced by half (operated by one rheumatologist and one physiotherapist) and only open for half a day, once per week, which significantly impacted the speed of recruitment due to limited time available to review new referrals. However, interviews with these clinicians suggested that settings with administration support could help to reduce the time needed to book appointments and lead to substantially faster recruitment. Given the small sample size and differences in baseline characteristics, the interpretation of additional outcomes is limited. We found similar pain and satisfaction ratings between participants in the intervention and usual care groups but higher disability ratings for participants in the intervention group. The larger, adequately powered future RCT will use a non-inferiority design to further evaluate clinical outcomes.

5. Conclusion

This study found that our Rapid Stratified Telehealth model of care is largely feasible to deliver and evaluate in a future fully-powered RCT. Key process outcomes provided important information to guide modifications to our model of care and trial processes for a large multisite RCT in outpatient hospital settings that manage patients with a variety of musculoskeletal conditions. Participants in the intervention group waited 13 days fewer for their first appointment with a rheumatologist compared to the usual care group but the additional outcomes should be interpreted with caution.

Supplementary files:

Supplementary file 1: CONSORT extension for randomised pilot and feasibility trials

Supplementary file 2: 32-item Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist

Supplementary file 3: Participant Information Statement for participants in the pilot and feasibility RCT

Supplementary file 4: Consent form for participants in the pilot and feasibility RCT

Supplementary file 5: Participant Information Statements for qualitative interviews

Supplementary file 6: Participant Consent Forms for qualitative interviews

Supplementary file 7: Semi-structured interview guides

Supplementary file 8: Characteristics of interviewed participants

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CHAPTER Seven

Discussion

Discussion

7.1 Overview

The overall aims of this thesis were to evaluate if improved online information and patient decision aids are potential options to reduce unnecessary surgery for people with musculoskeletal conditions and evaluate if a new model of care could reduce waiting times for people with musculoskeletal conditions referred to public hospital outpatient clinics. The specific aims were: 1) to summarise the portion of webpages on the management of Anterior Cruciate Ligament (ACL) rupture that are aligned with the best available evidence; 2) to describe the development and evaluate the acceptability of patient decision aids for two musculoskeletal conditions where evidence guiding recommendations for non-surgical vs. surgical management are very uncertain (children and adolescents with ACL rupture and adults with degenerative cervical myelopathy); and 3) to describe the development and evaluation of an innovative new model of care for people with musculoskeletal conditions that aims to reduce waiting times in public hospital outpatient clinics in Australia.

7.2 Principal findings

This thesis highlights that online information may be misleading by encouraging people with musculoskeletal conditions to have unnecessary surgery and patient decision aids could better align management decisions to patient values and evidence. The thesis also showed an innovative model of care involving a triage and treatment service in public hospital outpatient clinics is feasible to deliver to people with low back pain and feasible to evaluate in a large multi-site trial including people with a range of musculoskeletal conditions.

The content analysis presented in Chapter Two suggested that improved online information is a potential target to reduce unnecessary surgery for people with musculoskeletal conditions. Chapter Two showed that most consumer webpages on the management of ACL rupture are not aligned with the best available evidence and recommended guidelines. Two randomised controlled trials (n=121 and n=167) suggest that early ACL surgery in adults does not result in superior knee function, sport participation and quality of life compared to those who have non-surgical management alone with the option for delayed ACL surgery.[1,2] Despite this, our analysis of 115 webpages on the management of ACL rupture found that less than half (48%) suggested people can return to some form of sport with non-surgical management. Additionally, the benefits of ACL surgery were mentioned more often (43% of webpages) than benefits of non-surgical management (14% of webpages). We also found that just one in four of the webpages (23%) mentioned the risk of re-injury when returning to sport following ACL reconstruction, despite evidence suggesting that 22% of people who return to pivoting and cutting sports following surgery will experience a subsequent ACL rupture.[3] These findings showcase how inaccurate or insufficient online information may lead people with musculoskeletal conditions to have false expectations that surgery is the only effective treatment option (Chapter 2). A previously conducted content analysis of 50 webpages on degenerative cervical myelopathy has also suggested online information on surgery and treatment expectations may be misleading patients.[4]

Chapters Three and Four presented mixed methods studies using triangulation[5] which build on findings from Chapter Two and previous research[4] which suggested that patient decision aids are a potential method to improve patient education and reduce unnecessary surgery. Chapters Three and Four described the development and acceptability testing of patient decision aids for two musculoskeletal conditions where evidence guiding recommendations for non-surgical compared with surgical management was very uncertain. The musculoskeletal conditions were selected to include in this thesis to provide a contrast in the duration of the causative event commonly leading to the condition. The patient decision aid for children and adolescents considering ACL reconstruction surgery presented in Chapter Three is an example of an acute sporting injury where management decisions occur relatively early.[6] The patient decision aid in Chapter Three was rated as an acceptable tool to help patients choose between non-surgical and surgical management with support from their parents and health professionals. The patient decision aid for adults with degenerative cervical myelopathy presented in Chapter Four is an example of a chronic condition where management decisions commonly occur much longer after diagnosis.[7] The patient decision aid in Chapter Four for adults with degenerative cervical myelopathy was rated as an acceptable tool by both health professionals who treat degenerative cervical myelopathy and people with lived experience of degenerative cervical myelopathy. Both studies highlight the need to further evaluate these patient decision aids to understand whether they can positively influence informed choice, decisional conflict, patient-clinician communication, satisfaction with choice, and healthcare use.[8]

Chapters Five and Six described the development and early evaluation of an innovative model of care for people with musculoskeletal conditions, designed to reduce waiting times in public hospital outpatient clinics. The model of care enabled early identification of patients who can be managed with less resources (e.g. brief telephone appointment, self-management advice), thereby freeing up clinic-based resources for people with more complex management needs. Chapter Five described a mixed methods development paper outlining the three-stages of development of an innovative model of care. Development was guided by current research and models used overseas, findings from the feasibility randomised controlled trial (detailed in Chapter 6) and an analysis of 23 qualitative interviews with patients, health professionals and key stakeholders. Qualitative interviews from Chapter Five identified key modifications needed before the model of care is evaluated in an adequately-powered trial for people with musculoskeletal conditions referred to public hospital outpatient clinics (Chapter 5).

Chapter Six presented a feasibility and pilot randomised controlled trial which showed that the new model of care involving a triage and treatment service for patients with low back pain is largely feasible to deliver to people with musculoskeletal conditions and evaluate in future adequately-powered randomised controlled trials. Over half of the feasibility targets set a priori were met which included patients and clinicians suggesting the model and trial process were acceptable (assessed via qualitative interviews), intervention fidelity, treatment adherence and missing data. Recruitment and consent rate targets were not met largely due to clinic disruptions during the COVID-19 pandemic (e.g. reduction in staff and clinic operating days). The trial also found patients receiving the new model of care waited 13 days less for their first appointment compared to those receiving usual care and both groups had largely similar clinical outcomes (e.g. pain and satisfaction).

7.3 Clinical implications and comparison to existing literature

The findings of this thesis emphasise that improved online information and patient decision aids are potential targets to reduce unnecessary surgery for musculoskeletal conditions and that the innovative model of care aiming to reduce waiting times for people with musculoskeletal conditions referred to public hospital outpatient clinics is feasible to deliver and evaluate in a large clinical trial.

7.3.1 Online information and unnecessary surgery

Chapter Two highlighted that a delay in translating evidence-based information to consumer webpages could contribute to increases in unnecessary surgery. Despite evidence showing non-surgical and surgical management are viable treatment options for people following ACL rupture,[1,2] consumer webpages analysed on the management of ACL rupture (n=115) omit key information which may lead patients to believe surgery is their only option if they want to return to sport.[9,10] The need for evidence-based online information to align patient management expectations with the best available evidence for a variety of musculoskeletal conditions is supported by previous research. A content analysis replicating a Google search of webpages presenting information on degenerative cervical myelopathy (n=50) found almost three-quarters of webpages provided misleading information which included complications and treatment outcomes not aligned with the best available evidence.[4] Another previously content analysis of consumer webpages on knee arthroscopy for osteoarthritis (n=93) found only eight webpages (9%) acknowledged evidence that knee arthroscopy is not superior to placebo surgery or non-surgical management.[11] Another analysis of supposably trustworthy websites providing recommendations for low back pain management (n=79) also showed less than half of webpages made accurate recommendations.[12] Overall, research suggested that it can take up to 17 years for only 14% of published research to be translated into practice[13,14] and there is an opportunity to better align online information with guideline recommendations to help expedite this translation.

Chapter Two also found that only five webpages (4%) mention evidence that approximately 65% of people will return to their pre-injury level of sport following surgery.[3] Previous research has shown that 84-91% of young adults falsely expect to return to their same pre-injury level of sport before having surgery,[15,16] and poor online information about return to sport data may be partially to blame. In Australia, 84% of people who had an ACL reconstruction surgery had used the internet to search for information about their procedure preoperatively.[17] Omission of strong evidence detailing potential harms of surgery could therefore contribute to increase rates of surgery.[18] Patients are increasingly using social media platforms (e.g. Instagram, Facebook, Tik Tok) and artificial intelligence such as large language models (e.g. ChatGPT) to find health information.[19-22] Previous research suggest that social media can be unlikely to mention harms of popular medical tests and responses produced by large language models could be based on unreliable webpages.[19-22] Chapter Two strengthens the argument for the need to develop evidence-based resources that outline information on the benefits and harms of management options to combat patients being exposed to misleading online information.

7.3.2 Patient decision aids and unnecessary surgery

Chapters Three and Four described the development of patient decision aids which could improve patient confidence to ask questions and engage in shared decision making. Shared decision making is a process that encourages health professionals to work with patients to consider patients values and evidence to inform management decisions.[23,24] Shared decision-making tools such as patient decision aids are important to overcome information overload and facilitate patient engagement in their treatment decisions.[23] This is particularly important given the changes in the use of large language models which may provide information that does not align with the best available evidence.[22] Both patient decision aids are four-page documents co-designed with a graphic designer which outline non-surgical vs surgical management options using subheadings, bullet points, images, numeric estimates of benefits and harms using the highest quality evidence, and questions to ask a health professional. Chapter Three found that 87% of adolescents (43% had surgery) and parents interviewed agreed the patient decision aid on management following ACL rupture would have made their decision easier. Chapter Four found that 89% of people with degenerative cervical myelopathy (79% had surgery) interviewed agreed the patient decision aid would have made their decision easier. The perceived ease of making decisions using the patient decision aids could be due to the features described above which frequently received positive feedback during interviews.[25] Compared to usual care, use of patient decision aids in clinical practice has led to patients being more likely to participate in management decisions.[8] This highlights the promise of patient decision aids for reducing unnecessary surgery for musculoskeletal conditions with the changing landscape of how patients access health information.[8,21]

Interviews in Chapters Three and Four highlighted the importance of considering health literacy and using visual media in patient decision aids. Health literacy refers to people's knowledge, motivation and competence to access, understand, appraise and apply health information to make health decisions.[26] The patients interviewed frequently suggested using more concise language, removing unnecessary text, using practical examples and gave positive feedback on visual media which they reported make the patient decision aids more patient-friendly.[27-29] A recent online randomised controlled trial (n=1439) examining the effect of health literacy on involvement in shared decision-making found those with limited health literacy had lower scores on decision-making outcomes and supports the need to develop resources considering health literacy and shared decision-making.[30] Importantly, resources using visual media and text have been shown to facilitate communication between health professionals and patients.[31,32] In particular, visual media has been shown to increase patient interactivity,[33] reduce reading efforts,[31] provide cultural relevance when used appropriately,[34] and encourage greater patient participation in management decisions.[32] The use of these elements in both the patient decision aids could therefore facilitate patient engagement with evidence-based information beyond current capabilities of artificial intelligence.

Interviews regarding the patient decision aid for children and adolescents following ACL rupture demonstrated a need for resources to encourage individualised management and psychosocial support following ACL rupture. The post interview questionnaire showed adolescents interviewed (n=7, 100%) decided to have (or not have) ACL reconstruction surgery based on various individual reasons. Management decisions were made based on influence from someone they know (e.g. a friend) (n=2, 29%), their age (e.g. being young) (n=1, 14%), wanting to return to sport (n=2, 29%) or a recommendation from a health professional (n=2, 29%). Previous research suggests management decisions are driven by multiple factors such as cognitive processes, topic knowledge and literacy, attitudes and beliefs, and emotional states.[35] The variability found in the factors influencing adolescents to have surgery suggest a need for evidence-based resources which can align decisions with patient values and evidence by increasing knowledge.[35] The patient decision aid in Chapter Three also encourages planning for physical and psychological support for children and adolescents following ACL rupture which is particularly important for young people to reduce the prevalence of musculoskeletal conditions persisting into adulthood.[36]

Interviews regarding the patient decision aid for adults with degenerative cervical myelopathy suggested a strong need to increase awareness of the condition. Most people interviewed with degenerative cervical myelopathy had received their diagnosis at least twenty-four months after first noticing symptoms (58%). This corroborated with research showing diagnosis can be delayed up to 9 years after an initial visit with a health professional.[37] Delayed diagnosis is often due to patients having subtle, non-specific symptoms and limited disease awareness.[38] One potential avenue to increase awareness of degenerative cervical myelopathy is collaborating with global organisations. A partnership with Myelopathy.org during the development of the patient decision aid is an example of a collaboration with a global organisation which could support implementation and the evaluation findings could impact future policy change encouraging shared decision making.[39] Myelopathy.org is a global organisation based out of Cambridge University in the United Kingdom (UK) recognised for improving outcomes for people with degenerative cervical myelopathy.[40] Myelopathy.org provides an example of an active online global community involving people living with a musculoskeletal condition, and health professionals involved in its management, which could better align management with evidence.[41] The partnership with Myelopathy.org has potential to improve access to the patient decision aid via different media (e.g. social media support groups, video, podcast) and could prompt screening of patients presenting to primary care for degenerative myelopathy.[38]

7.3.3 New models of care and reducing waiting times to access care

Chapters Five and Six showed that the innovative new model of care could identify people with musculoskeletal conditions who can be managed with less resources (e.g. a brief telephone appointment, App-based exercise programmes), thereby reducing wait for a clinic-based appointments for more complex cases. The findings align with studies evaluating similar models overseas,[42] but also provided important learnings to modify the model before further evaluation in an adequately-powered randomised controlled trial. For example, the 'PhysioDirect' model of care[42] evaluated in the United Kingdom used a telephone call with a physiotherapist to determine those who needed minimal intervention (e.g. brief telephone advice, App-based exercises) due to a good prognosis and those who require clinic-based physiotherapist-led treatment.[42] The non-inferiority randomised controlled trial evaluating PhysioDirect found PhysioDirect reduced waiting times (median 7 days vs 34 days in usual care) across four physiotherapy services in England (n=2249)[42] and the reduced need for clinic-based appointments (40% relative reduction) compared to usual care. Chapter Five and Six suggest implementation of a similar model in the Australian healthcare landscape could be conducted by rheumatologists and physiotherapists. Including other health professions in the delivery of this model of care could also enhance the sustainability of this model within the Australian healthcare system. For example, a recent Australian survey (n=233) suggested that exercise physiologist can provide similar guideline-based recommendations as physiotherapist for patients with chronic low back pain.[43]

Chapter Five outlined the analysis of interviews with patients, health professionals and key stakeholders regarding the model of care, which suggested future evaluation of the model should plan for steps to improve access to care for people from cultural and linguistic diverse populations. Non-English speaking participants were not included in the feasibility and pilot trial (Chapter 6) nor in the future adequately-powered multisite trial we are currently recruiting for.[44] This was due to the cost and feasibility of using translation services at the point of referral and because selected outcome measures had not been sufficiently validated in common languages spoken at our recruiting sites. Improving access to care for all people with musculoskeletal conditions is a global challenge[45] and part of Australia's National Primary Care Strategic Framework.[46] One in five Australians speak English as their second language at home and nearly two in five Australians aged over 65 years belong to what is referred to as Culturally and Linguistically Diverse populations.[47] Disparities in access to care for Cultural and Linguistic Diverse populations can commonly be due to clinicians inability to speak languages other than English and a lack of resources to facilitate communication.[48] Therefore, planning guided by frameworks is needed to ensure innovative new models using telehealth can benefit all patients regardless of language spoken in the future.[48]

The pilot and feasibility randomised controlled trial (Chapter 6) provided valuable learnings about using telehealth as part of the innovative new model of care. We found telehealth was acceptable to patients with low back pain and clinicians, and using telehealth provided an opportunity to improve access to care. This aligns with findings from a recent randomised controlled trial (n=210) that found delivering physiotherapy via telehealth and an App-based exercise program was as effective as usual clinic-based care for improving function among people with a variety of musculoskeletal conditions.[49] Using mobile Apps to support therapeutic exercise has also been shown to improve clinical outcomes such as reducing pain intensity and improve physical function compared to usual care for patients with musculoskeletal conditions (n=845).[50]

The pilot and feasibility randomised controlled trial reported in Chapter 6 found nonattendance to allocated appointments could further impact waiting times to access care. Of the 26 patients allocated a physiotherapy appointment only 17 (65%) attended their appointments. Non-attendance of clinical appointments prevents other patients from accessing timely care and is a multifaceted issue. Non-attendance has been shown to be influenced by socioeconomic (e.g. lower socioeconomic background and education levels), demographic (e.g. gender) and systemic factors (e.g. source of referral).[51] Research has consistently found that patient forgetfulness, lack of awareness of the importance of attending appointments, younger age with childcare responsibilities, work commitments and better health status increase likelihood of missing appointments.[51] Studies have shown an important correlation between long waiting periods and volume of patient non-attendance at clinics[51] – which was a large issue in the pilot trial embedded in the public health system. This correlation also appears to be a cyclic issue as the longer the wait time, the higher the chance of a patient forgetting their appointment or seeking care elsewhere. By providing early telephone advice and treatment to those at low risk of persistent disabling symptoms, the new model of care could reduce waiting times and therefore reduce nonattendance.

7.4 Suggestions for future research

7.4.1 Optimising access to evidence-based online information

The way people search for information online is rapidly changing due to the development of Artificial Intelligence (AI) and learning models such as ‘Google AI’, Chat GPT and Microsoft Copilot which are providing information in new ways. Chapter Two analysed individual components of consumer webpages on the management of ACL ruptures, but future research is needed to evaluate if information delivered by increasingly popular methods to consumer information (‘Artificial Intelligence Overview’ of a Google Search) is aligned with evidence. Artificial intelligence summaries signal a paradigm shift in how users interact with search engines, and despite their limitations, they may present an opportunity to improve access to evidence-based information and care. Future analysis is needed to evaluate information generated by artificial intelligence and understand how people search for information in this new era. Search behaviours of people are known to be influenced by differences in personality traits, thinking styles and dispositions, beliefs and ideologies.[35] A recent cross-sectional observational study demonstrated that the large language processing models such as ChatGPT have potential to provide information aligned with recommended guidelines for musculoskeletal conditions.[52] However, there is conflicting evidence about the use of artificial intelligence as the recent analysis of information provided by ChatGPT about musculoskeletal condition assessment and rehabilitation suggest the tool should only supplement decision-making due to uncertain reliability in consistency, completeness and ability to replicate nuanced clinical reasoning.[52]

7.4.2 ***Optimising development and access to patient decision aids***

Further research is needed to evaluate if the patient decision aids considered in this thesis can inform patient choice, improve decisional conflict, patient-clinician communication, patient satisfaction, healthcare use and lead to a reduction in unnecessary surgeries or timely management via increased awareness.[53] Implementation of shared decision-making into routine practice has been slow, despite 40 years of research and considerable policy support.[54] The development process of both patient decision aids involved consumers which has been shown to facilitate future implementation in clinical practice.[53] A recent Cochrane review showed previous patient decision aids can be effective in improving patient knowledge about management options and outcomes, and accuracy of risk perceptions compared to usual care in preparation for or during a clinical appointment.[8] Planned clinical evaluation of the patient decision aids will allow better understanding of whether decision aids can reduce the use of unnecessary surgery and improve shared decision making outcomes.

There is an opportunity to investigate how artificial intelligence could be integrated into the development, update and use of patient decision aids. The patient decision aid for children and adolescents who rupture their ACL is currently being translated into Portuguese but there is a need to translate patient decision aids into multiple languages to improve usability globally. Artificial intelligence translation software could be used to expedite these processes, including translation and cultural adaptation so patient decision aids can be used in a variety of countries and healthcare settings. A recent systematic review (n=26 studies) on perspectives on artificial intelligence-enabled patient decision aids found patients found them easy to understand, user friendly and empowering.[55] Artificial intelligence-enabled patient decision aids are developed through learning from patterns using real patient data to provide more personalised information to inform shared decision making.[55] Despite advances in artificial intelligence to assist decision-making, health professionals have expressed concerns about information which may lead to over- or under-treatment.[55] ‘Prompt engineering’ frameworks aim to optimise large language models by helping to craft specific input instructions input to generate desired outputs.[56] This holds promise for better aligning AI-generated online health information with guideline recommendations.[56] Therefore, further research is needed to evaluate the use of artificial intelligence in providing decision support for health professionals (e.g. SupportPrim)[57,58] and patients (e.g. tools to facilitate self-management)[59] to improve the management of common musculoskeletal conditions.

7.4.3 Reducing waiting times using innovative new models of care

As suggested by Chapters Five and Six, the model of care is feasible to test in the WAIT-less randomised controlled trial recruiting people with various musculoskeletal conditions. As such, this trial is currently underway at multiple public hospital outpatient musculoskeletal clinics in Sydney, Australia, and evaluating whether the innovative new model can reduce waiting time to access care without compromising clinical outcomes compare to usual clinic-based care.[44] If successful, future research would be needed to adapt the model to different settings and evaluate a strategy to train physiotherapists to implement the new model. The future evaluation will also include a cost-effective analysis and process evaluation.

A future process evaluation including an analysis of qualitative interviews is needed before implementing the new model of care more broadly. A process evaluation will provide insights into how future studies can replicate and improve implementation of the new model of care.[60] Nested qualitative interviews from the pilot and feasibility randomised controlled trial (Chapter 5) identified a need for a multidisciplinary approach to facilitate wide-spread implementation of the new model of care. Interviews suggested the need to increase public knowledge of the model developed (e.g. use of telephone and telehealth appointments, recommended guidelines) and partnerships with primary care to better align initial management of patients with the principles guiding the model. A future implementation trial of the model of care could investigate how education materials can be used to increase awareness of the model, optimal strategies to train clinicians to use the model and automate administrative processe,[61] and avenues to optimise clinician and patient feedback on barriers to using the model.[62]

Embedding chatbots using artificial intelligence within the new model of care could further help align patient beliefs with evidence and support self-management. Chatbots have already shown they can better align beliefs with guidelines recommendations for people with musculoskeletal conditions,[63,64] and improve health knowledge.[65] A preliminary randomised controlled trial has also shown artificial intelligence chatbots can lead to behaviour change about protective behaviours in regards to COVID-19 (e.g. testing).[66] The STarT MSK tool was used in our model of care to match patient care to their risk of developing persistent disabling pain.[67] The STarTMSK tool includes questions about patients knowledge of self-management, expectations, beliefs, activity behaviours and pain.[67] Nested qualitative interviews from the pilot and feasibility randomised controlled trial (Chapter 5) suggested a chatbot could provide reassurance to patients and facilitate self-management while they wait to access care. Patients could receive individualised advice from a chatbot while waiting for care to encourage aligning beliefs and knowledge with guideline recommendations which may influence triage and treatment allocation in our model of care.

7.5 Strengths and limitations

The results presented in this thesis have several strengths. High quality RCTs provide strong evidence that surgical and non-surgical management are viable options following ACL rupture.[1,2] Chapter Two and three other content analyses of webpages providing information on the management of musculoskeletal conditions (n=337) suggest that much of online information is not aligned with the best available evidence for musculoskeletal conditions such as ACL rupture (Chapter 2),[68] degenerative cervical myelopathy,[4] knee arthroscopy[11] and low back pain.[12] High quality studies including a large RCT (n=1439)[30] and recent Cochrane review including 209 RCTs provide further evidence on the importance of health literacy in patient decision making and the benefits of patient decision aids compared to usual care.[8] The findings of Chapter Six also align with other high quality RCTs conducted in Australia evaluating models of care for musculoskeletal conditions involving telehealth (n=250) and App-based care (n=845).[49,50] They also align with a trial in the United Kingdom evaluating a similar model, PhysioDirect (n=2249), involving a telephone call with a physiotherapist to determine those who could be managed via telephone before being discharge and those who required clinic-based care.[42]

The findings presented in this thesis are not without limitations. The findings and interpretations of the content analyses discussed may change as webpages are updated and people change the way they search for information online (e.g. via social media and use of large language models such as ChatGPT).[21] Although the patient decision aids described in Chapter Three and Four were rated as acceptable, there is a need to investigate the effectiveness of their implementation in a RCT compared to usual care. There is an opportunity to integrate the development, use and updating of patient decision aids with artificial intelligence but most studies on this topic are exploratory and may not reflect current use due to rapid changes in tools such as ChatGPT. The development process of our innovative model of care did not include participants who do not speak English but instead provide insights into the barriers and facilitators for including participants from culturally and linguistically diverse backgrounds in the future.

7.6 Conclusions

New knowledge from this thesis could help to improve access to information and care for people living with musculoskeletal conditions by describing strategies that could facilitate reduction in unnecessary surgery and waiting times to access care. This thesis described strategies that could facilitate people with musculoskeletal conditions to receive the right care, at the right time, by the right team, in the right place, with the right resources. The studies included in this thesis have highlighted that online information and patient decision aids are potential targets to reduce unnecessary surgery for musculoskeletal conditions. The studies also showed that our innovative model of care involving a triage and treatment service in public hospital outpatient clinics is feasible to deliver to people with low back pain and feasible to evaluate in a large multi-site trial including people with a range of musculoskeletal conditions.

Chapter Two found that most consumers webpages about the management of ACL ruptures are not aligned with the best available evidence and suggested that misleading information could lead to patients having unnecessary surgery. It identified a need for evidence-based resources for patients who have rupture their ACL, such as patient decision aids, to help them understand the benefits and harms of treatment options and make evidence-informed choices. Chapter Three described the development and acceptability testing of a patient decision aid to help children and adolescents choose between surgical and non-surgical management which could reduce unnecessary surgery. Chapter Four described the development and acceptability testing of a patient decision aid for people with degenerative cervical myelopathy which could also reduce unnecessary surgery. Chapter Five described the three-stage development of an innovative new model of care for people with musculoskeletal conditions that aims to reduce waiting times. Chapter Six showed the feasibility and pilot randomised controlled trial involving a triage and treatment service for patients with low back pain is largely feasible to deliver to people with musculoskeletal conditions and evaluate in future adequately-powered randomised controlled trials. If effective, the innovative new model could reduce waiting times to access care for millions of Australians with musculoskeletal conditions.

Data availability statement: All data relevant to the study are included in the article or uploaded as supplementary information.

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APPENDICES

Appendix One: Chapter Two metrics and impact

Appendix Two: Chapter Three metrics, impact and supplementary material

Appendix Three: Chapter Four metrics, impact and supplementary material

Appendix Four: Chapter Five metrics, impact and supplementary material

Appendix Five: Chapter Six metrics, impact and supplementary material

Appendix Six: Additional publication forming part of the thesis (n=1)

Appendix Seven: Related publications not forming part of the thesis (n=11)

Appendix Eight: Research dissemination, media engagement, funding and awards

APPENDIX ONE

Chapter Two publication metrics

The work presented in Chapter Two has been published in Musculoskeletal Science and Practice which has an impact factor of 2.2, and is Q1 for Physical Therapy, Sports Therapy and Rehabilitation. The Scimago Journal and Country Rank (2024) is 0.850 and has a H-Index of 114.

Impact

The Chapter Two paper has been citated a total of five times (twice in 2025) and compared to other publications in the same field has received approximately 2.61 times more citations than average. It has been reported by 16 news outlets, 32 X users, 1 Facebook page and 39 readers on Mendeley as per Altmetric.

APPENDIX TWO

Chapter Three publication metrics

The work presented in Chapter Three has been published in the *BMJ Open* which has an impact factor of 2.4 and is Q1 for Medicine (miscellaneous). The Scimago Journal and Country Rank (2024) is 1.016 and it has a H-index of 176.

Impact

The Chapter Three paper has been citated a total of two times (twice in 2025) and it is too early to compare the number of citations this publication has received so far to other publications in the same field. It has been mentioned by 56 X users, 1 Facebook page and 50 readers on Mendeley as per Altmetric. It is in the top 5% of all research outputs scored by Altmetric and has a high attention score compared to outputs of the same age and score (96th percentile).

For recruitment via social media

Consent section

1. Please make sure you have read the Children and Adolescent Participant information statement before starting the survey.
2. CHILDREN AND ADOLESCENT PARTICIPANT CONSENT FORM

PARTICIPANT CONSENT FORM

What information is important when considering early anterior cruciate ligament (ACL) reconstruction in children?

By saying yes to being in this study, I am saying that:

Tick/initial boxes

- ☐ I know what I will be asked to do and have been given a Study Information Sheet to keep.
- ☐ I know that this study is about what information is important for children before deciding to have early ACL reconstruction surgery or rehabilitation with the option for delayed ACL reconstruction.
- ☐ Someone has talked to me about the study and what it means for me.
- ☐ I know that I will be asked to answer a questionnaire (5-minutes) before I attend an interview to provide feedback on educational information of treatment options following ACL injury (online, via telephone or in person if the COVID-19 situation allows) that will last 30 minutes.
- ☐ I know that I don’t have to be in the study if I don’t want to.
- ☐ I know that I can choose not to talk about something if I don’t want to.
- ☐ I have been asked if it is ok or not ok to record what I say.
- ☐ I have been told that I can change my mind at any time if I don’t want to take part anymore.
- ☐ I have been told that if I say yes or no it won’t change how the study team feel about me.
- ☐ I know that what I say or do in this study is private and when the study team write about what they learn they won’t use my name or anything that could tell other people who I am.
- ☐ I understand that after I sign and return this consent form it will be kept by the researcher, and that I can ask for a copy at any time.

☐ Yes, I would be happy to participate in this study
☐ No, I would prefer not to participate in this study

3. I would like to be emailed a copy of the study results:
   - ☐ Yes
   - ☐ No

If YES, my email address is____

4. I consent to the future use of any data I provide for research purposes. I understand that before the investigators or their collaborators use any data that I provide, they must seek additional ethics approval.
   - ☐ Yes
   - ☐ No

Pre-interview Questionnaire

Study ID: _______________

Thank you for your participation in this study, which is investigating what information is important when considering early anterior cruciate ligament (ACL) reconstruction in children.

We would like you to answer a few questions before the interview. This should not take more than 5-minutes.

First some quick questions about you...

1. Please indicate your gender:
   - ☐ Female
   - ☐ Male
   - ☐ Non-binary
2. Please indicate your age: [free text response]

____

3. In which country were you born? [free text response]

4. Are you currently at school?
   - ☐ Yes
   - ☐ No

   If Yes, What Grade are you in at school? ___________________________

   If No, What Grade did you finish/leave school? ______________________

5. Do you work?
   - ☐ Yes
   - ☐ No

   If Yes,

   - ☐ Part-time
   - ☐ Full-time

   What type of work do you do? _____________________________

6. How long ago did you rupture your ACL (weeks, months or years)?
   ____

7. When you ruptured your ACL, did you also damage any other structures in the knee (e.g., Meniscus or other ligament damage)?
   - ☐ Yes
   - ☐ No (skip to question 8)

☐ Unsure

Please specify the structures you damaged. Please select all that apply:

☐ Medial collateral ligament (MCL)
☐ Lateral collateral ligament (LCL)
☐ Posterior cruciate ligament (PCL)
☐ Medial meniscus
☐ Lateral meniscus
☐ Cartilage damage
☐ I am unsure of the structure

8. Did you have an ACL reconstruction surgery?

☐ Yes
☐ No > go to question 10

> If 'Yes' did you re-rupture your ACL after surgery?

☐ Yes
☐ No

> If 'Yes', did you have another ACL reconstruction?

☐ Yes
☐ No

9. How long ago did you have your most recent ACL reconstruction surgery?

☐ <1 month ago
☐ 1-3 months ago
☐ 4-6 months ago
☐ 6-12 months ago
☐ 12-24 months ago
☐ >24 months ago

10. Please indicate in the spaces below the HIGHEST level of activity that you participated in BEFORE YOUR INJURY and the highest level you can participate in CURRENTLY.

BEFORE INJURY: Level__________ CURRENT: Level___________

What information is important when considering early anterior cruciate ligament (ACL) reconstruction in children?

Please choose one of the following which best describes your current activity level.

○ Level 10	Competitive Sports(Soccer, Football, Rugby (national elite)
○ Level 9	Competitive Sports(Soccer, Football, Rugby (lower divisions), hockey, wrestling, gymnastics)
○ Level 8	Competitive Sports(Racquetball, Squash, Track and Field, Alpine Skiing)
○ Level 7	Competitive Sports(Tennis, Athletics(Running), Handball, Basketball, Motorcross, Cross country track) Recreational Sports (Soccer, Football, Hockey, Squash, Athletics(jumping), Cross country track)
○ Level 6	Recreational Sports (Tennis, Handball, Basketball, Alpine skiing, Jogging 5X/week)
○ Level 5	Work (Heavy Labor) Competitive Sports (Cycling, X-country Skiing) Recreational (Jogging on uneven ground 2x/week)
○ Level 4	Work (Moderately Heavy Labor (truck driving, etc) Recreational Sports (Cycling, Cross Country Skiing, Jogging on even ground 2X/week)
○ Level 3	Work (Light Labor) Comp & Rec Sports (Swimming), Hiking, Backpacking
○ Level 2	Work (Light Labor) Walking on uneven ground possible but impossible to backpack or hike
○ Level 1	Work (Light Labor) Walking on even ground possible
○ Level 0	Sick leave or disability pension because of knee problems

11. Which one factor most influenced your decision to have (or not have) an ACL reconstruction?
    - ☐ Pain
    - ☐ Return to sport
    - ☐ Prevent further damage
    - ☐ Age
    - ☐ Recommendation from a health professional (e.g., an Orthopaedic surgeon or Physiotherapist)
    - ☐ Online information
    - ☐ Someone you know (e.g., a Friend)
    - ☐ I don’t know

12. How happy were you with your treatment choice (either ACL reconstruction or non-surgical management)?
    - ☐ Extremely unhappy
    - ☐ Somewhat unhappy
    - ☐ Neither happy or unhappy
    - ☐ Somewhat happy
    - ☐ Extremely happy

Finally, when are the best times to schedule you for an online interview…

Please provide below your best contact details for a researcher from the University of Sydney to contact you and arrange the follow-up interview:

Name: ______________________________________

Email: ______________________________________

What information is important when considering early anterior cruciate ligament (ACL) reconstruction in children? v3, 23/3/2022

Best contact telephone number: ___________________________________

Best time/s to call: ___________________________________

Please mark the times that are suitable to arrange an interview in the boxes below:

	Monday	**Tuesday**	**Wednesday**	**Thursday**	**Friday**
8 – 10am					
10 – 12pm					
12 – 2pm					
2 – 4pm					
4 – 6pm					

Thank you for completing the questionnaire.

For recruitment via social media

Consent section

1. Please make sure you have read the Adult Participant information statement before starting the survey.
2. ADULT PARTICIPANT CONSENT FORM

PARTICIPANT CONSENT FORM

What information is important when considering early anterior cruciate ligament (ACL) reconstruction in children?

In giving my consent, I confirm that that:

Tick/initial boxes

- ☐ The details of my involvement have been explained to me, and I have been provided with a written Participant Information Statement to keep.
- ☐ I understand the purpose of the study is to investigate what information is important for children under 18 years old before deciding to have early ACL reconstruction surgery or rehabilitation with the option for delayed ACL reconstruction.
- ☐ I acknowledge that the risks and benefits of participating in this study have been explained to me to my satisfaction.
- ☐ I understand that in this study I will be required to answer a pre-interview questionnaire (5-minutes) and attend an interview to provide feedback on an educational pamphlet on treatment options following ACL rupture (online, via telephone or in person pending on the COVID-19 situation) that will last 30-minutes.
- ☐ I understand that my participation will involve my interview to be recorded.
- ☐ I understand that information may be used in future research and the data collected for this study may use it in future projects. By providing consent I allow my information to be shared locally and internationally with other research collaborators as needed. I understand that it is unknown at this stage what these other projects will involve, and ethical approval will be gained before my information in used in these future projects.
- ☐ I understand that being in this study is completely voluntary.
- ☐ I am assured that my decision to participate will not have an impact on any relationship with the research team or the University of Sydney or the Local Health District.
- ☐ I understand that I am free to withdraw from this study at any time and that I can choose to withdraw any information I have already provided (unless the data has already been de-identified or published).
- ☐ I have been informed that the confidentiality of the information I provide will be protected and will only be used for purposes that I have agreed to. I understand that information about me will only be told to others with my permission, except as required by law.
- ☐ I understand that the results of this study may be published, and that publications will not contain my name or any identifiable information about me.

☐ Yes, I would be happy to participate in this study

☐ No, I would prefer not to participate in this study

3. I would like to be emailed a copy of the study results:
   - ☐ Yes
   - ☐ No

If YES, my email address is____

4. I consent to the future use of any data I provide for research purposes. I understand that before the investigators or their collaborators use any data that I provide, they must seek additional ethics approval.
   - ☐ Yes
   - ☐ No

Pre-interview Questionnaire

Study ID: _______________

Thank you for your participation in this study, which is investigating what information is important when considering early anterior cruciate ligament (ACL) reconstruction in children under 18 years old.

We would like you to answer a few questions before the interview. This should not take more than 5-minutes.

First some quick questions about you...

1. Please indicate your gender:
   - ☐ Female
   - ☐ Male
   - ☐ Non-binary

2. Please indicate your age: [free text response]

____

3. In which country were you born? [free text response]

____

4. What option best describes your highest level of education?
   - ☐ Primary school or less
   - ☐ High school (not completed)
   - ☐ High school (completed)
   - ☐ TAFE/Trade
   - ☐ University- undergraduate degree/s (completed)
   - ☐ University- postgraduate degree/s e.g. Masters, PhD (completed)
   - ☐ Other (please specify) ______________________________

5. What is your employment status?
   - ☐ Employed part-time
   - ☐ Employed full-time
   - ☐ Casual work
   - ☐ Retired
   - ☐ Unemployed
   - ☐ Student
   - ☐ Sick/disability leave
   - ☐ Other (please specify) ______________________________

6. Do you have private health insurance?
   - ☐ Yes
   - ☐ No

7. How long ago did you rupture your ACL? ___________________

8. When you ruptured your ACL, did you also damage any other structures in the knee (e.g., Meniscus or other ligament damage)?
   - ☐ Yes
   - ☐ No (skip to question 9)

   Please specify the structures you damaged. Please select all that apply:

   - ☐ Medial collateral ligament (MCL)
   - ☐ Lateral collateral ligament (LCL)
   - ☐ Posterior cruciate ligament (PCL)
   - ☐ Medial meniscus
   - ☐ Lateral meniscus
   - ☐ Cartilage damage
   - ☐ I am unsure of the structure

9. Did you have an ACL reconstruction surgery?
   - ☐ Yes
   - ☐ No > go to question 11

   > If ‘Yes’ did you re-rupture your ACL after surgery?
   - ☐ Yes
   - ☐ No

   > If ‘Yes’, did you have another ACL reconstruction?
   - ☐ Yes
   - ☐ No

10. How long ago did you have your most recent ACL reconstruction surgery?
    - ☐ <1 month ago
    - ☐ 1-3 months ago
    - ☐ 4-6 months ago
    - ☐ 6-12 months ago
    - ☐ 12-24 months ago
    - ☐ >24 months ago

11. Please indicate in the spaces below the HIGHEST level of activity that you participated in BEFORE YOUR INJURY and the highest level you can participate in CURRENTLY.

BEFORE INJURY: Level___________ CURRENT: Level____________

Please choose one of the following which best describes your current activity level.

○ Level 10	Competitive Sports(Soccer, Football, Rugby (national elite)
○ Level 9	Competitive Sports(Soccer, Football, Rugby (lower divisions), hockey, wrestling, gymnastics)
○ Level 8	Competitive Sports(Racquetball, Squash, Track and Field, Alpine Skiing)
○ Level 7	Competitive Sports(Tennis, Athletics(Running), Handball, Basketball, Motorcross, Cross country track) Recreational Sports (Soccer, Football, Hockey, Squash, Athletics(jumping), Cross country track)
○ Level 6	Recreational Sports (Tennis, Handball, Basketball, Alpine skiing, Jogging 5X/week)
○ Level 5	Work (Heavy Labor) Competitive Sports (Cycling, X-country Skiing) Recreational (Jogging on uneven ground 2x/week)
○ Level 4	Work (Moderately Heavy Labor (truck driving, etc) Recreational Sports (Cycling, Cross Country Skiing, Jogging on even ground 2X/week)
○ Level 3	Work (Light Labor) Comp & Rec Sports (Swimming), Hiking, Backpacking
○ Level 2	Work (Light Labor) Walking on uneven ground possible but impossible to backpack or hike
○ Level 1	Work (Light Labor) Walking on even ground possible
○ Level 0	Sick leave or disability pension because of knee problems

12. Which one factor most influenced your decision to have (or not have) an ACL reconstruction?
    - ☐ Pain
    - ☐ Return to sport
    - ☐ Prevent further damage
    - ☐ Age
    - ☐ Recommendation from a health professional (e.g., an Orthopaedic surgeon or Physiotherapist)
    - ☐ Online information
    - ☐ Someone you know (e.g., a Friend)
    - ☐ I don't know

13. How happy were you with your treatment choice (either ACL reconstruction or non-surgical management)?
    - ☐ Extremely unhappy
    - ☐ Somewhat unhappy
    - ☐ Neither happy or unhappy
    - ☐ Somewhat happy
    - ☐ Extremely happy

Finally, when are the best times to schedule you for an online interview…

Please provide below your best contact details for a researcher from the University of Sydney to contact you and arrange the follow-up interview:

Name: ______________________________________

Email: ______________________________________

Best contact telephone number: __________________________________

Best time/s to call: ___________________________________

Please mark the times that are suitable to arrange an interview in the boxes below:

	Monday	**Tuesday**	**Wednesday**	**Thursday**	**Friday**
8 – 10am					
10 – 12pm					
12 – 2pm					
2 – 4pm					
4 – 6pm					

Thank you for completing the questionnaire.

For recruitment via social media

Consent section

1. Please make sure you have read the Parent Participant information statement before starting the survey.
2. PARENT PARTICIPANT CONSENT FORM

PARTICIPANT CONSENT FORM

What information is important when considering early anterior cruciate ligament (ACL) reconstruction in children?

In giving my consent, I confirm that that:
Tick/initial boxes

- ☐ The details of any involvement have been explained to me, and I have been provided with a written Participant Information Statement to keep.
- ☐ I understand the purpose of the study is to investigate what information is important for children under 18 years old before deciding to have early ACL reconstruction surgery or rehabilitation with the option for delayed ACL reconstruction.
- ☐ I acknowledge that the risks and benefits of participating in this study have been explained to me to my satisfaction.
- ☐ I understand that in this study I and my child will both be required to answer a pre-interview questionnaire (5-minutes) and attend an interview to provide feedback on an educational pamphlet on treatment options following ACL rupture (online, via telephone or in person pending on the COVID-19 situation) that will last 30-minutes.
- ☐ I understand that my participation will involve my interview to be recorded.
- ☐ I understand that information may be used in future research and the data collected for this study may use it in future projects. By providing consent I allow my information to be shared locally and internationally with other research collaborators as needed. I understand that it is unknown at this stage what these other projects will involve, and ethical approval will be gained before my information in used in these future projects.
- ☐ I understand that being in this study is completely voluntary.
- ☐ I am assured that my decision to let my child participate will not have an impact on any relationship with the research team or the University of Sydney or the Local Health District.
- ☐ I understand that we (myself and/or my child) are free to withdraw from this study at any time and can choose to withdraw any information already provided (unless the data has already been de-identified or published).
- ☐ I have been informed that the confidentiality of the information provided by myself and/or my child will be protected and will only be used for purposes that has been agreed to. I understand that information will only be told to others with my permission, except as required by law.
- ☐ I understand that the results of this study may be published, and that publications will not contain any identifiable information about myself or my child.

☐ Yes, I would be happy to participate in this study
☐ No, I would prefer not to participate in this study

3. I would like to be emailed a copy of the study results:
   - ☐ Yes
   - ☐ No

If YES, my email address is____

4. I consent to the future use of any data I provide for research purposes. I understand that before the investigators or their collaborators use any data that I provide, they must seek additional ethics approval.
   - ☐ Yes
   - ☐ No

Pre-interview Questionnaire

Study ID: _______________

Thank you for your participation in this study, which is investigating what information is important when considering early anterior cruciate ligament (ACL) reconstruction in children under 18 years old.

We would like you to answer a few questions before the interview. This should not take more than 5-minutes.

First some quick questions about you...

1. Please indicate your gender:
   - ☐ Female
   - ☐ Male
   - ☐ Non-binary

2. Please indicate your age: [free text response]

____

3. In which country were you born? [free text response]

____

4. What option best describes your highest level of education?
   - ☐ Primary school or less
   - ☐ High school (not completed)
   - ☐ High school (completed)
   - ☐ TAFE/Trade
   - ☐ University- undergraduate degree/s (completed)
   - ☐ University- postgraduate degree/s e.g. Masters, PhD (completed)
   - ☐ Other (please specify) ______________________________

5. What is your employment status?
   - ☐ Employed part-time
   - ☐ Employed full-time
   - ☐ Casual work
   - ☐ Retired
   - ☐ Unemployed
   - ☐ Student
   - ☐ Sick/disability leave
   - ☐ Other (please specify) ______________________________

6. Do you have private health insurance?
   - ☐ Yes
   - ☐ No

7. How long ago did your child rupture their ACL? ___________________

8. When your child ruptured their ACL, did they also damage any other structures in the knee (e.g., Meniscus or other ligament damage)?
   - ☐ Yes
   - ☐ No (skip to question 9)
   - ☐ Unsure

   Please specify the structures your child damaged. Please select all that apply:

   - ☐ Medial collateral ligament (MCL)
   - ☐ Lateral collateral ligament (LCL)
   - ☐ Posterior cruciate ligament (PCL)
   - ☐ Medial meniscus
   - ☐ Lateral meniscus
   - ☐ Cartilage damage
   - ☐ I am unsure of the structure

9. Has your child have an ACL reconstruction surgery?
   - ☐ Yes
   - ☐ No > go to question 11

   > If 'Yes' did your child re-rupture their ACL after surgery?
   - ☐ Yes
   - ☐ No

   > If 'Yes', did your child have another ACL reconstruction?
   - ☐ Yes
   - ☐ No

10. How long ago did your child have their most recent ACL reconstruction surgery?
    - ☐ <1 month ago
    - ☐ 1-3 months ago
    - ☐ 4-6 months ago
    - ☐ 6-12 months ago
    - ☐ 12-24 months ago
    - ☐ >24 months ago

11. Please indicate in the spaces below the HIGHEST level of activity that your child participated in BEFORE THEIR INJURY and the highest level they can participate in CURRENTLY.

BEFORE INJURY: Level__________ CURRENT: Level___________

Please choose one of the following which best describes your current activity level.

○ Level 10	Competitive Sports(Soccer, Football, Rugby (national elite)
○ Level 9	Competitive Sports(Soccer, Football, Rugby (lower divisions), hockey, wrestling, gymnastics)
○ Level 8	Competitive Sports(Racquetball, Squash, Track and Field, Alpine Skiing)
○ Level 7	Competitive Sports(Tennis, Athletics(Running), Handball, Basketball, Motorcross, Cross country track) Recreational Sports (Soccer, Football, Hockey, Squash, Athletics(jumping), Cross country track)
○ Level 6	Recreational Sports (Tennis, Handball, Basketball, Alpine skiing, Jogging 5X/week)
○ Level 5	Work (Heavy Labor) Competitive Sports (Cycling, X-country Skiing) Recreational (Jogging on uneven ground 2x/week)
○ Level 4	Work (Moderately Heavy Labor (truck driving, etc) Recreational Sports (Cycling, Cross Country Skiing, Jogging on even ground 2X/week)
○ Level 3	Work (Light Labor) Comp & Rec Sports (Swimming), Hiking, Backpacking
○ Level 2	Work (Light Labor) Walking on uneven ground possible but impossible to backpack or hike
○ Level 1	Work (Light Labor) Walking on even ground possible
○ Level 0	Sick leave or disability pension because of knee problems

12. Which one factor most influenced the decision for your child to have (or not have) an ACL reconstruction?
    - ☐ Pain
    - ☐ Return to sport
    - ☐ Prevent further damage
    - ☐ Age
    - ☐ Recommendation from a health professional (e.g., an Orthopaedic surgeon or Physiotherapist)
    - ☐ Online information
    - ☐ Someone you know (e.g., a Friend)
    - ☐ I don’t know

13. How happy was your child with their treatment choice (either ACL reconstruction or non-surgical management)?
    - ☐ Extremely unhappy
    - ☐ Somewhat unhappy
    - ☐ Neither happy or unhappy
    - ☐ Somewhat happy
    - ☐ Extremely happy

Finally, when are the best times to schedule you for an online interview…

Please provide below your best contact details for a researcher from the University of Sydney to contact you and arrange the follow-up interview:

Name: ____________________________________

Email: ____________________________________

Best contact telephone number: ___________________________________

Best time/s to call: ___________________________________

We would like to interview you and your child together. Is this okay?

☐ Yes
☐ No

Please mark the times that are suitable to arrange an interview in the boxes below:

	Monday	**Tuesday**	**Wednesday**	**Thursday**	**Friday**
8 – 10am					
10 – 12pm					
12 – 2pm					
2 – 4pm					
4 – 6pm					

Thank you for completing the questionnaire.

For recruitment via email

Consent section

1. Please make sure you have read the Health Professional Participant information statement before starting the survey.
2. HEALTH PROFESSIONAL PARTICIPANT CONSENT FORM

PARTICIPANT CONSENT FORM

What information is important when considering early anterior cruciate ligament (ACL) reconstruction in children?

In giving my consent, I confirm that that:

Tick/initial boxes

- ☐ The details of my involvement have been explained to me, and I have been provided with a written Participant Information Statement to keep.
- ☐ I understand the purpose of the study is to investigate what information is important for children under 18 years old before deciding to have early ACL reconstruction surgery or rehabilitation with the option for delayed ACL reconstruction.
- ☐ I acknowledge that the risks and benefits of participating in this study have been explained to me to my satisfaction.
- ☐ I understand that in this study I will be required to answer a pre-interview questionnaire (5-minutes) and attend an interview to provide feedback on an educational pamphlet on treatment options following ACL rupture (online, via telephone or in person pending on the COVID-19 situation) that will last 30-minutes.
- ☐ I understand that my participation will involve my interview to be recorded.
- ☐ I understand that information may be used in future research and the data collected for this study may use it in future projects. By providing consent I allow my information to be shared locally and internationally with other research collaborators as needed. I understand that it is unknown at this stage what these other projects will involve, and ethical approval will be gained before my information in used in these future projects.
- ☐ I understand that being in this study is completely voluntary.
- ☐ I am assured that my decision to participate will not have an impact on any relationship with the research team or the University of Sydney or the Local Health District.
- ☐ I understand that I am free to withdraw from this study at any time and that I can choose to withdraw any information I have already provided (unless the data has already been de-identified or published).
- ☐ I have been informed that the confidentiality of the information I provide will be protected and will only be used for purposes that I have agreed to. I understand that information about me will only be told to others with my permission, except as required by law.
- ☐ I understand that the results of this study may be published, and that publications will not contain my name or any identifiable information about me.

☐ Yes, I would be happy to participate in this study
☐ No, I would prefer not to participate in this study

3. I would like to be emailed a copy of the study results:
   - ☐ Yes
   - ☐ No

If YES, my email address is____

4. I consent to the future use of any data I provide for research purposes. I understand that before the investigators or their collaborators use any data that I provide, they must seek additional ethics approval.
   - ☐ Yes
   - ☐ No

Pre-interview Questionnaire

Study ID: _______________

Thank you for your participation in this study, which is investigating what information is important when considering early anterior cruciate ligament (ACL) reconstruction in children.

We would like you to answer a few questions before the interview. This should not take more than 5-minutes.

First some quick questions about you...

1. Please indicate your gender:
   - ☐ Female
   - ☐ Male
   - ☐ Non-binary
2. Please indicate your age: [free text response]

____

3. In which country did you receive your health professional training/qualification? [free text response]

____

4. What type of health professional are you?
   - ☐ Orthopaedic surgeon
   - ☐ General practitioner
   - ☐ Sports medicine doctor
   - ☐ Physiotherapist
   - ☐ Other (please specify) ______________________________
5. How many years have you been practicing? [free text response]

____

6. Which clinical setting have you spent the most time practicing in?
   - ☐ Private practice
   - ☐ Public hospital
   - ☐ Private hospital
   - ☐ Sports teams
   - ☐ Other (please specify) ______________________________

7. On average, how many patients with an ACL rupture do you manage/review per year? [free text response]

____

8. On average, what percentage of these patients do you advise to have ACL reconstruction surgery when they first visit you? [free text response]

____

Finally, when are the best times to schedule you for an online Zoom interview…

Please provide below your best contact details for a researcher from the University of Sydney to contact you and arrange the follow-up interview:

Name: ____

Email: ____

Best contact telephone number: ____________________________________

Best time/s to call: ____________________________________

Please mark the times that are suitable to arrange an interview in the boxes below:

	Monday	**Tuesday**	**Wednesday**	**Thursday**	**Friday**
8 – 10am					
10 – 12pm					
12 – 2pm					
2 – 4pm					
4 – 6pm					

Thank you for completing the questionnaire.

Example structure of interviews with parents, children and adolescent participants

Note: The topics below will serve as an outline to guide the interview

Introductions

- Brief explanation of the interview

Opening questions

- What treatments options have you heard of or been suggested to try following your ACL rupture?
- What do you think of ACL reconstruction surgery as a treatment?

Explain ACL reconstruction surgery to patients

"I am now going to give you a short explanation of ACL reconstruction and why it is indicated that has been standardised to read to each participant."

"ACL reconstruction requires admission to hospital, anesthetic and multiple surgical cuts to the knee. A 'graft' taken from the patient's own hamstring or quadriceps tendon, from another person's or made from synthetic material is used to reconstruct the ruptured ACL by fixating it between the bones of the knee joint. Immediately following surgery there is pain, swelling, reduced movement and a need for crutches. The aim of ACL reconstruction is to restore functional stability of the knee."

If reviewing an existing patient decision aid or investigator-developed one (relevant to focus groups in the later stages of developing the patient decision aid)

Instructions to parents, children and adolescents (as an example): The material we want you to review has been developed for parents, children and adolescents to improve their knowledge and confidence in making the decision to have early ACL reconstruction surgery or rehabilitation with the option for delayed ACL reconstruction surgery. We would like for you to help us better understand your experience of this material – for example, how you find the visual appeal, readability, content, and what are your overall experiences using this material**.**

To do this, I am going to ask you to think out loud while you read through the material. Just say everything that goes through your mind- if you are finding anything challenging, what your eye is drawn to. If a page is easy, and you understand what to do – just say that. Providing examples is very helpful (e.g. "look at a table", "look at a page with just text vs with an image").

Prompt questions as patients are reading through the material:

- How are you finding reading through this section?
- Did you feel like you knew where to look, and what to do next?
- Did you feel like you knew the relevance of this section in your decision?

- How did you find the content of this section?
- Were the instructions clear/helpful?
- How easy was it to understand the section? (readability)
- Was there anything that was unclear or confusing?
- How were the visual aids?
- How was the functionality?
- Is there anything that you would improve in this section?
- What did you like most about this material?
- What did you like least about this material?

Core questions

If we were designing an education leaflet to help you decide whether to have early ACL reconstruction surgery or begin rehabilitation with the option for delayed ACL reconstruction….

- What information is most important to know? (Prompt for views on presenting different treatment options, benefits and harms, recovery time, likelihood of need for revision surgery, details of the procedure)

"How do the following statements influence your thoughts about ACL reconstruction and non-surgical management?"

Osteoarthritis risk

- Surgery does not reduce the risk of OA compared to rehabilitation only or delayed surgery.

Rehabilitation with the option for delayed surgery:

Harms:

- Delayed ACL reconstruction > 12 weeks significantly increases the risk of meniscus injury in children.

Benefits:

- Studies in those aged 20-30 years old show 50% can avoid ACL reconstruction with rehabilitation.

ACL reconstruction:

Harms:

- Those younger than <20-25 years old who return to high-risk sport following ACL reconstruction have a second ACL injury rate of 23% (nearly 1 in 4).
- Note: Less risky sports were defined as: "pivoting with no contact", "weight bearing with no pivoting", and "non-weight bearing".

Benefits:

- Studies showed that you are 10 % more likely to return to your previous level of sport and 9% less likely to experience a serious complication with early ACL reconstruction."

(Ask if need prompting) "Do any of these statements stand out to you?"

Further questions:

Return to sport:

- Do you expect to return to your pre-injury level of sport?
- How long do you expect recovery to take?
- Would you consider activity modification?

Goals:

- What do you aim to achieve with management and how does this influence your decision?

Decision regret:

- Do you regret your decision (if they already had ACL reconstruction or re-rupture)?
- If you re-injure your knee, would you take the same management approach?

- How would you like information to be presented in terms of visual aids, text, tables, pictures, etc.? (Example below, but exact topics will depend on what arose from the previous question)
  - Different treatment options
  - Benefits and harms
  - Recovery time
  - Likelihood of need for revision surgery
  - Details of the procedure

General feedback at the end

- Are there any topics that you would like to see in future versions of this tool?
- Do you have any other general feedback, thoughts, or comments?

Example structure of interviews with adult participants

Note: The topics below will serve as an outline to guide the interview

Introductions

- Brief explanation of the interview

Opening questions

- What treatments options have you heard of or been suggested to try following your ACL rupture?
- What do you think of ACL reconstruction surgery as a treatment?

Explain ACL reconstruction surgery to patients

"I am now going to give you a short explanation of ACL reconstruction and why it is indicated that has been standardised to read to each participant."

"ACL reconstruction requires admission to hospital, anesthetic and multiple surgical cuts to the knee. A 'graft' taken from the patient's own hamstring or quadriceps tendon, from another person's or made from synthetic material is used to reconstruct the ruptured ACL by fixating it between the bones of the knee joint. Immediately following surgery there is pain, swelling, reduced movement and a need for crutches. The aim of ACL reconstruction is to restore functional stability of the knee."

If reviewing an existing patient decision aid or investigator-developed one (relevant to focus groups in the later stages of developing the patient decision aid)

Instructions to adult participants (as an example): The material we want you to review has been developed for parents, children and adolescents to improve their knowledge and confidence in making the decision to have early ACL reconstruction surgery or rehabilitation with the option for delayed ACL reconstruction surgery. We would like for you to help us better understand your experience of this material – for example, how you find the visual appeal, readability, content, and what are your overall experiences using this material taking your experience into account**.**

To do this, I am going to ask you to think out loud while you read through the material. Just say everything that goes through your mind- if you are finding anything challenging, what your eye is drawn to. If a page is easy, and you understand what to do – just say that. Providing examples is very helpful (e.g. "look at a table", "look at a page with just text vs with an image").

Prompt questions as patients are reading through the material:

- How are you finding reading through this section?
- Did you feel like you knew where to look, and what to do next?
- Did you feel like you knew the relevance of this section in your decision?

- How did you find the content of this section?
- Were the instructions clear/helpful?
- How easy was it to understand the section? (readability)
- Was there anything that was unclear or confusing?
- How were the visual aids?
- How was the functionality?
- Is there anything that you would improve in this section?
- What did you like most about this material?
- What did you like least about this material?

Core questions
If we were designing an education leaflet to help you decide whether to have early ACL reconstruction surgery or begin rehabilitation with the option for delayed ACL reconstruction….

- What information is most important to know? (Prompt for views on presenting different treatment options, benefits and harms, recovery time, likelihood of need for revision surgery, details of the procedure)

"How do the following statements influence your thoughts about ACL reconstruction and non-surgical management?"
<u>Osteoarthritis risk</u>

- Surgery does not reduce the risk of OA compared to rehabilitation only or delayed surgery.

<u>Rehabilitation with the option for delayed surgery:</u>
Harms:

- Delayed ACL reconstruction > 12 weeks significantly increases the risk of meniscus injury in children.

Benefits:

- Studies in those aged 20-30 years old show 50% can avoid ACL reconstruction with rehabilitation.

<u>ACL reconstruction:</u>
Harms:

- Those younger than <20-25 years old who return to high-risk sport following ACL reconstruction have a second ACL injury rate of 23% (nearly 1 in 4).
- Note: Less risky sports were defined as: "pivoting with no contact", "weight bearing with no pivoting", and "non-weight bearing".

Benefits:

- Studies showed that you are 10 % more likely to return to your previous level of sport and 9% less likely to experience a serious complication with early ACL reconstruction."

(Ask if need prompting) "Do any of these statements stand out to you?"

Further questions:
<u>Return to sport:</u>

- Did you expect to return to your pre-injury level of sport?
- How long did you expect recovery to take?
- Did you consider activity modification?

<u>Goals:</u>

- What did you aim to achieve with management and how did this influence your decision?

<u>Decision regret:</u>

- Do you regret your decision (if they already had ACL reconstruction or re-rupture)?
- If you re-injure your knee, would you take the same management approach?

- How would you like information to be presented in terms of visual aids, text, tables, pictures, etc.? (Example below, but exact topics will depend on what arose from the previous question)
    - Different treatment options
    - Benefits and harms
    - Recovery time
    - Likelihood of need for revision surgery
    - Details of the procedure

General feedback at the end

- Are there any topics that you would like to see in future versions of this tool?
- Do you have any other general feedback, thoughts, or comments?

Example structure of interviews with health professional participants

Note: The topics below will serve as an outline to guide the interview

Introductions

- Brief explanation of the interview

Opening questions

- What is your understanding of the treatment options following an anterior cruciate ligament (ACL) rupture? What causes it? How can it be treated?
- What do you think of ACL reconstruction surgery as a treatment?

Brief explanation of ACL reconstruction surgery to health professionals (depending on their current level of understanding e.g. do not explain this to an orthopedic surgeon)

"I am now going to give you a short explanation of ACL reconstruction and why it is indicated that has been standardised to read to each participant."

"ACL reconstruction requires admission to hospital, anesthetic and multiple surgical cuts to the knee. A 'graft' taken from the patient's own hamstring or quadriceps tendon, from another person's or made from synthetic material is used to reconstruct the ruptured ACL by fixating it between the bones of the knee joint. Immediately following surgery there is pain, swelling, reduced movement and a need for crutches. The aim of ACL reconstruction is to restore functional stability of the knee."

Core questions

If we were designing an education leaflet to help patients decide whether to have ACL reconstruction surgery or not….

- What information is most important for them to know? (prompt for views on presenting different treatment options, benefits and harms, recovery time, likelihood of need for revision surgery, details of the procedure, etc.)
- How would you like information to be presented in terms of visual aids, text, tables, pictures, etc.? (example below, but exact topics will depend on what arose from the previous question)
    - Different treatment options
    - Benefits and harms
    - Recovery time
    - Likelihood of need for revision surgery
    - Details of the procedure
- How would your response to the above options differ if the information was intended to be used during a consultation with a health professional?

If reviewing an existing patient decision aid or investigator-developed one (relevant to focus groups in the later stages of developing the patient decision aid)

Instructions to health professionals (as an example): The material we want you to review has been developed for parents, children and adolescents to improve their knowledge and confidence in making the decision to have ACL reconstruction surgery or not. We would like for you to help us refine this material – for example, how you find the visual appeal, readability, content, and what are your overall thoughts on patients using this material?

To do this, I am going to ask you to think out loud while you read through the material. Just say everything that goes through your mind- if you are finding anything confusing, what your eye is drawn to. If a page is easy, and you understand what to do – just say that. Providing examples is very helpful (e.g. "look at a table", "look at a page with just text vs with an image").

Prompt questions as health professionals are reading through the material:

- How do you think patients would find this section?
- Did you feel like patients will know where to look, and what to do next?

- Did you feel like patients knew the relevance of this section in their decision?
- How do you think patients will find the content of this section?
- Were the instructions clear/helpful?
- How easy was it to understand the section? (readability)
- Was there anything that was unclear or confusing?
- How were the visual aids?
- How was the functionality?
- Is there anything that you would improve in this section?
- What did you like most about this material?
- What did you like least about this material?

General feedback at the end

- Are there any topics that you would like to see in future versions of this tool?
- Do you have any other general feedback, thoughts, or comments?

Supplementary File 10: Acceptability questionnaire for children, adolescents, parents, and adults

We would like to know what you think about the patient decision aid you have just read.

Which participant group are you?

- Parent/Gaurdian
- Child or Adolescent
- Adult

1. Please rate each section by circling 'poor', 'fair', 'good', or 'excellent' to show what you think about the way the information was presented on:

Who should read this decision aid?	Poor	Fair	Good	Excellent
Diagram of management options following ACL rupture	Poor	Fair	Good	Excellent
The treatment options covered in this decision aid	Poor	Fair	Good	Excellent
Comparing benefits and harms of each management option for those aged < 18 years old	Poor	Fair	Good	Excellent
Summary of benefits and harms of each option	Poor	Fair	Good	Excellent

2. The length of the decision aid was:
    a. Too long
    b. Too short
    c. Just right
3. The amount of information was:
    a. Just right
    b. Too much
    c. Too little
4. I found the decision aid:
    a. Balanced
    b. Slanted towards rehab only (or delayed ACL surgery)
    c. Slanted towards ACL reconstruction surgery (early ACL surgery)
5. Would you find (or would you have found) this decision aid useful when/if you were making your decision about ACL reconstruction surgery?
    a. Not at all useful
    b. Slightly useful
    c. Moderately useful
    d. Very useful

    e. Extremely useful

6. Did this decision aid/would this decision aid make your decision to have ACL reconstruction surgery…?
    a. Easier (option to comment)
    b. More difficult (option to comment)

Supplementary File 11: Acceptability questionnaire for Health Professionals

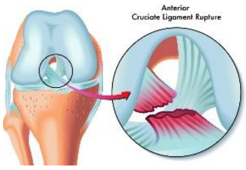
We would like to know what you think about the patient decision aid you have just read.

Please rate each section by selecting 'strongly agree', 'agree' 'neutral', 'disagree' or 'strongly disagree' to show what you think about the way the information was presented on:

In general:	**Strongly agree**	**Agree**	**Neutral**	**Disagree**	**Strongly disagree**
It will be easy for me to use	1	2	3	4	5
It is easy for me to understand	1	2	3	4	5
It will be easy for me to experiment with using it before making a final decision to adopt it	1	2	3	4	5
The results of using the decision aid will be easy to see	1	2	3	4	5
This decision aid is better than how I usually go about helping patients decide about ACL reconstruction surgery	1	2	3	4	5
This decision aid is compatible with the way I think ACL ruptures should be managed	1	2	3	4	5
Compared with my usual approach, this decision aid will result in my patients making more informed decisions	1	2	3	4	5
Using this decision aid will save me time	1	2	3	4	5
This decision aid is a reliable method of helping patients make decisions about ACL reconstruction surgery	1	2	3	4	5
Pieces or components of the decision aid can be used by themselves	1	2	3	4	5
This type of decision aid is suitable for helping patients make value laden choices	1	2	3	4	5
This decision aid complements my usual approach	1	2	3	4	5
Using this decision aid does not involve making major changes to the way I usually do things	1	2	3	4	5
There is a high probability that using this decision aid may cause/result in more benefit than harm	1	2	3	4	5

I ruptured my ACL: Should I have surgery?

Who should read this decision aid?



This decision aid is for children or adolescents who have ruptured their anterior cruciate ligament (ACL). ACL rupture is when the two ends of the ligament become completely separated, often because of quickly changing direction or landing from a jump. If you also injured other parts of your knee (e.g., meniscus) or your knee continues to 'give way' or feel unsteady, your treatment needs may be different.

This decision aid should be used with parents/guardians and a health professional team. For example: Physiotherapist, Orthopaedic surgeon, General Practitioner.

Option #1 **Rehab only*** **(or delayed ACL surgery)**	**Management options after ACL rupture**	Option #2 **ACL surgery** **(early ACL reconstruction)**
	Health professionals will prescribe your exercises and perform testing to guide progression and return to activity, training or sport.	
6-9 months	Potential return to sport	9-12 months
After 9 months	Continue exercises + injury prevention	After 12 months

*Talk to a health professional if your knee keeps 'giving way' despite following advice.

No option guarantees you won't injure your knee again, but this decision aid was developed to assist patients with choosing the best option.

Remember to consider long-term goals and see people who can support you (e.g., friends).

What is covered in the decision aid?

Page

Important: This decision aid is not a substitute for advice from a health professional who should confirm your diagnosis.

Disclosure: There was no funding to develop this tool. The developers of this decision aid include orthopaedic surgeons, physiotherapists, psychology researchers & occupational therapists. None of the developers will gain or lose anything based on the choices that people make. **Last reviewed:** Updated 17.10.2023 and to be updated by 17.10.2025. Developed by Andrew Gamble, Institute for Musculoskeletal Health, School of Public Health, The University of Sydney, NSW, Australia.

Institute for Musculoskeletal Health

THE UNIVERSITY OF SYDNEY

What are the treatment options covered in this decision aid?

2

1. Rehab only (or delayed ACL surgery)

Exercise-based rehabilitation is used to improve movement, strength, control and fitness. You can see if you can gradually progress to harder exercises without surgery. It is okay to experience some discomfort with exercise.

After an ACL rupture occurs

See a health professional.

0-1 month post injury

With the help of a health professional, gradually perform harder exercises at home or in a gym. You may be recommended to wear a brace.

1-3 months post injury

You may begin activities like running, swimming or outdoor cycling.

6-9 months post injury

You may return to sports like soccer, basketball, volleyball or rugby.

After 9 months post injury

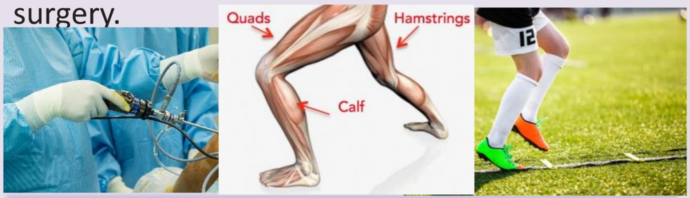
Continue exercises to help your functional recovery and keep the knee strong.

If you decide to have **delayed ACL surgery** at any point, then you should follow the milestones from option 2 (ACL surgery) from the beginning.

Caution: If your knee ‘gives way’ after **3 months**, talk to your health professional. You may be at risk of further injury.

2. ACL surgery (early ACL reconstruction)

During surgery you are put to sleep. A replacement ACL from another part of your leg or from a donor is attached by drilling into the bone inside the knee. For weeks after surgery, you will need crutches to walk and for months, you will have pain and swelling in the knee. Expect to have small scars from surgery.



After an ACL rupture occurs

See a health professional.

0–1 month post surgery

After surgery you will have pain and difficulty with self-care/walking. With the help of a health professional, gradually start exercises. You may be recommended to wear a brace.

1-3 months post surgery

With the help of a health professional, gradually start harder exercises at home or in a gym.

3 months post surgery

You may begin activities like running, swimming or outdoor cycling.

9-12 months post surgery

You may return to sports like soccer, basketball, volleyball or rugby.

After 12 months post surgery

Continue exercises to help your functional recovery and keep the knee strong.

Caution: You are twice as likely to have another ACL rupture if you return to competitive sport at 8 months compared to 9 months. The risk is even higher if you return to sport before 8 months.[1]

Comparing potential benefits and harms between rehab only (or delayed ACL surgery) and ACL surgery (early ACL surgery) using data from people under 18 years old

This page is based on the best but **very low-quality evidence** in people under 18 years old at approximately 2 years post injury. People participated in pivoting sports (e.g., soccer or skiing).[2] High-quality evidence shows that adults who choose rehab only (with the option for delayed ACL surgery) or early ACL surgery can achieve similar function and return to sport outcomes.[3,4]

1. Rehab only (or delayed ACL surgery)

Delayed ACL surgery = 3 months or later

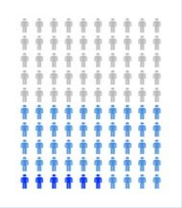
2. ACL surgery (early ACL reconstruction)

Early ACL surgery = before 3 months

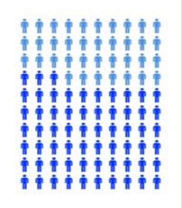
+ Return to pre-injury sport

Not everyone will return to their pre-injury level of sport with either option.

Rehab only:
Between
6 and 50 people per 100
return to their pre-injury sport
around 20 months after injury.[2]



Delayed ACL surgery:
Between
63 and 100 people per 100
return to their pre-injury sport
around 22 months after injury.[2]



Early ACL surgery:
Between
57 and 100 people per 100
return to their pre-injury sport
around 24 months after injury.[2]

− Precautions and potential harms

- Between 0 and 40 people per 100 decide to have **ACL surgery** after 6 months or longer.[2]
- Delaying **ACL surgery** if the knee is unstable may increase the risk of meniscus* injury or ongoing knee instability.[2]

* meniscus are important shock absorbing structures that protect the knee against osteoarthritis.[2]

- On average, 1 in 4 people rupture their ACL graft or have another ACL rupture on the other knee after 12 months or longer.[5]
- 2 people per 100 can experience growth issues due to ACL surgery.[6]
- ACL surgery also has other risks (e.g., infection, general anaesthetic, graft site issues and loss of feeling around the knee).[7]

Questions to consider when talking to a health professional…

- Will my choice affect what sport I play?
- If I am still growing, will this affect my management?
- What type of graft is best for me if I have ACL surgery?
- Is there any psychological support available?
- What should I do now? How do previous injuries and the timing of the sport season influence me? What experience do you have with people my age? Do I need pain medication? and what are the potential costs involved?

Summary of potential benefits and harms of rehab only (or delayed ACL surgery) and ACL surgery (early ACL surgery) using data from people under 18 years old

4

1. Rehab only (or delayed ACL surgery)

+ Positives and potential benefits

- Between 41 – 100 children and adolescents per 100 may avoid having ACL surgery.[2]
- In some countries you may save money by avoiding ACL surgery.
- You may return to sport sooner.[2]
- You will not increase your risk of knee osteoarthritis.[8]
- Your ACL may heal.[9]

− Precautions and potential harms

- You may still have delayed ACL surgery and slow your return to sport or activity.
- You may experience ‘giving way’ of the knee which could cause further injury.
- Cost of rehabilitation.
- Consider the risk of meniscus damage if the knee continues to be unstable.[2]
- You may be recommended to use a brace when returning to activity and sport. [2]

2. ACL surgery (early ACL reconstruction)

+ Positives and potential benefits

- You may be more likely to return to your pre-injury level of sport.[2]

− Precautions and potential harms

- On average, 1 in 4 people rupture their ACL graft or have another ACL rupture on the other knee after 12 months or longer. [5]
- It can take 12 months to return to competitive sport.[7]
- Cost of ACL surgery plus rehabilitation.
- You will need time off school/work due to pain, swelling, reduced movement and the need to use crutches.
- 2 children per 100 may experience growth issues following surgery.[6]
- ACL surgery also has other risks (e.g., infection, general anaesthetic, graft site issues and loss of feeling around the knee).[7]

+ Key points

- Choose what is best for your situation
- If you chose rehab only, you could still decide to have delayed ACL surgery later
- See family, friends and health professionals for support
- Listen and care for your whole-body
- Care for your mental and physical health
- Plan to try new activities
- Don’t rush – expect challenges
- Stay positive!

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1) Grindem H, et al. Br J Sports Med. 2016;50(13):804–8
2) James EW, et al. Am J Sports Med. 2021; 49(14):4008-4017
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7) Ardern CL, et al. KSST. 2018;26(4):898-1010
8) Webster, K et al. CJSM. 2022;32(2):145-152
9) Pitsillides, A et al. J Bodyw Mov Ther. 2021;28:246-254

COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	6
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	1
Occupation	3	What was their occupation at the time of the study?	1
Gender	4	Was the researcher male or female?	6
Experience and training	5	What experience or training did the researcher have?	6
Relationship with participants			
Relationship established	6	Was a relationship established prior to study commencement?	5
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	5
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	5
Domain 2: Study design			
Theoretical framework			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	7
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	5
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	5
Sample size	12	How many participants were in the study?	7
Non-participation	13	How many people refused to participate or dropped out? Reasons?	8
Setting			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	6
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	6
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	9
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	6
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	8
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	6
Field notes	20	Were field notes made during and/or after the inter view or focus group?	6
Duration	21	What was the duration of the inter views or focus group?	6
Data saturation	22	Was data saturation discussed?	7
Transcripts returned	23	Were transcripts returned to participants for comment and/or	7

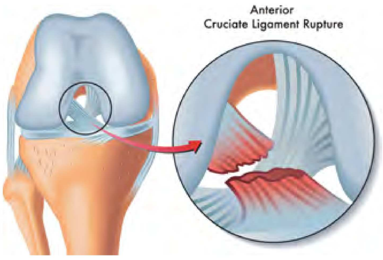
Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	7
Description of the coding tree	25	Did authors provide a description of the coding tree?	7
Derivation of themes	26	Were themes identified in advance or derived from the data?	7
Software	27	What software, if applicable, was used to manage the data?	7
Participant checking	28	Did participants provide feedback on the findings?	7
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	14
Data and findings consistent	30	Was there consistency between the data presented and the findings?	14
Clarity of major themes	31	Were major themes clearly presented in the findings?	14
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	16 and 17

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

Once you have completed this checklist, please save a copy and upload it as part of your submission. DO NOT include this checklist as part of the main manuscript document. It must be uploaded as a separate file.

I RUPTURED MY ACL:
SHOULD I HAVE SURGERY?

Who should read this decision aid?



This decision aid is for children or adolescents who have ruptured their anterior cruciate ligament (ACL).

ACL rupture is when the two ends of the ligament become completely separated, often because of quickly changing direction or landing from a jump. If you also injured other parts of your knee (e.g., meniscus) or your knee continues to 'give way' or feel unsteady, your treatment needs may be different.

This decision aid should be used with parents/guardians and a health professional team. For example: Physiotherapist, Orthopaedic surgeon, General Practitioner.

OPTION 1 - REHAB ONLY* (or delayed ACL surgery)	MANAGEMENT OPTIONS AFTER ACL RUPTURE	OPTION 2 - ACL SURGERY (early ACL reconstruction)
	Health professionals will prescribe your exercises and perform testing to guide progression and return to activity, training or sport.	
6 - 9 months	Potential return to sport	9 - 12 months
After 9 months	Continuous exercises + injury prevention	After 12 months

*Talk to a health professional if your knee keeps 'giving way' despite following advice.

No option guarantees you won't injure your knee again, but this decision aid was developed to assist patients with choosing the best option.

Remember to consider long-term goals and see people who can support you (e.g., friends).

What is covered in the decision aid?

Important information: This decision aid is not a substitute for advice from a health professional who should confirm your diagnosis.

Disclosure: There was no funding to develop this tool. The developers of this decision aid include orthopaedic surgeons, physiotherapists, psychology researchers & occupational therapists. None of the developers will gain or lose anything based on the choices that people make. Last reviewed: updated 17.10.2023 and to be updated by 17.10.2025. Developed by Andrew Gamble, Institute for Musculoskeletal Health, School of Public Health, The University of Sydney, NSW, Australia.

Institute for Musculoskeletal Health

THE UNIVERSITY OF SYDNEY

+ What are the treatment options covered in this decision aid?

OPTION 1 - REHAB ONLY*

(or delayed ACL surgery)

Exercise-based rehabilitation is used to improve movement, strength, control and fitness. You can see if you can gradually progress to harder exercises without surgery. It is okay to experience some discomfort with exercise.

✓ **After an ACL rupture occurs**

See a health professional.

✓ **0-1 month post injury**

With the help of a health professional, gradually perform harder exercises at home or in a gym. You may be recommended to wear a brace.

✓ **1-3 months post injury**

You may begin activities like running, swimming or outdoor cycling.

✓ **6-9 months post injury**

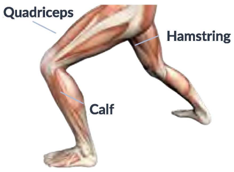
You may return to sports like soccer, basketball, volleyball or rugby.

✓ **After 9 months post injury**

Continue exercises to help your functional recovery and keep the knee strong.

If you decide to have delayed **ACL surgery** at any point, then you should follow the milestones from option 2 (ACL surgery) from the beginning.

Caution: If your knee 'gives way' after **3 months**, talk to your health professional. You may be at risk of further injury.



OPTION 2 - ACL SURGERY

(early ACL reconstruction)

During surgery you are put to sleep. A replacement ACL from another part of your leg or from a donor is attached by drilling into the bone inside the knee. For weeks after surgery, you will need crutches to walk and for months, you will have pain and swelling in the knee. Expect to have small scars from surgery.

✓ **After an ACL rupture occurs**

See a health professional.

✓ **0-1 month post surgery**

After surgery you will have pain and difficulty with self-care/walking. With the help of a health professional, gradually start exercises. You may be recommended to wear a brace.

✓ **1-3 months post surgery**

With the help of a health professional, gradually start harder exercises at home or in a gym.

✓ **3 months post surgery**

You may begin activities like running, swimming or outdoor cycling.

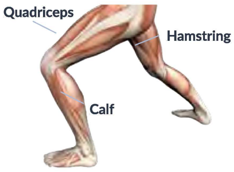
✓ **9-12 months post surgery**

You may return to sports like soccer, basketball, volleyball or rugby.

✓ **After 12 months post surgery**

Continue exercises to help your functional recovery and keep the knee strong.

Caution: You are twice as likely to have another ACL rupture if you return to competitive sport at 8 months compared to 9 months. The risk is even higher if you return to sport before 8 months.[1]



Comparing potential benefits and harms

Between rehab only (or delayed ACL surgery) and ACL surgery (early ACL surgery) using data from people under 18 years old

This page is based on the best but **very low-quality evidence** in people under 18 years old at approximately 2 years post injury. People participated in pivoting sports (e.g., soccer or skiing).[2]

High-quality evidence shows that adults who choose rehab only (with the option for delayed ACL surgery) or early ACL surgery can achieve similar function and return to sport outcomes.[3,4]

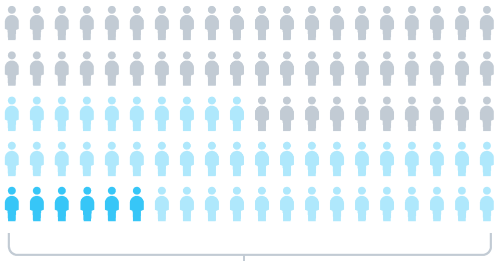
OPTION 1 - REHAB ONLY

(or delayed ACL surgery = 3 months or later)

Return to pre-injury sport

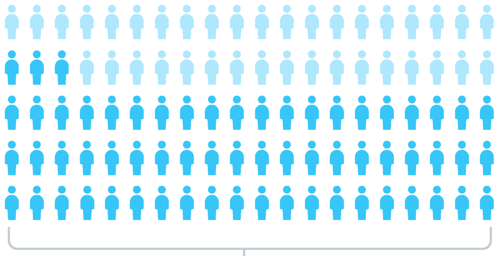
(Not everyone will return to their pre-injury level of sport)

Rehab only:



Between 6 and 50 people per 100 return to their pre-injury sport around 20 months after injury.[2]

Delayed ACL surgery:



Between 63 and 100 people per 100 return to their pre-injury sport around 22 months after injury.[2]

Precautions and potential harms

- Between 0 and 40 people per 100 decide to have **ACL surgery** after 6 months or longer.[2]
- Delaying **ACL surgery** if the knee is unstable may increase the risk of meniscus* injury or ongoing knee instability.[2]

*meniscus are important shock absorbing structures that protect the knee against osteoarthritis.[2]

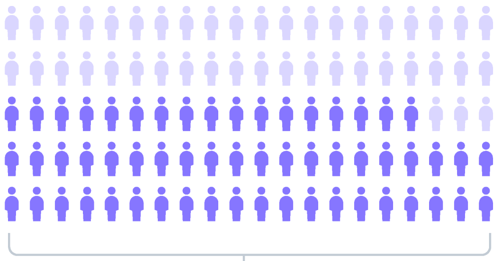
OPTION 2 - ACL SURGERY

(early ACL reconstruction = before 3 months)

Return to pre-injury sport

(Not everyone will return to their pre-injury level of sport)

Early ACL surgery:



Between 57 and 100 people per 100 return to their pre-injury sport around 20 months after injury.[2]

Precautions and potential harms

- On average, 1 in 4 people rupture their ACL graft or have another ACL rupture on the other knee after 12 months or longer.[5]
- 2 people per 100 can experience growth issues due to ACL surgery.[6]
- ACL surgery also has other risks (e.g., infection, general anaesthetic, graft site issues and loss of feeling around the knee).[7]

+ Summary of potential benefits and harms

Of rehab only (or delayed ACL surgery) and ACL surgery (early ACL surgery) using data from people under 18 years old

OPTION 1 - REHAB ONLY

(or delayed ACL surgery)

✓ Positives and potential benefits

- Between 41 - 100 children and adolescents per 100 may avoid having ACL surgery.[2]
- In some countries you may save money by avoiding ACL surgery.
- You may return to sport sooner.[2]
- You will not increase your risk of knee osteoarthritis.[8]
- Your ACL may heal.[9]

− Precautions and potential harms

- You may still have delayed ACL surgery and slow your return to sport or activity.
- You may experience 'giving way' of the knee which could cause further injury.
- Cost of rehabilitation.
- Consider the risk of meniscus damage if the knee continues to be unstable.[2]
- You may be recommended to use a brace when returning to activity and sport.[2]

OPTION 2 - ACL SURGERY

(early ACL reconstruction)

✓ Positives and potential benefits

- You may be more likely to return to your pre-injury level of sport.[2]

− Precautions and potential harms

- On average, 1 in 4 people rupture their ACL graft or have another ACL rupture on the other knee after 12 months or longer.[5]
- It can take 12 months to return to competitive sport.[7]
- Cost of ACL surgery plus rehabilitation.
- You will need time off school/work due to pain, swelling, reduced movement and the need to use crutches.
- 2 children per 100 may experience growth issues following surgery.[6]
- ACL surgery also has other risks (e.g., infection, general anaesthetic, graft site issues and loss of feeling around the knee).[7]

+ Key points

- Choose what is best for your situation
- If you chose rehab only, you could still decide to have delayed ACL surgery later
- Listen and care for your whole-body
- See family, friends and health professionals for support
- Care for your mental and physical health
- Plan to try new activities
- Don't rush - expect challenges and stay positive!

+ Questions to consider when talking with a health professional...

- Will my choice affect what sport I play?
- If I am still growing, will this affect my management?
- What type of graft is best for me if I have ACL surgery?
- Is there any psychological support available?

What should I do now? How do previous injuries and the timing of the sport season influence me? What experience do you have with people my age? Do I need pain medication? and what are the potential costs involved?

References: **1)** Grindem H, et al. Br J Sports Med. 2016; 50(13):804–8
2) James EW, et al. Am J Sports Med. 2021; 49(14):4008-4017
3) Frobell RB, et al. NEJM 2010; 363(4):331-342
4) Reijman M, et al. BMJ 2021; 372-375
5) Wiggins AJ, et al. Am J Sports Med. 2016; 44(7):1861–76
6) Frosch KH, Arthroscopy, 2010; 26:1539–50
7) Ardern CL, et al. KSST. 2018; 26 (4):898-1010
8) Webster, Ketal. CJSM. 2022; 32(2):145-152
9) Pitsillides, Aetal. J Bodyw Mov Ther. 2021; 28:246-254

Supplementary File 13. International Patient Decision Aid Standards checklist (IPDASi v4.0)

Qualifying criteria	**Answer**
1. The patient decision aid describes the health condition or problem (treatment, procedure, or investigation) for which the index decision is required.	Yes
2. The patient decision aid explicitly states the decision that needs to be considered (index decision).	Yes
3. The patient decision aid describes the options available for the index decision.	Yes
4. The patient decision aid describes the positive features (benefits or advantages) of each option.	Yes
5. The patient decision aid describes the negative features (harms, side effects, or disadvantages) of each option.	Yes
6. The patient decision aid describes what it is like to experience the consequences of the options (e.g., physical, psychological, social).	Yes
Certification criteria	**Answer**
1. The patient decision aid shows the negative and positive features of options with equal detail (e.g., using similar fonts, sequence, presentation of statistical information).	Yes
2. The patient decision aid (or associated documentation) provides citations to the evidence selected.	Yes
3. The patient decision aid (or associated documentation) provides a production or publication date.	Yes
4. The patient decision aid (or associated documentation) provides information about the update policy.	Yes
5. The patient decision aid provides information about the levels of uncertainty around event or outcome probabilities (e.g., by giving a range or by using phases such as ‘‘our best estimate is . . .’’).	Yes
6. The patient decision aid (or associated documentation) provides information about the funding source used for development.	Yes
7. The patient decision aid describes what the test is designed to measure.	N/A
8. If the test detects the condition or problem, the patient decision aid describes the next steps typically taken.	N/A
9. The patient decision aid describes the next steps if the condition or problem is not detected.	N/A
10. The patient decision aid has information about the consequences of detecting the condition or disease that would never have caused problems if screening had not been done (lead time bias).	N/A
Quality criteria	**Answer**
1. The patient decision aid describes the natural course of the health condition or problem, if no action is taken (when appropriate).	Yes
2. The patient decision aid makes it possible to compare the positive and negative features of the available options.	Yes
3. The patient decision aid provides information about outcome probabilities associated with the options (i.e., the likely consequences of decisions).	Yes
4. The patient decision aid specifies the defined group (reference class) of patients for whom the outcome probabilities apply.	Yes
5. The patient decision aid specifies the event rates for the outcome probabilities	Yes
6. The patient decision aid allows the user to compare outcome probabilities across options using the same time period (when feasible).	Yes

7. The patient decision aid allows the user to compare outcome probabilities across options using the same denominator (when feasible).	Yes
8. The patient decision aid provides more than 1 way of viewing the probabilities (e.g., words, numbers, and diagrams).	Yes
9. The patient decision aid asks patients to think about which positive and negative features of the options matter most to them (implicitly or explicitly).	Yes
10. The patient decision aid provides a step-by step way to make a decision.	Yes
11. The patient decision aid includes tools like worksheets or lists of questions to use when discussing options with a practitioner.	Yes
12. The development process included a needs assessment with clients or patients.	Yes
13. The development process included a needs assessment with health professionals.	Yes
14. The development process included review by clients/patients not involved in producing the decision support intervention.	Yes
15. The development process included review by professionals not involved in producing the decision support intervention.	Yes
16. The patient decision aid was field tested with patients who were facing the decision.	Yes
17. The patient decision aid was field tested with practitioners who counsel patients who face the decision.	Yes
18. The patient decision aid (or associated documentation) describes how research evidence was selected or synthesized.	Yes
19. The patient decision aid (or associated documentation) describes the quality of the research evidence used.	Yes
20. The patient decision aid includes authors’/developers’ credentials or qualifications.	Yes
21. The patient decision aid (or associated documentation) reports readability levels (using 1 or more of the available scales).	Yes
22. There is evidence that the patient decision aid improves the match between the preferences of the informed patient and the option that is chosen.	No*
23. There is evidence that the patient decision aid helps patients improve their knowledge about options’ features.	No*
24. The patient decision aid includes information about the chances of having a true-positive test result.	N/A
25. The patient decision aid includes information about the chances of having a true-negative test result.	N/A
26. The patient decision aid includes information about the chances of having a false-positive test result.	N/A
27. The patient decision aid includes information about the chances of having a false-negative test result.	N/A
28. The patient decision aid describes the chances the disease is detected with and without the use of the test.	N/A

N/A: not applicable.
*We plan to evaluate the decision aid in a randomised controlled trial.

Supplementary File 14. User-Centered Design 11-item measure (UCD-11)

Items	Explanations and examples	Yes/No
1. Were potential end users (eg, patients, caregivers, family and friends, surrogates) involved in any steps to help understand users (eg, who they are, in what context might they use the tool) and their needs?	Such steps could include various forms of user research, including formal or informal needs assessment, focus groups, surveys, contextual inquiry, ethnographic observation of existing practices, literature review in which users were involved in appraising and interpreting existing literature, development of user groups, personas, user profiles, tasks, or scenarios, or other activities	Yes
2. Were potential end users involved in any steps of designing, developing, and/or refining a prototype?	Such steps could include storyboarding, reviewing the draft design or content before starting to develop the tool, and designing, developing, or refining a prototype	Yes
3. Were potential end users involved in any steps intended to evaluate prototypes or a final version of the tool?	Such steps could include feasibility testing, usability testing with iterative prototypes, pilot testing, a randomized controlled trial of a final version of the tool, or other activities	Yes
4. Were potential end users asked their opinions of the tool in any way?	For example, they might be asked to voice their opinions in a focus group, interview, survey, or through other methods	Yes
5. Were potential end users observed using the tool in any way?	For example, they might be observed in a think-aloud study, cognitive interviews, through passive observation, logfiles, or other methods	Yes
6. Did the development process have 3 or more iterative cycles?	The definition of a cycle is that the team developed something and showed it to at least one person outside the team before making changes; each new cycle leads to a version of the tool that has been revised in some small or large way	Yes
7. Were changes between iterative cycles explicitly reported in any way?	For example, the team might have explicitly reported them in a peer-reviewed paper or in a technical report. In the case of rapid prototyping, such reporting could be, for example, a list of design decisions made and the rationale for the decisions	No
8. Were health professionals asked their opinion of the tool at any point?	Health professionals could be any relevant professionals, including physicians, nurses, allied health providers, etc. These professionals are not members of the research team. They provide care to people who are likely users of the tool. Asking for their opinion means simply asking for feedback, in contrast to, for example, observing their interaction with the tool or assessing the impact of the tool on health professionals' behavior	Yes

9. Were health professionals consulted before the first prototype was developed?	Consulting before the first prototype means consulting prior to developing anything. This may include a variety of consultation methods	Yes
10. Were health professionals consulted between initial and final prototypes?	Consulting between initial and final prototypes means some initial design of the tool was already created when consulting with health professionals	Yes
11. Was an expert panel involved?	An expert panel is typically an advisory panel composed of experts in areas relevant to the tool if such experts are not already present on the research team (eg, plain language experts, accessibility experts, designers, engineers, industrial designers, digital security experts, etc). These experts may be health professionals but not health professionals would provide direct care to end users	Yes

Supplementary file 12: Reasons for not implementing feedback for each section of the decision aid.

Themes	Sub themes	Feedback	Reason for not implementing feedback
Negative feedback on the decision aid	Negative feedback on the content	Health Professionals:	Health Professionals:
		A decision aid cannot be made for adolescents and children due to poor supporting evidence. [OS] It was suggested that pictures were not necessary in the decision aid. [PT]	We believe that it is still possible to create a decision aid using the best available evidence. We had a large amount of opposing feedback that participants liked the inclusion of some pictures.
Outline how the decision aid should be used	Improve clarity on the target population	Health Professionals:	Health Professionals:
		Add who does well with each option. For example, how many episodes of giving way is acceptable. [PT]	We couldn't do this as there is no evidence on who does well with each outcome.
	Clarify that choices should be made based on individual circumstances	Adults:	Adults:
		Provide definitions of what a successful or unsuccessful outcome.	Treatment success is individualised.
		Health Professionals:	Health Professionals:
		Add that decisions should be made based on skeletal maturity rather than age. [OS]	We decided to specify a recommended age limit for use of the decision aid and did not mention skeletal maturity directly due to feedback it was too complex for children and adolescents to understand.
More information about specific considerations	Highlight the importance of social and psychological support, and whole-body health	Parents:	Parents:
		Some parents suggested including information about alternative medicine.	There is a lack of supporting evidence for alternative medicine in both adults and children.
		Health Professionals:	Health Professionals:

following ACL rupture		Add information on methods of pain management. For example, the need for massage. [PT]	There is a lack of supporting evidence for pain management using massage in both adults and children.
	Revise the management options to include evidence on ACL healing, bracing and 'prehabiliation'	Children and adolescents:	Children and adolescents:
		Include non-operative bracing as another option. Give an estimation of the percentage of people that can have ACL healing.	There is currently no evidence comparing non-operative bracing to rehab only and ACL reconstruction. There is currently no strong link between ACL healing and outcomes so we did not want to overload children and adolescents with more statistics.
		Adults:	Adults:
		Include that it can take time to book ACL reconstruction, depending on if you have surgery privately or publicly.	This information was decided to be unnecessary as both rehabilitation timeframes mention the need to see a health professional.
		Health Professionals:	Health Professionals:
		Include recommendations of prehabiliation and checking if the ACL has healed after three months. [PT]	There is no evidence that prehabiliation is beneficial and there is currently no strong link between ACL healing and outcomes, so we did not want to overload children and adolescents with more statistics.
	Include more information on practical factors influencing management choices	Children and adolescents:	Children and adolescents:
		Include that COVID 19 may have influenced having an ACL rupture.	There is no evidence to support this claim, so we decide to exclude.
		Adults:	Adults:
		Add consider the time it can take to book surgery.	This information was decided to be unnecessary as both rehabilitation timeframes recommend seeing a health professional.

		Parents:	Parents:
		Add the consideration of scar size following ACL reconstruction surgery.	Scars are mentioned in the description of ACL reconstruction, but we do not expand beyond this as there is a lack of high-quality evidence on the importance of scar size following ACL reconstruction.
		Health Professionals:	Health Professionals:
		Add a statement that meniscus is a secondary restraint in pivoting without an ACL. [OS]	We did not include this statement as it was beyond the scope of this decision aid.
		Include the injury risk related to graft type. [PT]	We included a question about graft choices which provides an opportunity to discuss graft choice with a health professional.
	Add or remove questions	Parents:	Parents:
		The decision aid could prompt children and adolescents to ask about other previous injuries not just the ACL.	We included a question about previous injuries, but this was otherwise beyond the scope of this decision aid.
		Health Professionals:	Health Professionals:
		Add 'what factors have been shown to make a bigger difference' in achieving outcomes. [PT]	We did not include this statement directly as there is no evidence on who does well with each outcome.
		Add 'if I don't have surgery how would my knee function be in the future? [OS]	We did not include this question as it could be considered a leading question.
Change or add information on rehabilitation, exercises and return to sport	Include more detail on return to sport following ACL rupture	Health Professionals:	Health Professionals:
		Include a statistic that participation in change of direction sports in children following ACL rupture may mean a higher risk of meniscus damage. [PT]	We did not include this statement as it was beyond the scope of this decision aid.
		Children and adolescents:	Children and adolescents:

	Refine rehabilitation progression timeframes	Add remember to also focus on the uninjured leg during rehabilitation.	This information was decided to be unnecessary as both rehabilitation timeframes recommend seeing a health professional.
		Adults:	Adults:
		Add to settle the knee with bed exercises to avoid confusion that you start harder exercise straight away.	This information was decided to be unnecessary as both rehabilitation timeframes recommend seeing a health professional.
		Health Professionals:	Health Professionals:
		Add patient milestones or goals of each rehabilitation phase. [PT] Include when activities can be done. [OS]	This information was decided to be unnecessary as both rehabilitation timeframes recommend seeing a health professional.
	Clarify the importance of testing rehabilitation progress and return to training or competition sport	Health Professionals:	Health Professionals:
		Add more detail on the classification of the individual’s current level of sport and their desired level of sport. [PT]	We did not include this statement as it was beyond the scope of this decision aid.
	Expand on the type of exercises involved in management	Children and adolescents:	Children and adolescents:
		Include the need to get a gym membership.	We did not include this statement as it was beyond the scope of this decision aid.
		Adult:	Adult:
		Include the importance of hard work on quadriceps muscle at the gym.	Providing specific rehabilitation guidelines were beyond the scope of the decision aid.
		Health Professionals:	Health Professionals:
		It was suggested to provide more detail on muscle strengthening programs and how exercise can help to stabilise the knee. [PT]	Providing specific rehabilitation guidelines were beyond the scope of the decision aid.

	Consider the long-term need for ongoing "hard work" and injury prevention	Health Professionals:	Health Professionals:
		Note that if meniscus and cartilage injuries happen, this can have major impact on the future osteoarthritis. [PT]	We noted the link between meniscus damage and risk of osteoarthritis damage. The risk of cartilage damage can be discussed with a health professional.
Modify language and formatting used	Use simple language	Health Professionals:	Health Professionals:
		Reduce the number of words used in the headings to describe each option. [PT]	We decided to keep 'or delayed ACL surgery' and 'early ACL surgery' in brackets following the headings of each option throughout to keep consistency.
	Make the section more concise	Health Professionals:	Health Professionals:
		Remove the statement about quality of evidence. [PT] Soften the language around return to sport as people can return sooner and be ok [PT]	We did not remove the statement about the quality of evidence as we believe this is important in showing the uncertainty of evidence and feedback frequently reported this as important to convey. We used evidence-based ranges of times for an expected for return to sport.
	Modify presentation of harms, formatting, graphics, or statistics	Children and adolescents:	Children and adolescents:
		Add more pictures to the decision aid.	We received opposing feedback that too many visuals may take away from key information.
		Adult:	Adult:
		Highlight the statistics that were 'better'.	We did not apply highlighting around statistics to avoid bias.
		Parents:	Parents:

		Present statistics as percentages as it is easier to understand.	We received opposing feedback that ‘x amount of people per 100’ was preferable.
		Health Professionals:	Health Professionals:
		Include if there is a clinically significant difference in function scores between groups when presenting statistics. [PT]	We included a statement about the quality of evidence and presented statistics without significance values to avoid making the decision aid too complex.
		Use more visuals, pictures and make more like an infographic. [PT]	We received opposing feedback that too many visuals may take away from key information.
		Use a bar graph rather than an icon array. [PT]	We received opposing feedback that using icon array was preferable than a bar graph to represent statistics.
		Suggestion to include definitions of a complication. [PT]	The decision aid is designed to be used with a health professional who can clarify this information.
	Use positive messaging	Parents:	Parents:
		Include a statement that research is only presenting the average outcomes.	We used evidence-based statistics, but avoided using statements that may give unrealistic expectations.
		Health Professionals:	Health Professionals:
		Add a positive message in the form of a sentence at the end of the decision aid [PT]	It was decided that key points were more appropriate.
Understanding the translation of research	Usability of the decision aid	Health Professionals:	Health Professionals:
		Move the summary page to be the first page of the decision aid. [PT]	We received opposing feedback that it was appropriate to present the summary page on the last page of the decision aid.
		Children and Adolescents:	Children and Adolescents:

	Clarify the uncertainty of evidence and outcomes of each option	Add statistics that females can be at a higher risk of ACL rupture.	We did not include this statement as it was beyond the scope of this decision aid.
		Health Professionals:	Health Professionals:
		It was suggested to include that the position of the graft in ACL reconstruction can influence outcomes. [OS]	The inclusion of graft position as a variable is beyond the scope of our decision aid.
	Keep or remove statistics using adult data	Children and Adolescents:	Children and Adolescents:
		Adult statistics could be included as they may be more relevant for older skeletally mature adolescents.	We decided not to include adult statistics as we did not want to overload children and adolescents with more statistics.
		Adults:	Adults:
		Include adult data because if someone was 19 years old and they wanted to look at adult data then it could be relevant for them.	We decided not to include adult statistics as we did not want to overload children and adolescents with more statistics.
		Parents:	Parents:
		Include adult data as it was clear enough that it was data using adults.	We decided not to include adult statistics as we did not want to overload children and adolescents with more statistics.

Supplementary file 15: Themes, sub-themes, and example quotes

Themes	Sub themes	Feedback
1. Positive feedback on the decision aid	1.1. Positive feedback on the content	Adolescents:
		Female, 15-17 yrs old - “I like the page and it makes sense to me everything that it's saying.”
		Adults:
		Female, 18-20 yrs old - “So I guess informing people that have torn ACL and the benefits and limitations of each graph. And what they do would be good.” Male, 21-30 yrs old - “I wish I had something like this for either of my ACL ruptures as following the first one I may have tried not having surgery as I was already back running.” Male, 31-40 yrs old - “Giving them more information on what rehab they could be doing in the meantime, might lead to better outcomes until the surgery, there was for me, there was nothing in between in terms of exercise or rehab or anything. Yeah, and I didn't even know that, you know, that would have been something I should have been doing.” Male, 21-30 yrs old - “Like it's giving you the clear picture but also showing you the downside simultaneously.” Male, 21-30 yrs old - “Yeah, I like those, the data points there. That's pretty good. I like it as it shows you how many people out of 100. Nice. I also liked on the other page, you had the little infographic with the people bicolored.”
		Parents:
		Female, 41-50 yrs old - “I like all the information, the statistics are really good.” Female, 41-50 yrs old - “I think that's perfect.” and “I think it's really good.”
		Health Professionals:
		OS, Male, 31-40 yrs old - "Well thought out, nice and balanced." PT, Male, 31-40 yrs old - "I like this. I like the summary. I think it's a good, I think is where you get a lot of information, which is really, really nice."

	1.2. Positive feedback on design	Adolescents:
		Female, 15-17 yrs old - "I think it will be really valuable. It doesn't look boring as I get bored really quickly with medical brochures but this is engaging." Female, 15-17 yrs old - "I like reading it and I would go highlight it. I also like the cute little numbers and like percentage size. So I feel like this is like really good. So this is engaging." Female, 15-17 yrs old - "I think it's really good. I like the pictures"
		Adults:
		Male, 21-30 yrs old - "I like that flowchart, it's pretty straight forward." Female, 21-30 yrs old - "I think the pictures are good." Female, 21-30 yrs old - "I do like that it kind of has a timeline shows you the differences and similarities and each timeline." Female, 21-30 yrs old - "I do like that they are like side by side. It's easy to look from one to the other." Female, 21-30 yrs old - "I think that I don't think that's too long or too short. I think it gives enough information without necessarily overloading someone with it. It gives you the information you need to know without being overwhelming."
		Parents:
		Female, 41-50 yrs old - "I love the little pictures. Great. Easy to read. Logical. Succinct." Female, 41-50 yrs old - "I like it. I like how the benefits and harms are highlighted. And the numbers really pop out." Female, 41-50 yrs old - "Remember, choose what is best for your situation. Think of whole-body health. See family, friends and health professionals for support and stay positive. Love that."
		Health professionals:
		OS, Male, 31-40 yrs old - "That's really good, the pictures there are great and it's really good to compare."

		OS, Male, 31-40 yrs old - "It's really nicely displayed. So it's very easy to understand."
	1.3. Positive feedback on usability	Adults:
		Female, 21-30 yrs old - "I think this is probably something that would have been nice to have." Male, 31-40 yrs old - "It's easy to follow."
		Parents:
		Female, 41-50 yrs old - "Easy to follow." Female, 41-50 yrs old - "I like to timeframe because it sort of shows a comparison, especially what I've been reading a lot. So it kind of brings it together. So I can see, I like how it's broken down. Because most of the time when you go to the doctor, they don't discuss anything into this, this much detail" Female, 41-50 yrs old - "I actually had had a study in my hand and he didn't even look at it."
		Health professionals:
		PT, Female, 41-50 yrs old - "I really liked the first page, I think it makes it really clear that there are two options, it makes it clear that you know that if you try exercise, you still got the option for surgery, I think that's good. And that if you have successful rehab from either of them, then they return to sport or other activities. So I really liked that first page and I like the questions underneath."
2. Negative feedback on the decision aid	2.1. Negative feedback on the content	Adolescents:
		Male, 15-17 yrs old - "The pictures. I mean, it might make it look a little nicer, but it's not really giving you information. I think take the pictures away."
		Adults:
		Male, 21-30 yrs old - "Formatting could just be a no having pictures on both sides and having the legend somewhere else, but I think that was overkill with pictures."
		Health Professionals:
		OS, Male, 31-40 yrs old - "This language is too academic. Provide some more simple options."

		PT, Male, 31-40 yrs old - "Could have it more infographic style." OS, Male, 51-60 yrs old - "What you're doing is intrinsically incorrect."
3. Outline how the decision aid should be used	3.1. Improve clarity on the target population	Children and adolescents:
		Female, 15-17 yrs old - “It makes sense to me.”
		Parents:
		Female, 41-50 yrs old - “Have you thought about doing separate ones of these for boys versus girls being those girls have such a higher reinjury rate?” Female, 41-50 yrs old - “Females may be at a greater risk of re injury or something like along those lines.”
		Health Professionals:
		PT, Female, 21-30 yrs old - “Because the well, if yeah, if this depends where you're putting it, but I assume that if you were 19, and you had just done your ACL, then you'd want some data on that as well, because you wouldn’t really fit into the other category. I feel like this is a bit more like it gets into like function and, and stuff. And more into like complications, which is a bit more of a adult topic.” PT, Male, 31-40 yrs old - “So I think, obviously, there are patients that are going to do better with a reconstruction, particularly if they have a knee that for them feels unstable or is objectively unstable, either passively with bedside ligament testing, or in weight bearing their knee gives up or has given way.” PT, Male, 41-50 yrs old - “I believe that as a sports physical therapist, there's a certain population of athletes and younger athletes that could be fine without an ACL reconstruction surgery. I don't know exactly in my mind what that percentage is, I do think it's a smaller number. And then those who will need a reconstruction surgery to get back to all functional activity and high level of sport, especially playing catch pivot activities.”
	3.2. Highlight that patients need to discuss the decision	Adolescents:
		Female, 15-17 yrs old - “So just knowing the fact that they've had some someone go in there, like a professional and fix everything up. I feel like that helps.”

	aid with health professionals	Adults:
		Male, 21-30 yrs old - “It was for children and adolescents. But should be used with a parent and guardian with health professional. So I thought that was good.” Male, 21-30 yrs old - “But if that disclaimers at the top, and it's you know, in bigger writing, you say like, okay, if I'm going to do this option, I should still speak to a professional rather than making this decision on my own.” Male, 21-30 yrs old - “Your final step should be going to see a healthcare professional like a physio before you go back.” Female, 18-20 yrs old - “Added on to the second one. Like should be used with guardians and health professionals. And then like in brackets, it's not made to replace advice from health question or something.” Male, 21-30 yrs old - “I think that when I got mine down, I didn't really know what they were doing. And you wake up and your knees so sore. And you're like, “Why was my knee so swollen? But they've drilled through your tibia to attach this new data graph there?”
		Parents:
		Female, 41-50 yrs old - “Discharge procedures is that they do the medications, etc. And again, for myself, as a mother, none of it was discussed with myself.”
		Health Professionals:
		PT, Male, 41-50 yrs old - "And it's also getting parents to understand what that is going to mean through the health professional. In terms of giving way – swelling, locking, hints of an unhappy knee is indicative of chondral damage, or meniscal tears."
	3.3. Clarify that choices should be made based on individual circumstances	Adolescents:
		Female, 15-17 yrs old - “Like the psychological issue, like it depends on like your circumstance, but I feel like it should still be talked about with your professional.” Female, 15-17 yrs old - “You gotta listen to your own body, because someone could be telling you something, and you could not feel the same.”

		Male, 15-17 yrs old - “You know you might get clearance from your health professional but you don't feel confident in your knee yet, for example.”
		Adults:
		Female, 21-30 yrs old - “I do like to this says Not everyone will return to pre injury sport. Because lots of things can happen. And all of the recoveries can be different.”
		Parents:
		Female, 41-50 yrs old - “Delayed ACL surgery doesn't sound that bad. But also I feel like it is very circumstantial.” Female, 41-50 yrs old - “It should be an individual choice. And I think what you're saying there is sort of reflecting that, you know, you make this decision.” Female, 41-50 yrs old - “Remembers that everybody's gonna have different results.”
		Health Professionals:
		PT, Male, 31-40 yrs old - "Yeah, I so I like it. And I what I really like about it, is the questions to consider, you know, particularly around, you know, individual factors, age, sporting participation cost, all those kinds of things."
4. More information about specific considerations following ACL rupture	4.1. Highlight the importance of social and psychological support, and whole-body health	Adolescents:
		Female, 15-17 yrs old - “Only thing I think about is how long will I sort of be limited in my sort of getting around and being able to socialise or how long have you crutches for. like you're saying you to how long to kind of walk around and go see your friends that sort of thing. That's important.” Female, 15-17 yrs old - “Yeah, I feel like the immobility that you have. I feel like that's really important. Because for like that first month, you're completely reliant on like, whoever you haven't house with you. Yeah, and you just can't do anything. Really.” Female, 15-17 yrs old - “I wasn't really offered any psychological help.”

		Female, 15-17 yrs old - “I noticed that because I had put most of my weight on my right leg instead of my left like white bear in it. I my hip my like lowered discs in my back have like never really been the same.” Female, 15-17 yrs old - “I didn't see any of my friends for like, two months, I barely saw my family. Like, I was literally in my house for like, two months, I didn't see anyone, so it was like, very isolating.” Female, 15-17 yrs old - “But I think there should be a lot more psychological support. Yeah. I think mentally, it's just as hard or harder than the actual physical injury. And often, that's missed as well, like, it's not even talked about how hard it is.” Female, 15-17 yrs old - “Fear of and it wouldn't be whether you have ACL surgery or not afraid of re injuring and I think that that's a really big psychological step to get over whether you have surgery or not.” Female, 15-17 yrs old - “So, with weightlifting, I kind of I don't even back off, but like, I can feel that my legs are a lot weaker that certain time of the month. But then two days later, it'll be completely fine.” Male, 15-17 yrs old - “It was hard. But the mental part of it the hardest part, like getting past that.” Male, 15-17 yrs old - “Like mental health that you're looking after, as well. Yeah. Because it's such a mental battle for you to get back and feel ready to play and be confident. Or as well, because you're consistent with the rehab.”
		Adults:
		Female, 21-30 yrs old - “Psychological support is also important, that's something that I didn't really think about. Yeah, was like, how tough it would be mentally. So that would definitely be a good thing to have.” Male, 21-30 yrs old - “For example, my glutes not switching on because of the knee and then like not focusing enough on them, which then puts more pressure on the knee that puts more pressure on my back can lead to complications elsewhere? Like it's not just a knee problem?”

		Male, 21-30 yrs old - “So definitely highlighting the whole psychological impact of if you're not ready, you don't have to go back.” Female, 18-20 yrs old - “Remember when I was disappointed people told me that, like, you're not a full-time athlete. You're not getting paid to rehab. Yeah. And yeah, so it's like, to me, it's, it's like, important that kids know that that like when they say nine to 12 months, like that's what professional athletes are coming back in.” Female, 18-20 yrs old - “Um, the psychological health. I think that's good. And really important that it stays there.” Male, 31-40 yrs old - “That's a big component as well. I think just anything with any injury, really just a psychological rehab.”
		Parents:
		Female, 41-50 yrs old - “Not just about that what sport she can play but about the effect of the slow recovery on their social life. Being able to go and like walk.” Female, 41-50 yrs old - “It doesn't incorporate any alternative things.” Female, 41-50 yrs old - “Especially the psychological support or something. I figured it would kick in eventually, when finally realising how severe I guess the injury was. But no one ever talks to us about that.” Female, 41-50 yrs old - “If you don't feel like doing your exercises, things like that, to know that, you know, that's normal that, that, you know, a lot of people experience the same thing, which is why those groups are good. That you can see what other people are doing as well.” Female, 41-50 yrs old - “The big thing with the ACL with them and actually speaking to people who have returned the ACLs, because we do know, quite a few people that have”
		Health Professionals:
		PT, Male, 41-50 yrs old - “I think one of the factors that needs to be considered is your psychological support. That's probably the biggest one of the biggest issues that I think is coming more and more to the forefront.”

		PT, Male, 21-30 yrs old - "Whether a patient needs surgery or not, is highly dependent on the person and what their needs and goals are."
	4.2. Revise the management options to include evidence on ACL healing, bracing and 'prehabiliation'	Adults:
		Male, 21-30 yrs old - "I feel like besides those three routes, like you either, we could have option four do nothing." Male, 21-30 yrs old - "There's only like exercise and delayed and earlier ACL surgery – had you just thought about doing the other options like the brace protocol? If you've seen that the doctor cross brace one?" Male, 21-30 yrs old - "Like prehab like before you have surgery. It can take a long time to get an ACL surgery appointment. Even like, mine was two weeks. But like, in those two weeks, I was like, rehabbing my knee to the best I could before my surgery."
		Parents:
		Female, 41-50 yrs old - "So for us option one, we didn't really consider option one we considered our option one was bracing protocol option two surgery, and we decided we'd go first and bracing protocol."
		Health Professionals:
		PT, Female, 41-50 yrs old - "At the time, [ACL surgery] was what we thought was the only option. We thought that that was important to do. And then honestly, then I had a few people who, like, they weren't actually great surgical candidates, but they still went and had it because we thought that's what you had to do. And it really made me question like the necessity of it." PT, Male, 31-40 yrs old - "Yeah, so obviously, there is a few treatment options that are available in the sense of early reconstruction prehabilitation, or delayed reconstruction with a set date. So you can do prehab and then reconstruction, or rehabilitation exercise therapy/physiotherapy on its own with the option of surgery later if you need it."
	4.3. Include more information on practical factors	Adolescents:
		Female, 15-17 yrs old - "It would have been good to know what like where the incisions would be, yeah, just so that you could have been prepared."

	influencing management choices	Adults:
		Female, 18-20 yrs old - “As someone who did it in high school, you've got school, you've got a job, or at a job, you've got, like, you got to go to the gym, like four or five times a week, and then go for it again, as well, whilst you're going to the gym.”
		Parents:
		Female, 41-50 yrs old - “The length of time on crutches and sort of you know, those length of time using sort of walking aids or with braces those sorts of things? I think that'd be something that a kid wants to know about.” Female, 41-50 yrs old - “The options of quad, the quad graft, the patella graft, the hamstring graft, the donor graft. I mean, those are all the things that we've looked at.” Female, 41-50 yrs old - “Is there anything about the requirement to have it immobilised? With a teenager, it was very hard to get them to wear a big, ugly, chunky brace.”
		Health Professionals:
		PT, Female, 41-50 yrs old - “I treated someone years ago, who was the donor site for their child. And so I don't know if they're still doing that” PT, Female, 21-30 yrs old - “Add in something around ‘Maybe even if I do have surgery quickly, what should I be doing until then?’”
	4.4. Add or remove questions	Adolescents:
		Female, 15-17 yrs old - “I think they're good questions. I guess the main thing that you want to know is like, how long does it take to get back? If I don't have surgery?”
		Adults:
		Male, 21-30 yrs old - “That's pretty good. Like that first one, because that's like, good, roundabout way of saying that you might not get back to pivoting sports, which is good.” Female, 21-30 yrs old - “But a lot of people, well, they can be pretty clueless about these things. So I think that's a really good thing to have.” Female, 18-20 yrs old - “I think the questions down the bottom are super good.”

		Parents:
		Female, 41-50 yrs old - “Considering the cost Yeah and even a child is gonna be aware of those stresses and a family's, economics. so maybe having a question about the cost as well.”
		Health Professionals:
		PT, Male, 31-40 yrs old - “What happens in the surgery? You know, like, because we've paid, you've obviously got a few graft choices. So I think they should know whether they're going to have it taken from themselves, or whether they're going to have a donor, or whether they're going to get a cadaver for. And then what that entails, like, you know, so they kind of have an explanation of it. And so they need to ask about that would be my something that, I would say, just as a side point” OS, Male, 41-50 yrs old - "Yeah, basically, what happens if I don't have surgery? The benefits of surgery, basically, are the two main things. Well, I need to change if I don't have surgery. Well, I need to change what sport I play but also if I don't have surgery, what will happen in the future? Like, what if my knee function without the ACL? They want to know if there's any long-term problems."
5. Change or add information on rehabilitation, exercises and return to sport	5.1. Include more detail on return to sport following ACL rupture	Adolescents:
		Female 15-17 yrs old - “I don't have the desire to go into a club anymore. Because I'm so scared that it will happen again, because I know that they still like a huge chance that will happen.”
		Adults:
		Female, 18-20 yrs old - “I was all for surgery, because my goal was to get back to sport, and I just didn't think I trusted the process of having gone through rehab without having the surgery.” Male, 21- 30 yrs old - “The takeaway you'd get from that page. Like it's possible. But it's, you know, a little bit of a risk. You know, yeah, you get through or not, but I guess you're doing it, knowing that's the case.” Male, 21- 30 yrs old - “If you don't feel comfortable going back to sport, once fully recovered, you don't have to go straight back to sport.” Female, 18-20 yrs old - “Feel like, yeah, you got a lot of false hope from people. Yeah. So I think that, like the tie, like giving a timeline is good. But it can also be like, really dangerous, because

		then people get to that 12. Like, I mean, I was at 12 months being like, I'm still not playing sport like.”
		Parents:
		Female, 41-50 yrs old - “I read statistics like that. Something very, similar, in my little delving down little rabbit holes, to find out outcomes. And when there was talk about returning to play soccer, I wasn't supportive of that. Yeah, for that very reason.”
		Health Professionals:
		OS, Male, 31-40 yrs old - "I think patients might read that like running, cycling, swimming, and they might go, I can't do anything for three months. Yeah, rather than I can do some of this stuff, but I can't do it in the same fashion." OS, Male, 41-50 yrs old - "I would be very hesitant to recommend a return to pivoting sports with no ACL for the younger people, because they are already a little bit lax in their joints."
	5.2. Refine rehabilitation progression timeframes	Adults:
		Male, 21-30 yrs old - “Well, for my second one, where I did conservative I was, I was cycling within a couple of weeks. I'm running after about a month.” Male, 31-40 yrs old - “All those timeframes that seem pretty accurate.” Female, 18-20 yrs old - “These timelines are a guide. Like, and like aren't certain. Yeah, but yeah, I think the other thing that's hard with it as well is like adolescence.”
		Health Professionals:
		PT, Male, 31-40 yrs old - “Rehabilitation for two to three months is not enough. Like it's just not enough. You know, we need at least three to six months like there's, it's hard because as we've said, it's like the research and guideline evidence is very thin on the ground, particularly for paediatric populations. But the Swedish guidelines for adults would be three to six months.” PT, Female, 41-50 yrs old - "Nine months, nine to 12 months with surgery. And without surgery, I don't see a reason why it should be shorter. Without of course, the [duration of] swelling may be shorter, because you don't have an operation. But it isn't always faster. It can be really the same. It depends on if it's only the ACL or there are also other structures which are injured."

		PT, Male, 31-40 yrs old - "It's rare that I see anyone get back to sport at nine months, then maybe that's me holding them back a little bit. It's not almost always 12 plus. I, but I don't know, maybe that's a confidence thing, or not a confidence, but a motivational thing for patients to if you say to them talk, it's gonna be 12 months. Sometimes that can be a bit confronting early on No, nine sounds a little bit better. You know? I think they think, you know, we definitely know it's possible, right? "
	5.3. Clarify the importance of testing rehabilitation progress and return to training or competition sport	Adolescents:
		Female, 15-17 yrs old - “So because I know this is return to sport. But to me is returning to sport. Unrestricted.” Male, 15-17 yrs old - “Physio was really good. So he'd basically tell us every week yeah, okay, you can do this. And then he'd give us a letter to say, okay, she's allowed to do, you know, this part of that in her training, she's not allowed to do directionals she was only allowed to run straight lines or whatever.” Male, 15-17 yrs old - “I do think to add in the just for the general person a clearance for return to sport that then must do a proper documented return to play protocol and “when cleared by medical professional.”
		Adults:
		Male, 31-40 yrs old - “In that middle section here could have like, you know, clearance or passing test or something.” Male, 21-30 yrs old - “Like a clearance to return to sport with testing or like something like that.” Female, 18-20 yrs old - “I don't know, maybe you could do like a staggered return to sport and other activities or like something.” Female, 18-20 yrs old - “Even adding the word gradual into the return to sport.”
		Parents:
		Female, 41-50 yrs old - “Like with that clearance with a health professional. It's the what do you call it? like the return to sport criteria? I think that's really important.”

		Female, 41-50 yrs old - “Return to sport, they do a psychological assessment, as well. And it's sort of not just physical, it's a psychological test, as well. And I think that's pretty important.” Female, 41-50 yrs old - “You know, they look for, you know, strength testing of at least 90% of your other side. So, you know, on your leg press or knee extensions, or you know, isometric testing.”
		Health Professionals:
		PT, Male, 21-30 yrs old - “So you have a lot of people who come out of surgery if they're not like physically active in general did struggle or like physically active prior to surgery would find it much harder. Yeah, it would be a good way to like, have that looked at as for so like, objectively measuring whether your injured limb is at least at a certain percentage of your non injured limb prior to surgery.” PT, Female, 41-50 yrs old - “I would rather say “If your knee is giving way, please talk to your health professional” because if you write it like that it's kind of already the decision if it's more giving where you need to do the operation and I find it it's more individual and it's makes sense maybe to talk to a health professional to really decide if this is a reason to opt for the surgery or not.” PT, Male, 31-40 yrs old - “Mention that the body can or the muscle system can learn to take over the role of an injured ACL to restabilise the knee something like that.”
	5.4. Expand on the type of exercises involved in management	Adolescents:
		Female, 15-17 yrs old - “And that's why I said we need to get your gym membership.”
		Adults:
		Female, 21-30 yrs old - “One could be a little more than what someone should be doing right after surgery. So it could be the exercises that your doctor or physical therapist, like prescribes you as to not do something too fast.”
		Parents:
		Female, 41-50 yrs old - “You're not sure what kind of muscles are talking about the kind of description of the treatment is unclear.”

		Female, 41-50 yrs old - “Was just thinking is the range of movement and the flexion so there was so much emphasis with flexion and he needed to get it.”
		Health Professionals:
		PT, Male, 31-40 yrs old - “I primarily sort of focused on the types of exercises, I just focus on giving them information about exercises. Giving them that and then sort of telling them that they need, like, probably adjunct therapies, like, hands on physiotherapy as well to go to go with the exercise as well.”
	5.5. Consider the long-term need for ongoing “hard work” and injury prevention	Adolescents:
		Female, 15-17 yrs old - “This is a requirement to think about the longevity of it. And obviously staying light and life is going to support that structure better.” Female, 15-17 yrs old - “Without Surgery, you still put a lot of effort into your exercises, which is not easy to do and be consistent.” Female, 15-17 yrs old - “I wouldn't say like missing school, but I would just say time consuming.”
		Adults:
		Male, 21-30 yrs old - “Just emphasis on either option, you need to continuously keep it up. Something like both options, have uncertainty with the standard of recovery and require hard work. Yeah. With exercises now and continuously going forwards.” Male, 31-40 yrs old - “More emphasis on how on the hard work on exercises to get better. I guess a lot of people don't know that that's going to happen. So even like just that image of like, you know, someone doing the knee extension machine or something. Or like just an image of their quad and saying like it takes hard work.” Female, 18-20 yrs old - “I did mine four years ago, and like, I still have to go to the gym, otherwise, my knee feels weak. And like that was four. So I think some people assume that once you're back, you're back” Female, 18-20 yrs old - “Mean, to me now long term is like my whole life. whether we say like, you know, like, lifelong exercise or something like that to make them consider that.”

		Parents:
		Female, 51-60 yrs old “Unfortunately, there's so much pressure on these kids to get back to sport. And, you know, they feel the need that they're missing out and stuff like that. There's, you know, and it's hard trying to tell someone not to rush not to rush it back.” Female, 41-50 yrs old - “I think it would say need a certain level of dedication or something like that. Yeah. Because I think that's what made her successful is that she was dedicated to doing it.” Female, 41-50 yrs old - “Because it's that consistency, as you probably saw, you know, you have to keep going with it.” Female, 41-50 yrs old - “Some people may think once I finished my nine months of therapy, I'm done. But it's like, it's a lifelong journey, if you will.” Female, 41-50 yrs old - “I've been reading a lot about them. And later on down the road, like a lot of people look at right now. And I want to look at how's the knee gonna be when they are 25 or 30.”
		Health Professionals:
		PT, Male, 41-50 yrs old - “But the recovery and the rehab is actually the hardest bit. And most surgeons will tell you, or at least most of the surgeons are as actually more and more don't really matter what sort of version of the surgery we do. As indeed, we do the hard work afterwards. We are the ones that have to. I think probably in terms of decision making, whichever one you choose, you need to do a boatload of hard work.” PT, Male, 41-50 yrs old - “So I stress immediately that the hard work begins on the moment you wake up from surgery and will not stop, you will have a year of rehab. And after that, you will still have to maintain the strength and do spend a lot of time focusing on your knee control. It becomes it needs to become a lifestyle change rather than just yeah, I'll turn up for physio every so often. And I don't think surgeons because they haven't got the time they stress it enough.” PT, Male, 31-40 yrs old - “But I liked that closing, you know, use, you know, require ongoing hard work and exercises and use the people around you for support and choose whatever option is best for your situation. I think that's nice as a closing statement.”
	6.1. Use simple language	Adolescents:

6. Modify language and formatting used		Female, 15-17 yrs old - “Irrepairable was that a bit hard to understand”
		Adults:
		Male, 31-40 yrs old - “You're not using any technical, like overly technical terms, not using any jargon that people can't understand. It's simple language.” Male, 31-40 yrs old - “Think it's all sort of worded. Like, easy to understand. it's all it's all pretty clear to me how its worded.”
		Health Professionals:
		PT, Male, 31-40 yrs old - “Adult comprehension and health literacy isn't so good, but in kids, it may not be even as good.” PT, Male, 31-40 yrs old - “We're assuming that the patients who go to weigh all this information up will have the health literacy, the time to do so and the interest in doing so.”
	6.2. Make the section more concise	Adults:
		Male, 21-30 yrs old - “I like now it's nice and simple.” Male, 21-30 yrs old - “No more stuff in the graph, I think we'll clutter it too much.”
		Health Professionals:
		PT, Female, 41-50 yrs old - "Yeah, I find this whole page quite confusing. I would say I would remove the issues of the knee not necessarily caused by the treatment choice." OS, Male, 41-50 yrs old - "I found this whole thing very wordy. wordy. Yeah. Yeah. So unless the parents are completely involved, right, they don't really would read all of it. They would not read all of it. Unless they're that sort of parents like very much. Totally involved. When he comes to see me, they just want to know, the very simple stuff."
	6.3. Modify presentation of harms, formatting, graphics, or statistics	Adolescents:
		Female, 15-17 yrs old - “I think the little people, I just think it'd be better set. If like 10 of those people were purple, and it was just on the one graph than the rest of them were blue.”
		Adults:

		Male, 21-30 yrs old - “I liked on the other page, you had the little infographic with the people.” Female, 18-20 yrs old - “If it does give way, pretty heavily, then it could definitely injure something else.” Male, 31-40 yrs old - “If someone's got an unstable knee that keeps giving away and causing other injuries, is that not going to increase their risk? Of having osteoarthritis?”
		Parents:
		Female, 41-50 yrs old - “It might be worth keeping the left-hand side as sort of a shaded blue, and then the right hand side, a shaded purple.” Female, 41-50 yrs old - “It probably would be more clear, having the two distinct colours.” Female, 41-50 yrs old - “My brain went straight to I want to know whether there's early onset arthritis, and you see that more in people who have had knee surgery than those who haven't for example, like that, that was a real question in my head.” Female, 41-50 yrs old - “Visually the difference between the two actually jumps out at you. So what I would do is so these, this two to four weeks, move it up slightly”
		Health Professionals:
		PT, Male, 31-40 yrs old - "The pictures could have more impact for a kid" PT, Male, 31-40 yrs old - “I think that's a better representation for the patient than two scores that they have to then interpret, you know, filter through another level, and which they're not necessarily have the skills to do. So if it turns out that yeah, the clinically, minimal clinically important difference isn't there, then I would just say that you think that even maybe remove the graph and just have that summary. And it could even simplify it further?" PT, Male, 41-50 yrs old - “Yeah, I think the next one looks too busy. I know what you've kind of tried to do. But if you're a parent or a kid that's going to look at that that one doesn't. You know, you've got the coloured in people, and then you've got a bar graph. And then I think the first one works better. Just in terms of how it looks. This one is just statistics. Yeah, it's just a statistic box on the right where one person returning to pre injury sports."
		Adolescents:

	6.4. Use positive messaging	Female, 15-17 yrs old - “It’s hard because every injury is an individual injury and pending on how much you put into it, how active you are. You know, like, just because one person can do it doesn't mean the next person can't do it” Female, 15-17 yrs old - “When you've got a tough journey to get through, at least, you know, everyone else was stuck at home (COVID 19) as well, in some respects.”
		Parents:
		Female, 51-60 yrs old - “Your knee you know might be stronger if you need surgery later or delay something like that” Female, 41-50 yrs old - “These are just averages of research. And, you know, that doesn't mean this is what you have Yeah, something like that, just so that they always like to look at things from a more optimistic lens.” Female, 41-50 yrs old - “Making sure you've got people around you for support, you know, whole body health. Like we've mentioned before, taking care of like their mindset, some days, you're not going to feel like doing your exercises, and other days, you'll be more motivated. So being aware of that as well. And then staying positive, as you said, trying to be optimistic with how you're looking at it.”
		Health Professionals:
		PT, Male, 41-50 yrs old - “But we all when you when you talk to a patient, just to say, if it's unsuccessful, it's not your fault, it just happens. Sure, you know, and we need the time and from time to time we have just to change the process. Yeah. Because in my experience, people just react very self-criticism, like, ‘Oh, if it's not working, it's my fault because I didn't do enough training or I was too lazy.’” PT, Male, 21-30 yrs old - “Yeah, and I really liked that last bit down the bottom, like, it's quite obvious that whatever works best for you, in your situation, at the best at your time with your sport, remain positive is one of the main things because like, we know, obviously, there's a big psychological problem following ACL stuff. So use the people around you for support. So I like that.”
		Adults:

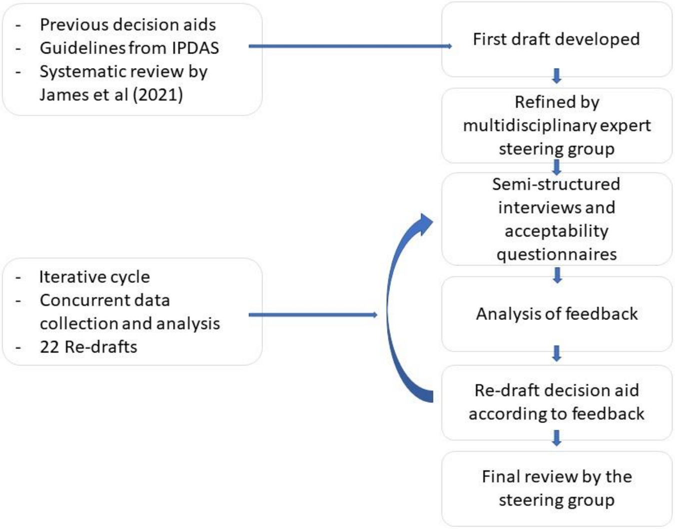
7. Understanding the translation of research	7.1. Improve the usability of the decision aid	Male, 21-30 yrs old - “If I had something like this I probably would have tried conservative but I didn't really have a there wasn't another option back then you're a young soccer player if you do your ACL you get surgery done.” Male, 21-30 yrs old - “You have a list of healthcare professionals or the route you should take, like being a physio prior to going straight to surgery. Even before Doctor.”
		Parents:
		Female, 41-50 yrs old - “I think it's better it's better to use as an aid for someone explaining it rather than just handing it to someone to kind of decipher.” Female, 51-60 yrs old - “Will this be like a document that people can look at? Or is it going to be like that, how's it going to be presented to people.”
		Health professionals:
		PT, Male, 31-40 yrs old - “I would be a bit overwhelmed by this, I think it was a patient to be like, can't make this simple in my own head, like, I don't know, just my experience with patients. Not that it is a simple decision. But I find when patients are overwhelmed, they tend to just kind of they grasp for certainty. And I always get that from surgeons, because they make it so black and white. And so that's a priority is to make sure that the information isn't overwhelming. And I think it's just a bit too much content. Maybe more could be presented graphically.”
	7.2. Clarify the uncertainty of evidence and outcomes of each option	Adolescents:
		Female, 15-17 yrs old - “Even if you have surgery, I guess it's not a guarantee to get back to sport, even, you know, at school and that as well.”
		Adults:
		Female, 18-20 yrs old - “I didn't want to take the chance of trying something new if it was, yeah, if it was less researched on or if it was less used.” Female, 18-20 yrs old - “I think maybe just something about like, both, like both options have uncertainty.” Female, 18-20 yrs old - “I really liked the preface about not everyone will return to pre injury sport with either option.”

		Parents:
		Female, 41-50 yrs old - “The first thing he said was, her ACL is torn, she needs to have surgery. And he wasn't open to telling me anything else.”
		Health professionals:
		PT, Male, 31-40 yrs old - "I always find it challenging when they're a little bit younger or elite level athletes, because obviously, they're not catered for in or looked at with the some of the research. So I think that's when it's really challenging, because you're already dealing with uncertainty. And I think it's always a difficult one, because they're looking for, I think they're kind of almost leaning on you for direct guidance. I think when you've got another operator, say, as a surgeon coming in and saying, This is what you need to do, it's much easier for them to take route, if that makes sense. I think, yeah, presenting uncertainty in itself, is a challenge to parents and adolescents, because I think they're looking at that stage in a, you know, what's probably a bit of a traumatic time for them for a clear answer and what they need to do."
	7.3. Keep or remove statistics using adult data	Adolescents:
		Female, 15-17 yrs old - “Even if you are younger athlete, to see what the outcome is later on.”
		Adults:
		Female 18-20 yrs old - “I feel like I have like, mixed feelings, because those could be this good. Adult is pretty much anyone over the age of 18. So I feel like you could do young adults, like let's say less than 25. Because I feel like the stats, if you can get that specific, wouldn't change the decision process behind let's say, the 17 year old if they work to re rupture in their early 20s.” Male, 21-30 yrs old - “But I assume that if you were 19, and you had just done your ACL, then you'd want some data.” Female, 18-20 yrs old - “What if someone was 17? Yeah. And they may want to look at both. If they're right on that edge, and not really knowing like, Okay, well, should I be considered an adolescent? Or should I be considered an adult, they may want to look at both.” Male, 21-30 yrs old - “It's obviously adult data. I was just confused jumping between the two.” Female, 18-20 yrs old - “Because well, if yeah, if this depends where you're putting it, but I assume that if you were 19, and you had just done your ACL, then you'd want some data on that

		as well, because you wouldn't really fit into the other category. I feel like this is a bit more like it gets into like function and, and stuff. And more into like complications, which is a bit more of a adult topic."
		Parents:
		Female, 41-50 yrs old - "I thought that I thought the whole study was the under 18. So I didn't realise you had both over and under 18. I think that was my I just assumed everything could be under 18." Female, 41-50 yrs old - "I think you should give someone all the information." Female, 41-50 yrs old - "Good to know that, you know, say if you were 17 or closer 18. You know, maybe you could pay more attention to these numbers."
		Health professionals:
		PT, Female, 41-50 yrs old - "If I was explaining this to someone, I'd say, Look, we don't have lots and lots of research on someone your age. But we have research on people who are 20 and 30. And they're weekend warriors. They're not elite athletes. This is this is the information we have." OS, Male, 31-40 yrs old - "So these are two different populations. And I stress that to patients, I treat my adolescent patients, and my young adults very differently to my adults, or my degenerative ACLs that are in their 40s or 50s, they get treated very differently, and more often non operative managed for that reason. But I think I treat them as three different categories of patients, in my mind, it's probably because we have poor data and understanding of them. But very poorly, we have higher risk factors in patients under the age of depends on how you classify them, but maybe under the age of 18, or maybe under the age of 25. These factors are very different. So yeah, I don't think this data is appropriate to use in that setting." OS, Male, 31-40 yrs old - "And if this was an adult one, sure I think but highlighting some of the drawbacks of the data is important. But yes, this is kind of what that research says. I think to use in adolescence is not appropriate." OS, Male, 51-60 yrs old - "You're using adult data to aid in decisions for children, and you can't do that. So the whole thing is terrible. I really would suggest that you reconsider what you're doing."

PT = physiotherapist; OS = orthopaedic surgeon

Supplementary file 17: Flow chart of the development process



IPDAS, International Patient Decision Aid Standards.

APPENDIX THREE

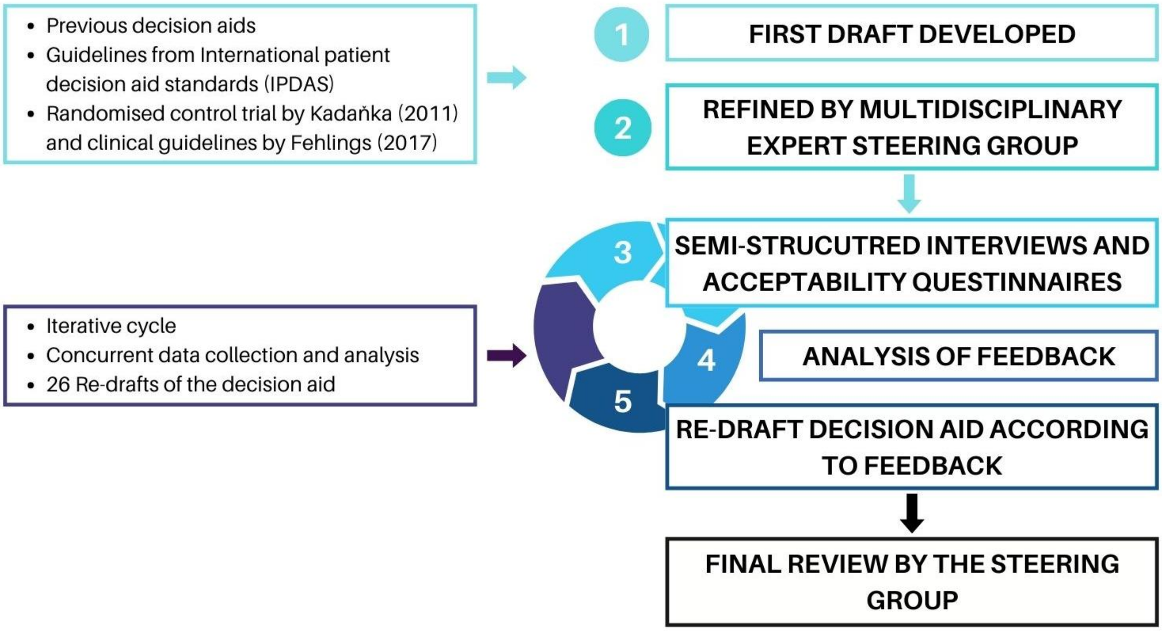
Chapter Four publication metrics

Under review

Impact

The Chapter Four paper describes the development and acceptability testing of the first patient decision for people with degenerative cervical myelopathy and involved an international collaboration with myelopathy.org, a global non-for-profit organisation. The paper contributes new knowledge to the field suggesting that a patient decision aid could make patient decisions easier when considering surgery. These findings could help to reduce unnecessary surgery and improving awareness of degenerative cervical myelopathy by encouraging evidence-based management.

Supplementary file 1: Flow chart of the development process



Supplementary file 2: Literature search strategy

Search for: 8 and 13 and 18

Results: 27

#	Search Statement	Results
1	clinical trial.pt.	540827
2	randomised.ab,ti.	143412
3	randomly.ab,ti.	449326
4	trial.ab,ti.	841770
5	humans/	22410505
6	1 or 2 or 3 or 4 or 5	22742159
7	animals/	7563615
8	6 not 7	20310887
9	exp spinal cord compression/	12077
10	myelopathy.mp.	17318
11	radiculomyelopathy.mp.	160
12	myeloradiculopathy.mp.	377
13	or/9-12	27326
14	exp surgery/	41215
15	exp surgical procedures,operative/	3682311
16	surgery.mp.	3240347
17	surgical.mp.	1685832
18	or/14-17	5303979
19	8 and 13 and 18	12209

Supplementary file 3: People with DCM pre-interview questionnaire

Consent section

1. Please make sure you have read the Patient Participant information statement before starting the survey.
2. PATIENT PARTICIPANT CONSENT FORM

PARTICIPANT CONSENT FORM

Degenerative Cervical Myelopathy: what information is required to make an informed management decision?

In giving my consent, I confirm that that have read and understood the Participant Information Sheet on the abovenamed research study and understand I can discuss the study with researchers of the study using contact details provided in the Participant Information Sheet if I have any questions about the study.

- I have been made aware of the procedures involved in the study, including any known or expected inconvenience, risk, discomfort, or potential side effect and of their implications as far as they are currently known by the researchers.
- I understand that the interview/focus group discussion will be audio-recorded and video-recorded, will then be transcribed (e.g. using Otter AI – a transcription software) and be kept in a manner in which I cannot be identified for analysis, and I agree to this.
- I understand that the University of Sydney software license for Qualtrics will be used to manage the collection and storage of my research data.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I freely choose to participate in this study and understand that I can withdraw at any time.

- I also understand that the research study is strictly confidential.
- I consent to the storage and use of my information collected from me for use, as described in the relevant section of the Participant Information Sheet, for:

  - This specific research project
  - Other research that is closely related to this research project
  - Any future research

I hereby agree to participate in this research study.

☐ Yes, I would be happy to participate in this study

☐ No, I would prefer not to participate in this study

3. I would like to review my interview or focus group transcripts

   ☐ Yes

   ☐ No

4. I consent to being contacted for future studies

   ☐ Yes

   ☐ No

5. I consent to the future use of any data by the researchers or other collaborators to use the data I provide for research purposes. I understand that before the investigators or their collaborators use any data that I provide, they must seek additional ethics approval.

   ☐ Yes

   ☐ No

6. I am willing to participate in a focus group (up to 2hrs in duration) instead of an interview (approximately 30-minutes in duration):

   ☐ Yes

   ☐ No

7. I would like to be emailed a copy of the study results when they become available:

☐ Yes

☐ No

8. I would like to be:

☐ Acknowledged in the publication (participate in an interview)

☐ An author (participate in an interview and contribute to further work on the publication)

Pre-interview Questionnaire

Study ID: _______________

Thank you for your participation in this study, which is investigating what information is important for people with DCM when considering surgery.

We would like you to answer a few questions before the interview. This should not take more than 5-minutes.

First, when are the best times to schedule you for an online interview…

Please provide below your best contact details for a researcher from the University of Sydney to contact you and arrange the follow-up interview:

Name: ______________________________________

Email: ______________________________________

Best contact telephone number: __________________________________

Best time/s to call: __________________________________

Please mark the times that are suitable to arrange an interview in the boxes below:

	Monday	Tuesday	Wednesday	Thursday	Friday
8 – 10am					
10 – 12pm					
12 – 2pm					
2 – 4pm					
4 – 6pm					

Please answer some quick questions about you...

1. Please indicate your gender:

   ☐ Female

   ☐ Male

   ☐ Non-binary

2. Please indicate your age: [free text response]

---

3. In which country do you currently live? [free text response]

____

4. What option best describes your highest level of education?

☐ Primary school or less

☐ High school (not completed)

☐ High school (completed)

☐ TAFE/Trade

☐ University- undergraduate degree/s (completed)

☐ University- postgraduate degree/s e.g. Masters, PhD (completed)

☐ Other (please specify) ____________________________

5. What is your employment status?

☐ Employed part-time

☐ Employed full-time

☐ Casual work

☐ Retired

☐ Unemployed

☐ Student

☐ Sick/disability leave

☐ Other (please specify) ____________________________

6. Do you have private health insurance?

☐ Yes

☐ No

7. How long ago were you diagnosed with DCM? __________________

8. How long before your diagnosis of DCM did you notice your symptoms?

   ☐ <1 month ago

   ☐ 1-3 months ago

   ☐ 4-6 months ago

   ☐ 6-12 months ago

   ☐ 12-24 months ago

   ☐ >24 months ago

9. Have you heard of the modified Japanese Orthopaedic Association scale that is used to rate the severity of DCM?

   ☐ Yes

   ☐ No

10. Have you had surgery for DCM?

    ☐ Yes

    ☐ No

11. How happy are you that your symptoms are currently being managed?

    ☐ Extremely unhappy

    ☐ Somewhat unhappy

    ☐ Neither happy or unhappy

    ☐ Somewhat happy

    ☐ Extremely happy

Thank you for completing the questionnaire.

Supplementary file 4: Health professional pre-interview questionnaire

Consent section

9. Please make sure you have read the Health Professional Participant information statement before starting the survey.
10. HEALTH PROFESSIONAL PARTICIPANT CONSENT FORM

PARTICIPANT CONSENT FORM

Degenerative Cervical Myelopathy: what information is required to make an informed management decision?

In giving my consent, I confirm that that:

Tick/initial boxes

- ☐ The details of any involvement have been explained to me, and I have been provided with a written Participant Information Statement to keep.
- ☐ I understand the purpose of the study is to investigate what information is important for people with DCM who are considering surgery.
- ☐ I acknowledge that the risks and benefits of participating in this study have been explained to me to my satisfaction.
- ☐ I understand that in this study I will be required to answer a pre-interview questionnaire (5-minutes) and attend an interview to provide feedback on an educational pamphlet on treatment options for people with DCM (online or via telephone) that will last 30-minutes.
- ☐ I understand that my participation will involve my interview to be recorded.
- ☐ I understand that information may be used in future research and the data collected for this study may use it in future projects. By providing consent I allow

my information to be shared locally and internationally with other research collaborators as needed. I understand that it is unknown at this stage what these other projects will involve, and ethical approval will be gained before my information in used in these future projects.

- ☐ I understand that being in this study is completely voluntary.
- ☐ I am assured that my decision to participate will not have an impact on any relationship with the research team or the University of Sydney or the Local Health District.
- ☐ I understand that I am free to withdraw from this study at any time and can choose to withdraw any information already provided (unless the data has already been de-identified or published).
- ☐ I have been informed that the confidentiality of the information provided by myself will be protected and will only be used for purposes that has been agreed to. I understand that information will only be told to others with my permission, except as required by law.
- ☐ I understand that the results of this study may be published, and that publications will not contain any identifiable information about me.

I hereby agree to participate in this research study.

☐ Yes, I would be happy to participate in this study

☐ No, I would prefer not to participate in this study

11. I would like to review my interview or focus group transcripts

☐ Yes

☐ No

12. I consent to being contacted for future studies

☐ Yes

☐ No

13. I consent to the future use of any data I provide for research purposes. I understand that before the investigators or their collaborators use any data that I provide, they must seek additional ethics approval.

    ☐ Yes

    ☐ No

14. I am willing to participate in a focus group (up to 2hrs in duration) instead of an interview (approximately 30-minutes in duration):

    ☐ Yes

    ☐ No

15. I would like to be emailed a copy of the study results when they become available:

    ☐ Yes

    ☐ No

16. I would like to be:

    ☐ Acknowledged in the publication (participate in an interview)

    ☐ An author (participate in an interview and contribute to further work on the publication)

Pre-interview Questionnaire

Study ID: ______________

Thank you for your participation in this study, which is investigating what information is important for people with DCM when considering surgery.

We would like you to answer a few questions before the interview. This should not take more than 5-minutes.

First, when are the best times to schedule you for an online interview…

Please provide below your best contact details for a researcher from the University of Sydney to contact you and arrange the follow-up interview:

Name: ____________________________________

Email: ____________________________________

Best contact telephone number: ________________________________

Best time/s to call: ________________________________

Please mark the times that are suitable to arrange an interview in the boxes below:

	Monday	**Tuesday**	**Wednesday**	**Thursday**	**Friday**
8 – 10am					

10 – 12pm					
12 – 2pm					
2 – 4pm					
4 – 6pm					

Please answer some quick questions about you...

12. Please indicate your gender:

    ☐ Female

    ☐ Male

    ☐ Non-binary

13. Please indicate your age: [free text response]

____

14. In which country did you receive your health professional training/qualification? [free text response]

____

15. What type of health professional are you?

    ☐ Neurosurgeon

    ☐ Orthopaedic surgeon

    ☐ Neurologist

☐ Rheumatologist

☐ General practitioner

☐ Physiotherapist

☐ Other (please specify) ____________________________

16. How many years have you been practicing? [free text response]

____

17. Which clinical setting have you spent the most time practicing in?

☐ Private practice

☐ Public hospital

☐ Private hospital

☐ Other (please specify) ____________________________

18. On average, how many patients with suspected or confirmed DCM do you manage/review per year? [free text response]

____

19. On average, of the people with diagnosed (mild, moderate or severe) DCM that you see – what percentage would you advise to have surgery?

Percentage (%): 0__10__20__30__40__50__60__70__80__90__100

20. If only seeing people with mild DCM – on average, what percentage would you advise to have surgery?

Percentage (%): 0__10__20__30__40__50__60__70__80__90__100

Thank you for completing the questionnaire.

Supplementary file 5: People with DCM interview guide

Example structure of interviews and focus groups with patient participants

Note: The topics below will serve as an outline to guide interviews and focus groups

I. INTRODUCTION

Hello, my name is [name of interviewer]. Introduce self and others in the room if appropriate (e.g. other team members).

1. *Introduce the project*
2. *The purpose of this study is to better understand what information is important for people with degenerative cervical myelopathy (DCM) when deciding to have surgery or use a non-surgical approach. Is this an appropriate time to interview you?*

   Yes CONTINUE

   No SET UP A TIME LATER

3. *Explain the purpose of the interview or focus group*
4. *The study aims to explore patient and health professional views on how treatment information should be presented.*
5. *Describe the audio recording and video recording, how we will assure confidentiality and answer any questions*
6. *This interview will be approximately 30 minutes (or 2 hours for focus groups), be audio recorded and transcribed* (e.g. using Otter AI – a transcription software) *so that we have an accurate record of your response. Please be assured that the recording and your transcript will be kept confidential. E.g., "Only researchers involved in the study will have access to your responses. Our study does have ethics approval. Once your interview has been transcribed, only a site identifier will be linked to the transcripts, while any information linking you to the transcript will be destroyed. The*

audio and video recording will be destroyed as soon as the transcript is verified and analyzed by research staff".

7. *If you need to contact me at any time after the interview or focus group to ask any questions, you can contact me via email (provide researcher email E.g., Mr. Andrew Gamble agam165@uni.sydney.edu.au)*
8. *You will be given the opportunity to review the recording/transcript/your responses prior to publication and analysis if you chose to do so.*
9. *If, at any time, you feel that the questions are too sensitive, I would be happy to turn off the recorder during that portion of questioning. You may also skip any questions you wish during the interview or focus group.*

Do you have any questions for me? [Answer any questions]

Opening questions

- What treatments options have you heard of or been suggested to try following your diagnosis of DCM?

Explain DCM surgery to patients

"I am now going to give you a short explanation of DCM surgery and why it is indicated that has been standardised to read to each participant."

"DCM surgery requires admission to hospital, anesthetic and small surgical cuts to the front or back of the neck to access the spinal cord. Immediately following surgery there can be pain, swelling, reduced movement and possible side effects such as difficulty swallowing.

The aim of surgery is to take pressure off the spinal cord from structures that may be compressing it and causing symptoms."

Core questions

If we were designing a decision aid to help you decide whether to have DCM surgery or try non-surgical management….

- What information is most important to know? (Prompt for views on presenting different treatment options, benefits and harms, recovery time, likelihood of need for revision surgery, details of the procedure)

- How would you like information to be presented in the decision aid in terms of visual aids, text, tables, pictures, etc.? (Example below, but exact topics will depend on what arose from the previous question)
    - Different treatment options
    - Benefits and harms
    - Recovery time
    - Likelihood of need for revision surgery
    - Details of the procedure

When reviewing the investigator-developed decision aid:

<u>Instructions to patients (as an example):</u> The material we want you to review has been developed for patients to improve their knowledge and confidence in making the decision to have DCM. We would like for you to help us better understand your experience of this material – for example, how you find the visual appeal, readability, content, and what are your overall experiences using this material**.**

To do this, I am going to ask you to think out loud while you read through the material. Just say everything that goes through your mind- if you are finding anything challenging, what your eye is drawn to. If a page is easy, and you understand what to do – just say that. Providing examples is very helpful (e.g. “look at a table”, “look at a page with just text vs with an image”).

Prompt questions as patients are reading through the material:

- How are you finding reading through this section?
- Did you feel like you knew where to look, and what to do next?
- Did you feel like you knew the relevance of this section in your decision?
- How did you find the content of this section?
- Were the instructions clear/helpful?
- How easy was it to understand the section? (readability)
- Was there anything that was unclear or confusing?
- How were the visual aids? (Any content supplementing written material in the decision aid)
- How was the functionality?
- Is there anything that you would improve in this section?
- What did you like most about this material?
- What did you like least about this material?

General feedback at the end

- Are there any topics that you would like to see in future versions of this decision aid?

Do you have any other general feedback, thoughts, or comments

Supplementary file 6: Health professional interview guide

Example structure of interviews and focus groups with health professional participants

Note: The topics below will serve as an outline to guide interviews and focus groups

I. INTRODUCTION

Hello, my name is [name of interviewer]. Introduce self and others in the room if appropriate (e.g. other team members).

10. *Introduce the project*
11. *The purpose of this study is to better understand what information is important for people with degenerative cervical myelopathy (DCM) when deciding to have surgery or use a non-surgical approach. Is this an appropriate time to interview you?*

    Yes CONTINUE

    No SET UP A TIME LATER

12. *Explain the purpose of the interview or focus group*
13. *The study aims to explore patient and health professional views on how treatment information should be presented.*
14. *Describe the audio recording and video recording, how we will assure confidentiality and answer any questions*
15. *This interview will be approximately 30 minutes (or 2 hours for focus groups), be audio recorded and transcribed (*e.g. using Otter AI – a transcription software) *so that we have an accurate record of your response. Please be assured that the recording and your transcript will be kept confidential. E.g., "Only researchers involved in the study will have access to your responses. Our study does have ethics approval. Once*

your interview has been transcribed, only a site identifier will be linked to the transcripts, while any information linking you to the transcript will be destroyed. The audio and video recording will be destroyed as soon as the transcript is verified and analyzed by research staff".

16. *If you need to contact me at any time after the interview or focus group to ask any questions, you can contact me via email (provide researcher email E.g., Mr. Andrew Gamble agam165@uni.sydney.edu.au)*
17. *You will be given the opportunity to review the recording/transcript/your responses prior to publication and analysis if you choose to do so.*
18. *If, at any time, you feel that the questions are too sensitive, I would be happy to turn off the recorder during that portion of questioning. You may also skip any questions you wish during the interview or focus group.*

Do you have any questions for me? [Answer any questions]

Opening questions

- What is your understanding of the treatment options for people with DCM? What causes it? How can it be treated?
- What do you think of DCM surgery as a treatment?

Brief explanation of DCM surgery to health professionals (depending on their current level of understanding e.g. do not explain this to a surgeon)

"I am now going to give you a short explanation of DCM surgery and why it is indicated that has been standardised to read to each participant."

"DCM surgery requires admission to hospital, anesthetic and small surgical cuts to the front or back of the neck to access the spinal cord. Immediately following surgery there can be pain, swelling, reduced movement and possible side effects such as difficulty swallowing. The aim of surgery is to take pressure off the spinal cord from structures that may be compressing it and causing symptoms."

Core questions

If we were designing a decision aid to help patients decide whether to have DCM surgery or not….

- What information is most important for them to know? (prompt for views on presenting different treatment options, benefits and harms, recovery time, likelihood of need for revision surgery, details of the procedure, etc.)
- How would you like information to be presented in the decision aid in terms of visual aids, text, tables, pictures, etc.? (example below, but exact topics will depend on what arose from the previous question)
    - Different treatment options
    - Benefits and harms
    - Recovery time
    - Likelihood of need for revision surgery
    - Details of the procedure
- How would your response to the above options differ if the information was intended to be used during a consultation with a health professional?

When reviewing the investigator-developed decision aid:

Instructions to health professionals (as an example): The material we want you to review has been developed for patients to improve their knowledge and confidence in making the decision to have DCM. We would like for you to help us better understand your experience of this material – for example, how you find the visual appeal, readability, content, and what are your overall experiences using this material**.**

To do this, I am going to ask you to think out loud while you read through the material. Just say everything that goes through your mind- if you are finding anything challenging, what your eye is drawn to. If a page is easy, and you understand what to do – just say that. Providing examples is very helpful (e.g. "look at a table", "look at a page with just text vs with an image").

Prompt questions as health professionals are reading through the material:

- How do you think patients would find this section?
- Did you feel like patients will know where to look, and what to do next?
- Did you feel like patients knew the relevance of this section in their decision?
- How do you think patients will find the content of this section?
- Were the instructions clear/helpful?
- How easy was it to understand the section? (readability)
- Was there anything that was unclear or confusing?
- How were the visual aids? (Any content supplementing written material in the decision aid)
- How was the functionality?
- Is there anything that you would improve in this section?
- What did you like most about this material?
- What did you like least about this material?

General feedback at the end

- Are there any topics that you would like to see in future versions of this tool?
- Do you have any other general feedback, thoughts, or comments?

Supplementary file 7: Acceptability questionnaire for people with DCM

We would like to know what you think about the patient decision aid you have just read.

1. Please rate each section by circling 'poor', 'fair', 'good', or 'excellent' to show what you think about the way the information was presented on:

Degenerative Cervical Myelopathy (DCM): Should I have surgery?	Poor	Fair	Good	Excellent
What is DCM? The diagnosis and symptoms of DCM	Poor	Fair	Good	Excellent
What are the categories of DCM?	Poor	Fair	Good	Excellent
Which DCM category are you in?	Poor	Fair	Good	Excellent
What are the recommended management options?	Poor	Fair	Good	Excellent
What do the management options involve?	Poor	Fair	Good	Excellent
Comparing non-surgical management to DCM surgery	Poor	Fair	Good	Excellent
Questions to consider when talking with your health professional	Poor	Fair	Good	Excellent

2. The length of the decision aid was (select one):
   a. Too long
   b. Too short

    c. Just right
3. The amount of information was (select one):
    a. Too much information
    b. Too little information
    c. Just right
4. I found the decision aid (select one):
    a. Slanted towards the non-surgical option
    b. Slanted towards surgery
    c. Balanced
5. How useful do you think this decision aid is (or would have been) when making a decision about DCM surgery?
    a. Not at all useful
    b. Slightly useful
    c. Moderately useful
    d. Very useful
    e. Extremely useful
6. Did this decision aid/would this decision aid make deciding whether to have surgery…?
    a. Easier
    b. More difficult
    c. Comments:
7. Do you think we provided enough information to help people with DCM decide on whether to have surgery or not?
    a. Yes
    b. No
    c. Comments:

Supplementary file 8 Acceptability questionnaire for health professionals

The following set of questions asks about your perceptions of the decision aid you just read. We are interested in your reactions to the decision aid. Please indicate how strongly you agree or disagree with each statement by *circling* the appropriate number.

In general:	**Strongly disagree**		→		**Strongly agree**
It will be easy for me to use	1	2	3	4	5
It is easy for me to understand	1	2	3	4	5
It will be easy for me to experiment with using it before making a final decision to adopt it	1	2	3	4	5
The results of using the decision aid will be easy to see	1	2	3	4	5
This decision aid is better than how I usually go about helping patients decide about DCM surgery	1	2	3	4	5
This decision aid is compatible with the way I think DCM should be managed	1	2	3	4	5
Compared with my usual approach, this decision aid will result in my patients making more informed decisions	1	2	3	4	5
Using this decision aid will save me time	1	2	3	4	5

This decision aid is a reliable method of helping patients make decisions about DCM surgery	1	2	3	4	5
Pieces or components of the decision aid can be used by themselves	1	2	3	4	5
This type of decision aid is suitable for helping patients make value laden choices	1	2	3	4	5
This decision aid complements my usual approach	1	2	3	4	5
Using this decision aid does not involve making major changes to the way I usually do things	1	2	3	4	5
There is a high probability that using this decision aid may cause/result in more benefit than harm	1	2	3	4	5

Please provide any further comments or feedback in the comments section below:

____

____

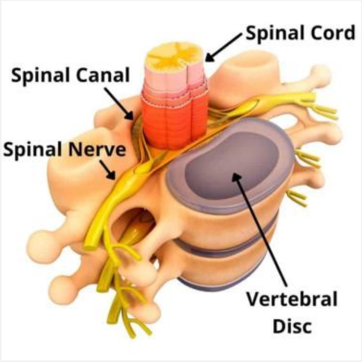
____

Degenerative Cervical Myelopathy (DCM):

Do I need surgery now?

- This decision aid is for people with DCM considering surgery
- All information should be discussed with a health professional

What is DCM?



- DCM results from changes in the spinal canal of the neck that compress the spinal cord.

- This ‘slow motion spinal cord injury’ can disturb nerve supply from the brain to the neck, shoulders, arms, hands or legs.

Diagnosis of DCM is based on:

- **Imaging**: MRI and other scans can show compression of the spinal cord.

  * **Caution -** image findings should not determine treatment choice alone as they may be due to normal aging or not directly causing your symptoms.

Compression of the spinal cord can lead to:

- **Symptoms:** pain or stiffness in the neck/shoulder/arms/hands or other areas, fatigue, pins and needles, numbness, reduced strength, clumsiness, difficulty using your hands or issues walking or toileting.

Questions to consider when talking with your health professional:

- What are the benefits and harms of surgery and non-surgical management?
- What do you offer as non-surgical management and how frequently will I be reassessed?
- What other factors do I need to consider? (age, weight, demands of leisure activity and work, sporting participation, cost of treatment and insurance cover)
- Do I need surgery now? Can I delay having surgery?

Important: This decision aid is not a substitute for advice from a health professional who should confirm your diagnosis. Radiculopathy, active infection, neoplastic disease, rheumatoid arthritis, thoracic myelopathy, trauma, ankylosing spondylitis and lumbar stenosis can all influence the decision-making process.

Disclosure: There was no funding to develop this tool. The developers of this decision aid include orthopaedic surgeons, physiotherapists, psychologists and occupational therapists. None of the developers will gain or lose anything based on the choices that people make.

Last reviewed: Update 10.5.2023. Developed by Andrew Gamble, Institute for Musculoskeletal Health, School of Public Health, The University of Sydney, NSW, Australia.

Which DCM category are you in?

- We can use the modified Japanese Orthopaedic Association (mJOA) score to classify DCM, and what treatment is most appropriate. [1]
- The scale ranges from 18 down to 0, with 18 being no symptoms (i.e., no spinal cord neurological symptoms) to 0 being severe symptoms (i.e., paralysed)*.

Scores are determined by the degree of difficulty when you:

- **0-5 Upper body movement**: button a shirt, use a spoon or move hands
- **0-7 Lower body movement:** walk, use stairs or move legs
- **0-3 Upper body:** feel or have increased pain with touch
- **0-3 Toileting:** have problems with toileting

Non-myelopathic (18)

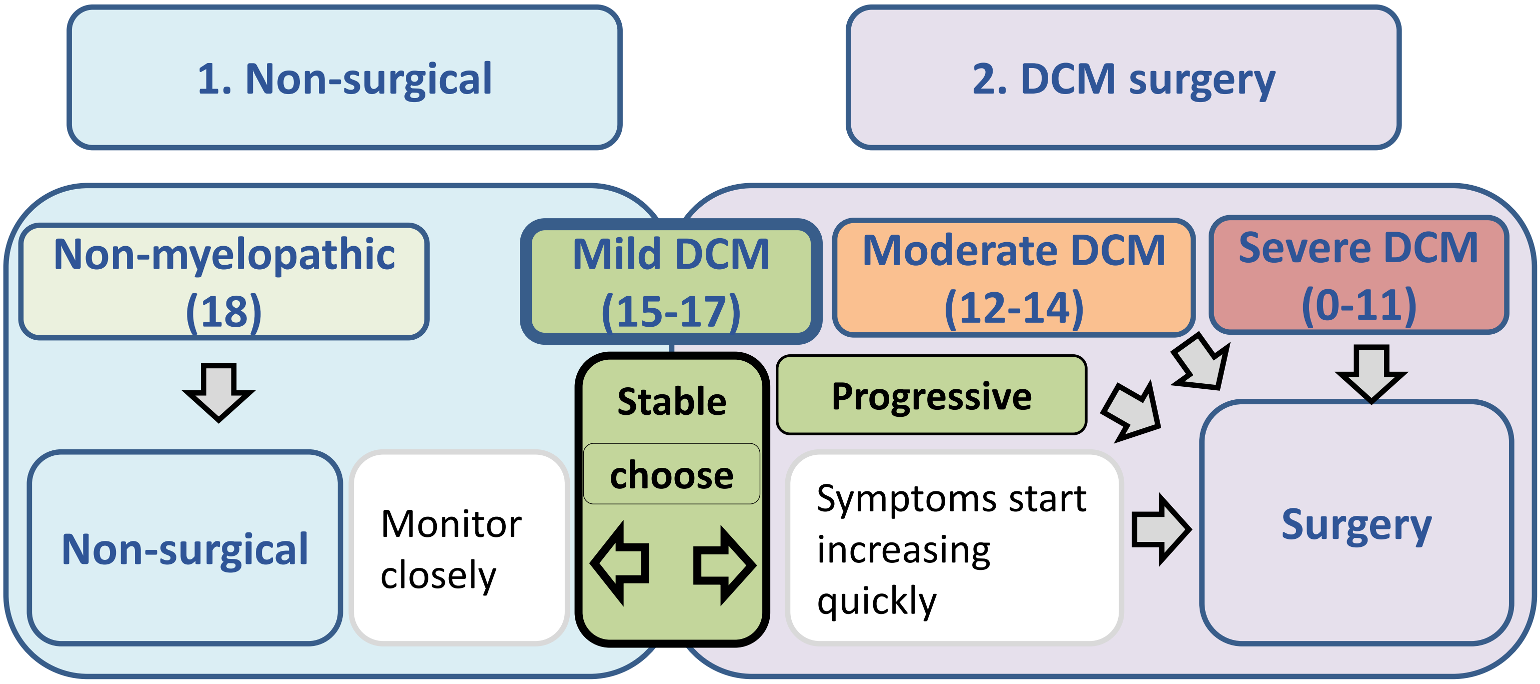
Mild (15-17)

Moderate (12-14)

Severe (0-11)

*Scoring should be done with a health professional (lower number scores = worse DCM)

What are the recommended management options?



- **Non-myelopathic symptoms:** Monitor closely, learn about risks and know what signs and symptoms to look for in the future. [2] Ask if you have radiculopathy (a different nerve issue to DCM with no spinal cord compression).
- **Mild DCM: If stable,** non-surgical or surgery may be appropriate. **If progressive,** and nerve symptoms get worse or fail to improve - surgery is recommended.[2]
- **Moderate and Severe DCM:** Surgery is recommended. [2]

What do the management options involve?

Mild (15-17)

Progressive

Moderate (12-14)

Severe (0-11)

Surgery is recommended for people with:

- Mild DCM that is progressive
- Moderate DCM
- Severe DCM.[2]

Below are your options for stable mild DCM

1. Non-surgical management

Mild (15-17) **Stable**

Trying non-surgical management before having surgery may be considered for people with **non-myelopathic or stable mild DCM. Milder DCM and a diagnosis before 6 months may mean you are more likely to feel benefits of non-surgical management.**[3]

Non-surgical management involves:

- Education
- Monitoring how quickly symptoms are changing
- Lifestyle and activity modification
- Structured exercise program to improve; strength, control and movement
- Medication or an injection

If you experience worsening of symptoms beyond 3-6 months despite doing your exercises and following advice, please talk to your health professional.

2. DCM surgery

Mild (15-17) **Stable**

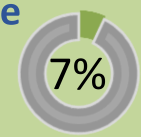
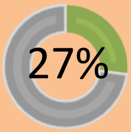
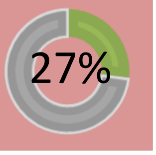
If your symptoms are quickly becoming worse with **mild DCM** and **non-surgical management** then please talk to your health professional about surgery. If your symptoms are getting worse (progressive), then surgery is recommended.

- Surgery involves a general anesthetic, making small cuts in the skin around your neck and using surgical tools to reduce spinal cord compression.
- There are different types of surgery e.g., approaching from the front or back of your neck.

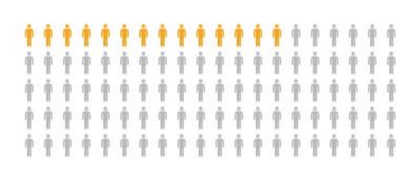
Following surgery, non-surgical management is needed over the next 3-6 months or longer depending on how you feel.

Comparing non-surgical management to DCM surgery

Mild DCM (15-17) stable	**1. Non-surgical**	**2. DCM surgery**
How much will I improve?	It is unknown how much you will improve. Mild DCM (stable) is more likely to improve with non-surgical management vs. mild DCM that is becoming progressive. [3]	
Do I need surgery now?	It is unknown if mild DCM will remain stable so the risk of surgery may be unnecessary. People who have worse DCM or had DCM more than 3 months may do better with surgery.[2]	
How likely will I get worse over time?	Depending on how bad your DCM is you may feel similar.[2]	
What is the cost?	May result in cost saving in the short-term	May result in cost saving in the long-term[2]
What are the risks?	After 1-year, you're 1.57x more likely to be admitted to hospital[4]	See risk of harms below
Will I need delayed surgery? (mJOA 11-15)[2]	23-54 in 100 people may still need DCM surgery	

Surgery is recommended[2] (Average mJOA improvement)	**Mild DCM (15-17) Progressive**	**Moderate DCM (12-14)**	**Severe DCM (0-11)**
			

Combined risk of DCM surgery harms

Minor and moderate harms	Swallowing issues (dysphagia), loss of voice, increased pain and infection. Some further spinal cord/nerve injury or worsening DCM[2]	14 in 100 people [2] 
Major harms	Death, heart and lung issues, fracture or the need for another surgery[2]	

References:
1. Tetreault, L. et al,. (2017). Eur Spine J, 26(1), 78-84. https://doi.org/10.1007/s00586-016-4660-8
2. Fehlings, M. G. et al,. (2017). Global Spine J, 7(3 Suppl), 70s-83s. https://doi.org/10.1177/2192568217701914
3. Butler, M. B., et al. (2022). Global Spine Journal, 12(4), 638-645. https://doi.org/10.1177/2192568220961357
4. Rhee, J., et al,. (2017). Global Spine Journal 7, 35S–41S. doi:10.1177/2192568217703083

COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	6
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	1
Occupation	3	What was their occupation at the time of the study?	1
Gender	4	Was the researcher male or female?	6
Experience and training	5	What experience or training did the researcher have?	6
Relationship with participants			
Relationship established	6	Was a relationship established prior to study commencement?	5
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	5
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	6
Domain 2: Study design			
Theoretical framework			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	7
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	6
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	6
Sample size	12	How many participants were in the study?	9
Non-participation	13	How many people refused to participate or dropped out? Reasons?	9
Setting			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	6
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	6
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	9
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	7
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	9
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	7
Field notes	20	Were field notes made during and/or after the inter view or focus group?	7
Duration	21	What was the duration of the inter views or focus group?	7
Data saturation	22	Was data saturation discussed?	7
Transcripts returned	23	Were transcripts returned to participants for comment and/or	7

Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	7
Description of the coding tree	25	Did authors provide a description of the coding tree?	7
Derivation of themes	26	Were themes identified in advance or derived from the data?	7
Software	27	What software, if applicable, was used to manage the data?	7
Participant checking	28	Did participants provide feedback on the findings?	7
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	13
Data and findings consistent	30	Was there consistency between the data presented and the findings?	13
Clarity of major themes	31	Were major themes clearly presented in the findings?	13
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	16,17 and 18

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

Once you have completed this checklist, please save a copy and upload it as part of your submission. DO NOT include this checklist as part of the main manuscript document. It must be uploaded as a separate file.

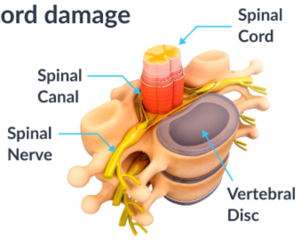
DEGENERATIVE CERVICAL MYELOPATHY

Decision Aid: *Should I have surgery?*

All information in this decision aid should be discussed with a health professional familiar with Degenerative Cervical Myelopathy (e.g., doctor, neurologist, surgeon, physiotherapist)

What is Degenerative Cervical Myelopathy?

- **Degenerative = change over time**
- **Cervical = neck related**
- **Myelopathy = due to spinal cord damage**



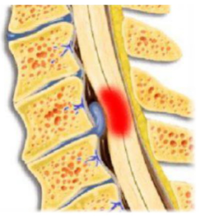
- Degenerative Cervical Myelopathy is often called 'DCM'
- In DCM, nerve signals going between the brain and body via the spinal cord are disrupted due to bone and soft tissue changes that compress the spinal cord in the neck
- This 'slowly, evolving spinal cord injury' can impact muscles, feeling on the skin and organ function

How is Degenerative Cervical Myelopathy diagnosed?

Changes And Symptoms Due To Spinal Cord Compression

- **What you feel** – pain, cramp, burning, numbness or pins and needles in the hands, arms or legs
- **Clumsiness or weakness** – dropping objects or less grip strength (e.g., trouble buttoning up a shirt)
- **Unsteady walking** – tripping or needing balance support

Note: Pain and stiffness is not always felt in the neck. Symptoms can be subtle and impact different parts of the body (e.g., bladder, bowel or sexual function changes).



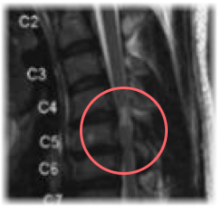
Pressure on the spinal cord

Imaging

- MRI scans can show narrowing of the spinal canal (stenosis) or compression of the spinal cord

Note: While spinal cord compression can show on your scan, it may not be causing symptoms.

Symptoms and scan results both influence management decisions.



MRI scan

What are the categories of Degenerative Cervical Myelopathy?

- The modified Japanese Orthopaedic Association (mJOA) scale is one way to classify the severity of DCM[1]
- Scores range from 18 (no spinal cord symptoms) to 0 (most severe)
- See page 2 for a link to calculate your score with a health professional who is familiar with DCM

mJOA	Category	Description and management recommendations (in bold)
18	Non-myelopathic	This may be early DCM or a different nerve issue without spinal cord compression. **Learn about risks (page 3) and monitor with a health professional (page 4).[2]**
15-17	Mild DCM	No significant issues with walking or loss of muscle strength. No or mild changes in physical function. **Non-surgical management or DCM surgery may be appropriate.[2]**
12-14	Moderate DCM	Your walking may feel unstable. You may have difficulty with hand coordination. **Timely surgery is recommended.[2]**
0-10	Severe DCM	Walking may be difficult. You may need a walking aid. You are likely to have significant muscle weakness or numbness. **Urgent surgery is recommended.[2]**

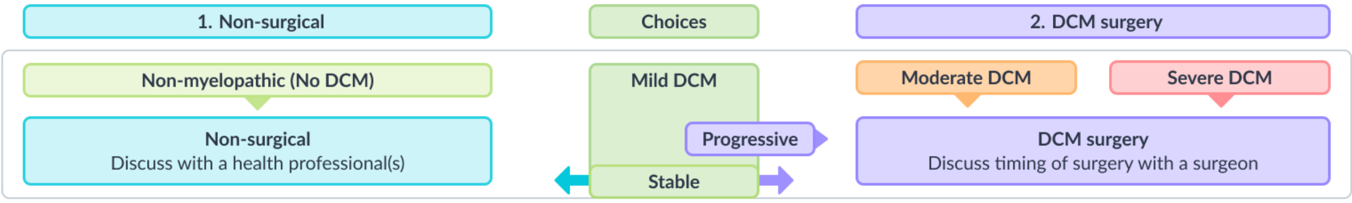
Which Degenerative Cervical Myelopathy category are you in when using the mJOA tool?

- The mJOA score rates difficulty using your arms, legs and toileting[1]
- Access the mJOA tool via the QR code or Assessment Scales - MYELOPATHY.ORG

Date: __________ Current mJOA total score: __________

○ Non-myelopathic (18)
○ Mild DCM (15-17)
○ Moderate DCM (12-14)
○ Severe DCM (0-11)

What is recommended?



- People with mild (stable) DCM have the option to choose between non-surgical management or DCM surgery
- Treatment for people with mild DCM is decided with a health professional and based on symptoms, imaging and personal preferences
- Researchers are still learning about how well nerves can heal on their own

① NON-SURGICAL MANAGEMENT

This is an option for people with DCM whose symptoms remain stable. The strategies below can be used without surgery. They can also be used before or after surgery with the aim to improve surgery outcomes.

A health professional can guide you with:

- Lifestyle and activity modification (e.g., physical activity levels or avoiding aggravating positions like looking up for a long time to cut hedges)
- Planning an exercise program to improve strength, movement and balance
- Self-management (e.g., pain, mindfulness and good sleep)
- Learning about DCM and monitoring symptoms (e.g., test grip strength and balance, discuss if you need a follow up MRI or use a diary to note key changes)
- Caring for your mental health and wellbeing. Join the the DCM social group via the QR code or Myelopathy.org Support Group | Facebook

② DCM SURGERY

This is an option for people with DCM whose symptoms do not remain stable or are significant.[3] Surgery aims to slow the progression of DCM and can improve some symptoms for some people.

- A surgical procedure is used to reduce spinal cord compression under general anaesthetic
- Surgery is performed either from the front or back of the neck. It involves joining bones of the spine together or inserting screws and plates to stabilise the spine
- Your surgeon will advise you on the type of surgery that is best for you (e.g., ACDF-Anterior Cervical Discectomy and Fusion, posterior cervical decompression)

Following surgery:

- Rehabilitation with other health professionals can help recovery (e.g., allied health professionals such as physiotherapists)
- Healing and adjusting to symptoms can occur over the next 1-2 years and beyond[3]

What are potential harms of non-surgical management vs DCM surgery?

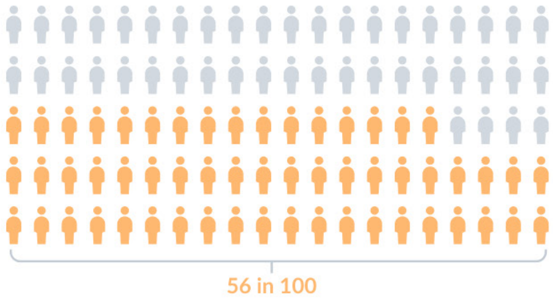
- This page shows estimates from the best available evidence from 5 studies including 1048 people with DCM.
- The results below are based on averages. We cannot tell if you will benefit from a particular treatment or experience a harm.

1 NON-SURGICAL MANAGEMENT

2 DCM SURGERY

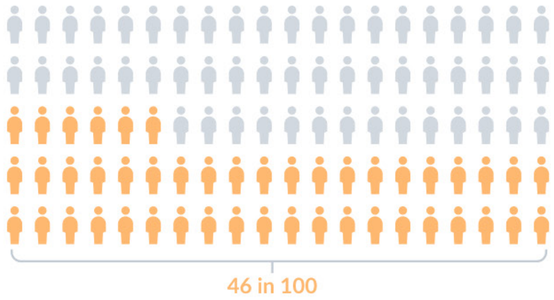
10 more people with **mild-moderate DCM** out of 100 get worse by at least 1 point on the mJOA scale with non-surgical management at 10 years[4]:

Key: People who get worse



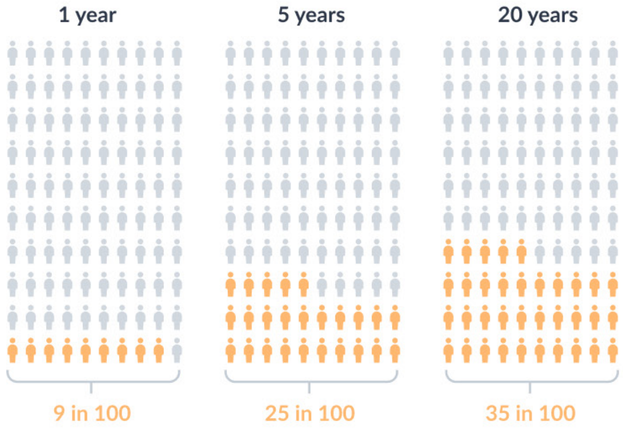
vs

Key: People who get worse



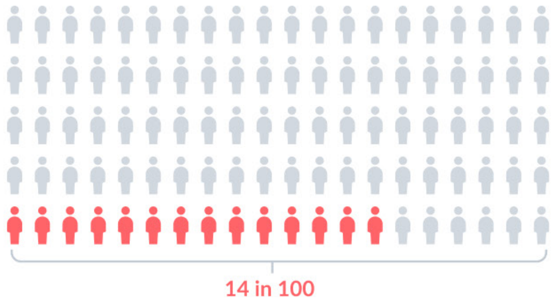
People with **mild DCM** managed non-surgically often get worse over time[5]:

Key: People who get worse



After surgery, 14 people out of 100 may experience harms, regardless of DCM severity[2]:

Key: People who experience harm



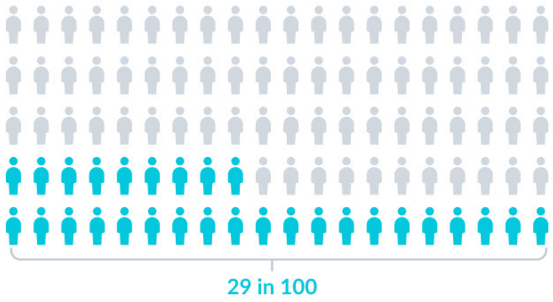
Examples of mild-moderate harms: Pain 6%, swallowing issues 2%, infection 2%, worse DCM 1%
Examples of serious harms: Death or stroke 0.3%, more surgery 1%, fracture 2%, heart and lung issues 3%

What are potential benefits of non-surgical management and DCM surgery?

1 NON-SURGICAL MANAGEMENT

29 people with **mild DCM** out of 100 report benefits of physiotherapy[6]:

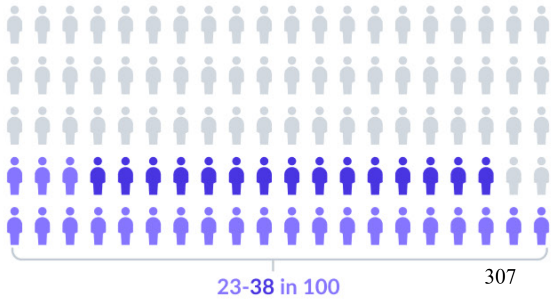
Key: People who benefit from physiotherapy



2 DCM SURGERY

Between 23 and 38 people with **mild-moderate DCM** out of 100 who start non-surgical management may need surgery at 2-7 years[7]:

Key: People who need surgery



Questions for when you talk with a health professional...

- What are the benefits and harms of surgery and non-surgical management for me?
- What do you offer as non-surgical management and how often will I be reassessed?
- Do I need surgery now? If I delay surgery, when should I return for follow up?
- What are my expected outcomes post-treatment? What will rehabilitation look like?
- What else do I need to consider? (general health e.g., age, weight; work; leisure activities e.g., gym, cycling)

Ask yourself..

1. Is your quality of life impaired by DCM?
2. Do you have significant pain?

People with low quality of life or neck pain may be candidates for DCM surgery.[8]

Monitor key changes with a health professional and mention if...

- Your walking changes or you become unsteady (e.g., using a handrail)
- Your hands become clumsy (e.g., buttoning a shirt or writing)
- You develop worsening neck or arm pain

Follow up date to review with a healthcare professional: ______________________

Where can I find more information?

Myelopathy.org
https://myelopathy.org/
(includes a UK helpline)

Spinal Injuries Association UK https://spinal.co.uk/

Spinal Injuries Association Australia https://scia.org.au/

Important information: This decision aid is not a substitute for advice from a health professional who should confirm your diagnosis. Having other conditions such as radiculopathy, an infection, neoplastic disease, rheumatoid arthritis, thoracic myelopathy, trauma, ankylosing spondylitis and lumbar stenosis can all influence the decision-making process.

Disclosure: The National Health and Medical Research Council (NHMRC) provided funding to develop this tool but had no involvement in the development process. The developers of this decision aid include physiotherapists, surgeons, neurologists, doctors, specialists and a chiropractor. None of the developers will gain or lose anything based on the choices that people make.

Last reviewed: 31.1.2025. Updated due 31.1.2027.

Lead developer: Andrew R Gamble, Institute for Musculoskeletal Health, The University of Sydney, NSW, Australia.

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3. Evaniew et al,. (2023) Spine J. 48(5):310-320.
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5. Sarraj M., et al,. (2024) Spine J. 24(1):46-56.
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7. Tetreault, L. et al,. (2017) Global Spine J. 7(3):42s-52s.
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Supplementary File 12: International Patient Decision Aid Standards checklist (IPDASi v4.0)

Qualifying criteria	Answer
1. The patient decision aid describes the health condition or problem (treatment, procedure, or investigation) for which the index decision is required.	Yes
2. The patient decision aid explicitly states the decision that needs to be considered (index decision).	Yes
3. The patient decision aid describes the options available for the index decision.	Yes
4. The patient decision aid describes the positive features (benefits or advantages) of each option.	Yes
5. The patient decision aid describes the negative features (harms, side effects, or disadvantages) of each option.	Yes
6. The patient decision aid describes what it is like to experience the consequences of the options (e.g., physical, psychological, social).	Yes
Certification criteria	**Answer**
1. The patient decision aid shows the negative and positive features of options with equal detail (e.g., using similar fonts, sequence, presentation of statistical information).	Yes
2. The patient decision aid (or associated documentation) provides citations to the evidence selected.	Yes
3. The patient decision aid (or associated documentation) provides a production or publication date.	Yes
4. The patient decision aid (or associated documentation) provides information about the update policy.	Yes

5. The patient decision aid provides information about the levels of uncertainty around event or outcome probabilities (e.g., by giving a range or by using phases such as ‘‘our best estimate is . . .’’).	Yes
6. The patient decision aid (or associated documentation) provides information about the funding source used for development.	Yes
7. The patient decision aid describes what the test is designed to measure.	N/A
8. If the test detects the condition or problem, the patient decision aid describes the next steps typically taken.	N/A
9. The patient decision aid describes the next steps if the condition or problem is not detected.	N/A
10. The patient decision aid has information about the consequences of detecting the condition or disease that would never have caused problems if screening had not been done (lead time bias).	N/A

Quality criteria	**Answer**
1. The patient decision aid describes the natural course of the health condition or problem, if no action is taken (when appropriate).	Yes
2. The patient decision aid makes it possible to compare the positive and negative features of the available options.	Yes
3. The patient decision aid provides information about outcome probabilities associated with the options (i.e., the likely consequences of decisions).	Yes
4. The patient decision aid specifies the defined group (reference class) of patients for whom the outcome probabilities apply.	Yes
5. The patient decision aid specifies the event rates for the outcome probabilities	Yes

6. The patient decision aid allows the user to compare outcome probabilities across options using the same time period (when feasible).	Yes
7. The patient decision aid allows the user to compare outcome probabilities across options using the same denominator (when feasible).	Yes
8. The patient decision aid provides more than 1 way of viewing the probabilities (e.g., words, numbers, and diagrams).	Yes
9. The patient decision aid asks patients to think about which positive and negative features of the options matter most to them (implicitly or explicitly).	Yes
10. The patient decision aid provides a step-by step way to make a decision.	Yes
11. The patient decision aid includes tools like worksheets or lists of questions to use when discussing options with a practitioner.	Yes
12. The development process included a needs assessment with clients or patients.	Yes
13. The development process included a needs assessment with health professionals.	Yes
14. The development process included review by clients/patients not involved in producing the decision support intervention.	Yes
15. The development process included review by professionals not involved in producing the decision support intervention.	Yes
16. The patient decision aid was field tested with patients who were facing the decision.	Yes
17. The patient decision aid was field tested with practitioners who counsel patients who face the decision.	Yes
18. The patient decision aid (or associated documentation) describes how research evidence was selected or synthesized.	Yes

19. The patient decision aid (or associated documentation) describes the quality of the research evidence used.	Yes
20. The patient decision aid includes authors'/developers' credentials or qualifications.	Yes
21. The patient decision aid (or associated documentation) reports readability levels (using 1 or more of the available scales).	Yes
22. There is evidence that the patient decision aid improves the match between the preferences of the informed patient and the option that is chosen.	No*
23. There is evidence that the patient decision aid helps patients improve their knowledge about options' features.	No*
24. The patient decision aid includes information about the chances of having a true-positive test result.	N/A
25. The patient decision aid includes information about the chances of having a true-negative test result.	N/A
26. The patient decision aid includes information about the chances of having a false-positive test result.	N/A
27. The patient decision aid includes information about the chances of having a false-negative test result.	N/A
28. The patient decision aid describes the chances the disease is detected with and without the use of the test.	N/A

N/A: not applicable.

*We plan to evaluate the decision aid in a randomised controlled trial.

Supplementary File 13. User-Centered Design 11-item measure (UCD-11)

Items	Explanations and examples	Yes/No
1. Were potential end users (eg, patients, caregivers, family and friends, surrogates) involved in any steps to help understand users (eg, who they are, in what context might they use the tool) and their needs?	Such steps could include various forms of user research, including formal or informal needs assessment, focus groups, surveys, contextual inquiry, ethnographic observation of existing practices, literature review in which users were involved in appraising and interpreting existing literature, development of user groups, personas, user profiles, tasks, or scenarios, or other activities	Yes
2. Were potential end users involved in any steps of designing, developing, and/or refining a prototype?	Such steps could include storyboarding, reviewing the draft design or content before starting to develop the tool, and designing, developing, or refining a prototype	Yes
3. Were potential end users involved in any steps intended to evaluate prototypes or a final version of the tool?	Such steps could include feasibility testing, usability testing with iterative prototypes, pilot testing, a randomized controlled trial of a final version of the tool, or other activities	Yes
4. Were potential end users asked their opinions of the tool in any way?	For example, they might be asked to voice their opinions in a focus group, interview, survey, or through other methods	Yes

5. Were potential end users observed using the tool in any way?	For example, they might be observed in a think-aloud study, cognitive interviews, through passive observation, logfiles, or other methods	Yes
6. Did the development process have 3 or more iterative cycles?	The definition of a cycle is that the team developed something and showed it to at least one person outside the team before making changes; each new cycle leads to a version of the tool that has been revised in some small or large way	Yes
7. Were changes between iterative cycles explicitly reported in any way?	For example, the team might have explicitly reported them in a peer-reviewed paper or in a technical report. In the case of rapid prototyping, such reporting could be, for example, a list of design decisions made and the rationale for the decisions	No
8. Were health professionals asked their opinion of the tool at any point?	Health professionals could be any relevant professionals, including physicians, nurses, allied health providers, etc. These professionals are not members of the research team. They provide care to people who are likely users of the tool. Asking for their opinion means simply asking for feedback, in contrast to, for example, observing their interaction with the tool or assessing the	Yes

	impact of the tool on health professionals' behaviour	
9. Were health professionals consulted before the first prototype was developed?	Consulting before the first prototype means consulting prior to developing anything. This may include a variety of consultation methods	Yes
10. Were health professionals consulted between initial and final prototypes?	Consulting between initial and final prototypes means some initial design of the tool was already created when consulting with health professionals	Yes
11. Was an expert panel involved?	An expert panel is typically an advisory panel composed of experts in areas relevant to the tool if such experts are not already present on the research team (eg, plain language experts, accessibility experts, designers, engineers, industrial designers, digital security experts, etc). These experts may be health professionals but not health professionals would provide direct care to end users	Yes

Supplementary file 14: Reasons for not implementing feedback for each section of the decision aid

Themes	Sub themes	Feedback	Reason for not implementing the feedback
2. Constructive feedback on the decision aid	2.1. Constructive feedback on the content	People with Degenerative Cervical Myelopathy	
		Some feedback indicated that certain content may be too complex.	Some content suggested to be too complex was necessary for accuracy of the decision aid. The decision aid also includes prompts to discuss content with a health professional.
3. Modify the decision aid to enhance understanding for people with DCM	3.1 Simplify the language used	People with Degenerative Cervical Myelopathy	
		Some people with Degenerative Cervical Myelopathy (DCM) suggested some language was too technical.	Some technical terms are necessary for accuracy of the decision aid.
	3.3 Modify the information included	People with Degenerative Cervical Myelopathy	
		Suggestions were made by people with DCM to remove less relevant information for example some pictures could be changed to be more relevant to the context.	Information has been prioritised, but some details remained essential for a complete understanding.

		Suggestions were made to restructure the information, so the decision portion of the decision aid was on the first page. A suggestion was made to provide the full Modified Japanese Orthopaedic Association scale rather than just the QR code for people with DCM who are less technology literate.	Information was restructured over the development process, but researchers felt it was important to have a description of DCM before the decision portion of the decision aid. Researchers felt that the QR code simplified the decision aid, and the decision aid is designed to be used with a health professional who could guide use of the QR code if required.
		Health Professionals	
		Health professionals suggested adding differential diagnosis information and additional information about scans.	The decision aid includes information about diagnosis but additional information about differential diagnosis should be discussed with health professionals to avoid confusion.

	3.4 Modify pictures and graphics	People with Degenerative Cervical Myelopathy	
		Suggestions were made by people with DCM to adjust visuals for better clarity.	Not all suggested changes were accommodated due to design constraints.
		Health Professionals	
		Some health professionals suggested making pictures more relevant to the context.	The pictures included were chosen to enhance understanding for people with DCM.
4. Improving awareness of DCM and acceptability of the decision aid	4.1 Clarify the purpose of the decision aid	People with Degenerative Cervical Myelopathy	
		There was a need for further explanation of the decision aid's purpose.	We decided to focus on using headings to describe the purpose of the decision aid to avoid confusion. For example, 'Should I have surgery?'.
		People with Degenerative Cervical Myelopathy	

	4.2 Increasing awareness of DCM and evidence-based management	Requests were made for more background on DCM and management strategies.	Feedback consistently suggested the decision aid should be simplified so it was decided that additional detail was unnecessary.
		Health Professionals	
		Health professionals sought more comprehensive details on DCM and evidence-based management to support their guidance of care of people with DCM. care.	The need to remain concise limited the depth of additional information that could be included.
	4.3 Increasing the potential for practical implementation of the decision aid	People with Degenerative Cervical Myelopathy	
		Suggestions were made to make the aid more applicable to real-life scenarios.	We avoided including case studies as frequent feedback suggested to keep the decision aid concise.
		Health Professionals	
		Health professionals requested changing the format of the Modified Japanese Orthopaedic Association scale to improve practical application.	Certain recommendations, such as modifying the Modified Japanese Orthopaedic Association scale were beyond the current scope of the aid.

	4.4 Determining how to best include the Modified Japanese Orthopaedic Association (mJOA) scale and encourage use of outcome measures	People with Degenerative Cervical Myelopathy	
		Requests were made to integrate the Modified Japanese Orthopaedic Association scale more effectively or change how scoring was presented	We were unable to change how the Modified Japanese Orthopaedic Association scale scoring was presented.
		Health Professionals	
		Health professionals suggested that the Modified Japanese Orthopaedic Association scale should be more prominently featured to guide clinical decisions.	Due to feedback about making the decision aid more concise we decided not to include the whole Modified Japanese Orthopaedic Association scale.
		Health Professionals	

5. Highlight variations in symptoms and promote individual management	5.1 Acknowledge the variation of DCM symptoms and individual circumstances	Health professionals emphasised the importance of recognising individual variations in symptoms.	To keep the decision aid concise, we avoided including every example of symptoms mentioned in interviews.
	5.2 Promote the use of multiple objective tools to guide timely management	People with Degenerative Cervical Myelopathy	
		Suggestions were made to include various tools for decision-making.	Not all decision-making tools could be included due to space and focus constraints.
		Health Professionals	
		Health professionals recommended including various objective tools to further guide decision making.	To keep the decision aid concise, not all suggestions could be incorporated.
		People with Degenerative Cervical Myelopathy	

6. Create realistic treatment expectations	6.1 Awareness of non-surgical and surgical management aims for people with DCM	There was a need to clarify goals for non-surgical and surgical treatments.	Some feedback on goals was too case-specific for broad application to be included.
		Health Professionals	
		Health professionals requested clearer goals for both non-surgical and surgical management.	Goals should be tailored to each person with DCM, so were not specific in the decision aid.
	6.2 Clarify guidelines for rehabilitation and potential for spinal cord healing	People with Degenerative Cervical Myelopathy	
		There was a need for clear rehabilitation and healing guidelines.	Due to the limited availability of evidence to guide rehabilitation for DCM and spinal cord healing we were unable to provide further detail.
		Health Professionals	
		Health professionals requested detailed guidelines on rehabilitation and spinal cord healing.	Due to the limited availability of evidence to guide rehabilitation for DCM and spinal cord

			healing we were unable to provide further detail.
	6.3 Highlight challenges to access and affordability of care for people with DCM	People with Degenerative Cervical Myelopathy	
		Concerns were raised about access to and affordability of care.	The decision aid is designed to be used globally. It can be adapted to incorporate specific access and affordability to care information for different countries in the future.
		Health Professionals	
		Health professionals stressed the need to address barriers to access and affordability.	Providing practical solutions around access and affordability of care was outside the scope of the decision aid due to differences between countries and to keep the decision aid more concise.

DCM, Degenerative Cervical Myelopathy, QR, quick response

Supplementary file 15: Interview themes and subthemes, and example quotes

Themes	Sub themes	Quotes
1. Positive feedback on the decision aid	1.1. Positive feedback on the content	People with Degenerative Cervical Myelopathy
		"I like the graphics that you've got on there. And I like the fact that it's putting the decision-making back with the patient but giving them information." (F, 51-60, patient) *"I wonder if I had had access to this clarity of information, if it would have helped me to think more logically at the time" (F, 61-70, patient)* *"Clearly listed in everyday language" (F, 41-50, patient)*
		Health Professionals
		"I mean, I think this is a really nice piece of piece of work developing something that, you know, is a, essentially, I would call it a shared decision-making tool." (F, 41-50, physiotherapist)

		"If neurologists had access to data like this then we would be better suited to help them or help triage them appropriately" (F, 31-40, neurologist)
	1.2 Positive feedback on the design	People with Degenerative Cervical Myelopathy
		""I really liked this; everything was presented objectively." (F, 61-70, patient) *"Everything was clear, I've been through the whole document, and I find it very clear, very easy to follow." (F, 61-70, patient)*
		Health Professionals
		"The layout is clean and easy to follow. It's not overwhelming like other medical guides I've seen." (F, 41-50, physiotherapist)
2. Constructive feedback on the decision aid	2.1. Constructive feedback on the content	People with Degenerative Cervical Myelopathy
		"Some of the medical jargon was difficult to understand without prior knowledge." (F, 61-70, patient)

		"Again, that first bit, it steers towards surgery... I feel that this still seems to stitch things in that the surgery is recommended for people with and I don't think it depends on the timeline." (F, 61-70, patient)
		Health Professionals
		"The document itself is dense with a lot of material but there are ways to simplify it" and "you could use more lay definitions" (M, 61-70, neurosurgeon) *"Needs to be more patient friendly" (M, 21-30, physiotherapist)*
	2.2 Constructive feedback on the design	People with Degenerative Cervical Myelopathy
		"Very text heavy, needs more white space" (F, 51-60, patient) *"...surgical cuts...I would have just said surgery from the front or the back of the neck...surgical procedure to reduce spinal cord compression." (F, 71-80, patient)*
		Health Professionals
		"I think we need you to modify this" (F, 21-30-, occupational physician)

		"It's quite text-heavy. More white space and bullet points would make it less daunting." (F, 41-50, physiotherapist)
3. Modify the decision aid to increase understanding for people with DCM	3.1 Simplify the language used	People with Degenerative Cervical Myelopathy
		"Simplifying the language and defining each part of DCM would make the information more accessible." (F, 61-70, patient) *"Breaking down complex terms into layman's language could help patients better understand their condition." (F, 61-70, patient)* *"For lay people, you may want to simplify it a little bit." (M, 71-80, patient)* *"I'm concerned in our increasingly sound bite-driven society of, you know, 150 characters or less, some of the info is going to get lost in the weeds." (M, 31-40, patient)*
		Health Professionals
		"Use lay language for the reader" (M, 41-50, neurosurgeon) *"You could use more lay definitions" (M, 61-70, neurosurgeon)*

	3.2 Modify how statistics are presented	People with Degenerative Cervical Myelopathy
		"Oh, perhaps you could add pictures to it like the other one." (F, 51-60, patient) *"One of the challenging things in deciphering this information is that it's dealing with different time scales... you have information for non-surgical management at one year, five years, and surgery at three months, one year." (M, 31-40, patient)*
		Health Professionals
		"I did wonder like whether a QR code would be helpful, that could take them through to either a website or an option for larger texts or different languages. Which would be the other thing, I don't know if there's a if you thought about other language versions, but certainly putting a QR code that then gives them because I think when I read this through" (F, 41-50, physiotherapist *"The statistics should be presented in a more visual format. Graphs or charts could make them easier to understand." (F, 41-50, physiotherapist)*
		People with Degenerative Cervical Myelopathy

	3.3 Modify the information included	*"And it's not just healing, it's adapting to the fused vertebra as well, depending on how much you know, range of movement, you have post-surgery." (F, 41-50, patient)* *"The symptoms of DCM can vary widely. Early symptoms often include loss of fine motor skills and balance issues, as you mentioned. It's useful to document specific experiences, such as difficulty with buttoning shirts or navigating stairs." (F, 41-50, patient)* *"It would be interesting to know if there's been a study that has looked at perceived benefit of surgery in people with mild DCM... So then you can have, like, what is the perceived benefit of both." (M, 31-40, patient)*
		Health Professionals
		"Including more information on the diverse symptoms of DCM would make it more relatable to different patients." (F, 41-50, physiotherapist)
		People with Degenerative Cervical Myelopathy

	3.4 Modify the pictures and graphics	*"Or you might have room for you know, if you change the picture of the lady walking to a different shape, you might have room for some graphics to put in, you know, a tablet and a pillow or an or mattress." (F, 41-50, patient)* *"The picture on the non-surgical one looks a bit too laid back and relaxed. I'd like to see that somebody can continue to be active there, rather than just sit by the bill and read a book." (F, 61-70, patient)*
		Health Professionals
		"The graphics need to be more illustrative and relevant to the text. They should help in explaining the content better." (F, 41-50, physiotherapist) *"Possibly use colour codes (green, yellow, red) to indicate severity levels." (F, 21-30, occupational physician)* *"Consider breaking down complex information into simpler chunks." (F, 21-30, occupational physician)*
		People with Degenerative Cervical Myelopathy

4. Improving awareness of DCM and acceptability of the decision aid	4.1 Clarify the purpose of the decision aid	*"I like that all information should be discussed with a health professional" (F, 41-50, patient)* *"I think what potentially we should have is a better explanation of the MJOA. And also explain how it's determined." (F, 51-60, patient)*
		Health Professionals
		"I like that it should be discussed with a health professional - people google or talk…" (M, 51-60, neurosurgeon) *"It should be clearer that this decision aid is meant to be used alongside a health professional to avoid causing unnecessary panic." (F, 41-50, physiotherapist)*
	4.2 Awareness of DCM and evidence-based management	People with Degenerative Cervical Myelopathy
		"I didn't know what it was until I found out I had it and I even have trouble explaining it to friends now so I just say I have a spinal cord injury" (F, 41-50, patient) *"5-7 years then deterioration and over really poorly diagnosed area" "overseas trained doctors sometimes have little knowledge of it" (F, 71-80, patient)*

		Health Professionals
		"Awareness is an issue in primary care" "thresholds can be subjective and people need to get the right information, can’t all talk to surgeons" (M, 21-30, physiotherapist) *"People don’t seek help in parts of Scotland until very late as they think it is normal aging and can be only 51 years old" (M, 41-50, neurosurgeon)*
	4.3 Increase the potential for practical implementation of the decision aid	People with Degenerative Cervical Myelopathy
		“...learning about DCM and monitor your symptoms with your health professional.” (F, 71-80, patient)
		Health Professionals
		"it's probably for me going back to where you think this is going to be the most useful. Because I think if you are trying to develop something for everybody, you might struggle." (F, 41-50, physiotherapist) *"So in primary care, we would say, in the UK, where this can be delivered by a healthcare professional, you can start to have those conversations, as you're referring a patient on*

		almost to get them ready for that surgical conversation, then that will be brilliant. From my perspective, when patients come to us, they are just not expecting the conversation about surgery. And the MJOA hasn't even been done, they haven't been categorised that when they get to us, and we say, okay, surgery is your option, they almost panic" (F, 41-50, physiotherapist)
	4.4 Determine how to best include the mJOA scale and encourage use of outcome measures	People with Degenerative Cervical Myelopathy
		N/A
		Health Professionals
		"We don't need to teach patients how to calculate the mJOA… (M, 61-70, neurosurgeon) *"Including quality of life scales instead of the full mJOA might be more useful for guiding management decisions." (F, 41-50, physiotherapist)*
		People with Degenerative Cervical Myelopathy

5. Highlight variations in symptoms and promote individual management	5.1 Acknowledge the variation of DCM symptoms and individual circumstances	*"You might just want to put in balance issues there as well. So you've got clumsiness difficult. Yeah. She's walking in, but you haven't got a lot of other... I've got quite a lot of balance issues." (F, 51-60, patient)* *"The clumsiness and tripping over were the main symptoms for me." (F, 51-60, patient)*
		Health Professionals
		"Pain in the arms can occur but the disease is more focused on lack of coordination and unsteady gait" (M, 41-50, neurosurgeon) *"Early symptoms look like this, you know, get an MRI scan done, they're covered by Medicare." (F, 21-30, occupational physician)*
	5.2 Promote the use of multiple objective tools to guide timely management	People with Degenerative Cervical Myelopathy
		"Let them know if your experience worsening, worsening of symptoms despite following medical advice." (F, 41-50, patient)
		Health Professionals

		"I talk to them about symptoms worsening or the impact of their life, but the score is just where they stand" (M, 41-50, neurosurgeon) *"Tools like the mJOA should be used to highlight the urgency and guide the management of the condition." (F, 41-50, physiotherapist)*
	5.3 Encourage the appropriate use of shared decision making	People with Degenerative Cervical Myelopathy
		"Your surgeon will help you decide on the type of surgery" (F, 41-50, patient) *"...talk to a health professional about potential surgery...your symptoms may not improve, or, you know, may only be, you know, minimal, but it's the aim is to prevent, or to try and stop symptom progression." (F, 71-80, patient)* *"Asking the patient, 'are you staying the same, getting better, getting worse'... might cause them to take a moment to reflect on what their state is before thinking about what these categories are." (M, 31-40, patient)*
		Health Professionals

		"Treatment is determined by symptoms and image findings" (M, 51-60, orthopaedic surgeon) *"This should be an individualised discussion specific to that patient (M, 21-30, physiotherapist)* *"It can be a silent bomb sometimes you know" (M, 41-50, neurosurgeon)* *Not only the mJOA that will dictate the treatment is good you have mentioned (F, 31-40, neurologist)*
6. Create realistic treatment expectations	6.1 Awareness of non-surgical and surgical management aims for people with DCM	People with Degenerative Cervical Myelopathy
		"No pain no gain common – not always the case particularly the case with the neck" (F, 41-50, patient) *"It's important to clearly state that non-surgical management is a viable option and can be effective for many individuals." (F, 61-70, patient)*
		Health Professionals
		"It is a degenerative condition, so management isn't a cure" (F, 41-50, patient)

		"The importance of setting a realistic expectation and the fact that people aren't necessarily cured by this." (M, 51-60, general practitioner) *Careful with language - is it a slowly progressive spinal cord injury vs scary slow motion spinal cord injury (M, 21-30, physiotherapist)* *"Quite often the expectations sign off for surgery is that it fixes everything and not realistic and not what they hear even if it has been said" (M, 41-50, rehabilitation and pain specialist)*
	6.2 Clarify guidelines for rehabilitation and potential for spinal cord healing	People with Degenerative Cervical Myelopathy
		"Post op care and rehab makes a huge difference – persistence with exercises and recommendations from OT" (F, 41-50, patient) *"I started doing step training, just to try and get my balance. And then I was able to do it with weights, you know how you can stay active?" (F, 61-70, patient)*
		Health Professionals

		"Rehabilitation is important post-surgery, but type and timing should be personalised. People may not have insurance or recover well with home exercise" (M, 61-70, neurosurgeon) *"Detailed recommendations for rehabilitation, including physiotherapy, should be clarified." (F, 41-50, physiotherapist)*
	6.3 Highlight challenges to access and affordability of care for people with DCM	People with Degenerative Cervical Myelopathy
		“So in the NHS, no rehabilitation is provided nothing. After my first operation, I was so traumatised, I was so traumatised after surgery. And adapting can take time. (F, 71-80, patient) *“...access and affordability of treatment options can vary significantly between public and private healthcare systems.” (F, 71-80, patient)* *“...many patients struggle with the cost of follow-up appointments and repeat scans, which are often necessary for ongoing management.” (F, 71-80, patient)* *"Surgery booking takes time, so the priority should go to people with fast-progressing symptoms." (M, 71-80, patient)*

		Health Professionals
		"Information on the affordability and accessibility of treatments, including the role of primary practitioners, is needed." (F, 41-50, physiotherapist)
7. Facilitate equitable access to care and active management strategies	7.1 Encourage monitoring of DCM symptoms with a health professional	People with Degenerative Cervical Myelopathy
		"It's important to monitor symptoms, especially on your worst days, as they can vary day to day." (F, 71-80, patient) *"...monitoring is about...self-awareness on the patients." (F, 71-80, patient)*
		Health Professionals
		"Non-myelopathic may not need to be monitored closely but rather come back if they develop changes" (M, 41-50, neurosurgeon) *"They may not need to see anyone, but they need to know the risk factors and when to come back" (M, 41-50, neurosurgeon)*

		"Patients can have this progressive condition that is silent, that they don't have any pain or there's just steadiness and they think it's old age." (F, 21-30, occupational physician)
	7.2 Participation in management and creating foundations for on-going support	People with Degenerative Cervical Myelopathy
		"Engage in regular, tailored physical therapy sessions to maintain muscle strength, improve balance, and enhance coordination. Focus on exercises that can be done safely under professional supervision." (F, 61-70, patient) *"Promoting active participation in management and building a support system for patients is crucial." (F, 41-50, physiotherapist)*
		Health Professionals
		"The key with these patients is the psychosocial factors which need to be delt with" (M, 31-40, orthopaedic surgeon) *"I talk to them about symptoms worsening or the impact of their life, but the score is just where they stand" (M, 41-50, neurosurgeon)*

	7.3 Acknowledge the adjustments to living with DCM and benefits of support groups	People with Degenerative Cervical Myelopathy
		"I was mild when they looked at me because I could walk into the room and if I could articulate everything, and I was still functioning at a level, where I was caring for my children, I was still driving. But I knew compared to what my function was in 2020, that I was vastly different." (F, 41-50, patient)
		Health Professionals
		"Providing information on support groups and realistic timeframes for adjusting to life with DCM would be very helpful." (F, 41-50, physiotherapist)
	7.4 Promote a positive mindset for the future management of people with DCM	People with Degenerative Cervical Myelopathy
		"My neurosurgeon saved my life... he has pointed me in the direction of how to best approach non-surgical routes." (F, 61-70, patient) *"...highlighting success stories of individuals who have managed their DCM well can provide hope and motivation." (F, 71-80, patient)*

		Health Professionals
		"Incorporating positive messages throughout the decision aid could help boost patients' morale and outlook on managing DCM." (F, 41-50, physiotherapist)

F, Female, M, Male, DCM, Degenerative cervical myelopathy, QR, quick response, UK, United Kingdom, mJOA, modified Japanese Orthopaedic Association, NHS, National Health Scheme, OT, Occupational Therapist

APPENDIX FOUR

Chapter Five publication metrics

Under review

Impact

Chapter Five led to the development of a new model of care which is currently being evaluated in an adequately-powered randomised controlled trial across multiple public hospital outpatient clinics in Sydney, Australia. It has led to $1.5 million grant funding from the Medical Research Future Fund (MRFF) for the WAIT-less trial.

Supplementary file 1: Semi-structured interview guides

INTERVIEW GUIDE FOR PATIENTS INCLUDED IN TRIAL

Questions do not have to be asked in this order, and not all questions have to be covered

Introduction

Hi, my name is [name]. Thank you for taking part in this interview. Researchers and health professionals at The University of Sydney and Royal Prince Alfred Hospital want to find out whether a new treatment pathway using telephone and virtual appointments, and App-based exercise programs, helps people receive treatment sooner and get better sooner.

We would like to ask you questions about the treatment you received in the Back Clinic. If at any time you would like to stop the interview, please let us know and we will stop. You can change your mind about talking to me at any time before or during the interview and stop the interview at any time. You can choose not to answer a question.

Are you happy to continue? [If no, thank them for their time and end the interview; if yes, continue].

Thank you [name] for agreeing to take part. We will use your feedback and the feedback of others to write a summary of what people have told us. There will be absolutely no identification of any real names or identification of where you live or which hospitals or health professionals you have seen.

Are you happy for me to record the interview? Do you have any questions before we start?

CONTEXT: TO UNDERSTAND WHAT WORKED, WHAT DIDN'T WORK, AND WHY/ WHY NOT FOR THE TWO METHODS OF SERVICE DELIVERY.

I am interested in exploring your experiences with the care you received in greater detail. Please feel free to be honest about what it was like for you.

All participants

1. Please tell me about your experiences overall of [face-to-face care, virtual consultation, App, pain education program, telephone consultation].

Prompts:

- What aspects of the experience do you like most, and why?
- What do you like least, and why?

2. Was your treatment convenient?

Prompts:

- How convenient was it for you to receive [face-to-face care, virtual consultation, App, pain education program, telephone consultation]?
- How do you feel about not having to attend the hospital for treatment (for low-, medium-, and high-risk participants)?
- How do you feel about having to attend the hospital for treatment (for participants with worrisome radicular symptoms and the usual care group)?

Low-risk participants

3. Next, I'd like to get your views about the virtual/telephone call you received (or why you did not receive it).

Prompts:

- How did you find the call? What was helpful? What wasn't?

- Do you feel as though you got any benefit from the phone call?
- What kinds of things did you talk about with the rheumatologist?
- Would you recommend this method of delivering for others? What kinds of people would this approach suit? Who wouldn’t it suit?
- What else would you liked to have received as part of your treatment during the trial?

Medium- and high-risk participants

4. Next, I’d like to get your views about the virtual consultation(s) you received (or why you did not receive them).

Prompts:

- How did you find the consultation(s)? What was helpful? What wasn’t?
- Do you feel as though you got any benefit from the virtual consultation(s)?
- Do you feel the benefit was similar to what you would have got with face-to-face appointment(s)?
- Would you recommend this method of delivering treatment for others? What kinds of people would this approach suit? Who wouldn’t it suit?
- What else would you liked to have received as part of your treatment during the trial?
- Can you comment on the frequency of your appointments?

5. Next, I want to discuss the PhysiTrack App.

- Did you ever use the App?
- If no, why was that?
- If yes, how easy was it to use the App? Did it get easier over time?
- Did you need help to use it? If yes, explore.

- What do you think about the physio using the App to monitor your compliance with the rehabilitation exercises? Why do you say that?
- Did your recording of exercises match what exercise you did?
- How long did you use the App?
- How long did you do the rehabilitation exercises? Why or why not?

6. Next, I want to discuss the self-directed pain education program. **(High risk participants)**

- Did you access the program?
- If no, why was that?
- If yes, how easy was it to navigate? Did it get easier over time?
- Did you need help to access it? If yes, explore.
- How did you find the information in the program?
- Did you watch all the videos? Explore

Participants with worrisome radicular pain (and people in the usual-care group)

7. Next, I'd like to get your views about the face-to-face appointments you received (or why you did not receive them).

Prompts:

- How did you find the appointment(s)? What was helpful? What wasn't?
- Can you tell me about the process of scheduling appointments? What was the availability of your rheumatologist and physiotherapist?
- Did you always have the same person?
- What is it about seeing a rheumatologist or physiotherapist in person that you like or don't like?

- How convenient was it for you to travel to and attend a face-to-face appointment(s) at the hospital?
- Can you comment on the frequency of your appointments? Is that what you expected? Why or why not?
- Do you feel as though you got any benefit from the appointment(s)?
- Would you recommend this method of delivering treatment for others? What kinds of people would this approach suit? Who wouldn't it suit?
- Do you feel you could have a got a similar benefit from a telephone or virtual consultation(s)?
- What else would you liked to have received as part of your treatment during the trial?

8. Is there anything else you would like to say that we have not talked about in this interview?

Thank you so much for your time.

INTERVIEW GUIDE FOR EXTERNAL PATIENTS

Questions do not have to be asked in this order, and not all questions have to be covered

Introduction

Hi, my name is [name]. Thank you for taking part in this interview. Researchers and health professionals at The University of Sydney and Royal Prince Alfred Hospital want to find out whether a new treatment pathway using telephone and virtual appointments, and App-based exercise programs, helps people receive treatment sooner and get better sooner.

We would like to ask you questions about your thoughts on the model of care (rapid virtual care) and our trial testing this model. If at any time you would like to stop the interview, please let us know and we will stop. You can change your mind about talking to me at any time before or during the interview and stop the interview at any time. You can choose not to answer a question.

Are you happy to continue? [If no, thank them for their time and end the interview; if yes, continue].

Thank you [name] for agreeing to take part. We will use your feedback and the feedback of others to write a summary of what people have told us. There will be absolutely no identification of any real names or identification of where you live or which hospitals or health professionals you have seen.

Are you happy for me to record the interview? Do you have any questions before we start?

All participants

Participants will be asked about basic demographic information and other questions to give further background on relevant characteristics (e.g., what is their current musculoskeletal condition).

1. What are your thoughts on the positives and negatives of this model of care?

2. What reason or reasons would (did) you decide to not participate in the trial testing this model?

3. What reason or reasons would (did) you not provide follow-up data (or stop providing data)?

Prompts

- *Explanation of the model of care*

- *Ask participants on their thoughts on what could be improved to make the model more suitable for them and more likely to participate*
- *Ask participants what information they would need to hear during the recruitment phone call to increase the likelihood they would participate and complete follow up data*

4. Do you have any other musculoskeletal pain?

- *If yes, do you think this model of care will be beneficial for this pain if you would otherwise see a physiotherapist or rheumatologist?*

5. Is there anything else you would like to say that we have not talked about in this interview?

Thank you so much for your time

INTERVIEW GUIDE FOR CLINICIANS INCLUDED IN THE TRIAL

(Questions do not have to be asked in this order, and not all questions have to be covered.)

Hi, my name is [name and background]. Thank you for taking part in this interview. Researchers and health professionals at The University of Sydney and Royal Prince Alfred Hospital want to find out whether a new treatment pathway using telephone and virtual appointments, and App-based exercise programs, helps people receive treatment sooner and get better sooner. We also want to see if the new treatment pathway is acceptable to clinicians.

We would like to ask you questions about the treatment you provided in the Back Clinic as part of the trial. You can change your mind about talking to me at any time before or during the interview and stop the interview at any time.

Are you happy to continue? [If no, thank them for their time and end interview; if yes continue.]

Thank you [name] for agreeing to take part. We will use your feedback and the feedback of others to write a summary of what people have told us. There will be absolutely no identification of any real names or identification of your professional details.

Are you happy for me to record the interview? Do you have any questions before we start?

CONTEXT: TO UNDERSTAND WHAT WORKED, WHAT DIDN'T WORK, AND WHY/ WHY NOT FOR THE TWO METHODS OF SERVICE DELIVERY

Participants will be asked about basic demographic information and other questions to give further background on relevant characteristics (e.g., hospital site, professional experience, years in current position and years since graduated).

1. Let's first talk about the way your service normally operates.

Prompt:

- How often would you typically see patients? Do you have a waiting list? How long is that waiting list usually?

2. Please tell me about your overall experiences coordinating the Rapid Virtual Stratified Care trial.

Prompts:

- What pleased you about the trial?
- What surprised you?
- What were your concerns?
- What would you do differently?

3. How did the clinicians and patients involved in the trial respond to being involved?

4. Please tell us about the recruitment process for the trial.

Prompts:

- How did you manage the logistics of recruitment?
- Was there any difficulty in recruiting participants? If so, please describe.

CONTEXT: TO UNDERSTAND THE PERCEIVED BARRIERS/ FACILITATORS FOR EVALUATING IN A LARGE, MULTI-SITE TRIAL

5. On the basis of your experience in the trial, how easy do you think it will be to introduce delivering this model of care in other outpatient musculoskeletal settings?

6. Has the COVID-19 crisis changed your or your colleagues' attitudes towards delivering rehabilitation remotely?

7. Looking back on the approach used to deliver treatment using eHealth in the trial – are there any aspects of the intervention that could have been delivered differently?

Prompts:

- Could participants at high-risk of persistent pain be better managed with face-to-face appointments?
- Could participants with worrisome radicular symptoms be managed equally effectively with virtual appointments?

8. What is the potential for eHealth-based stratified care to provide more patients with treatment sooner? How important is it to cut down waiting lists?

9. Thinking about what you have learnt from your experiences in the trial – what are the pros and cons of using eHealth-based stratified care, from patients' perspectives?

Prompts:

- What are the main advantages for patients compared to usual practice?
- How acceptable is eHealth-based stratified care likely to be to those accessing treatment for low back pain in a public hospital? Why or why not?
- What kinds of patients do you think are most suitable for being managed or monitored using eHealth?

10. What are the pros and cons from a clinician's perspective?

Prompts:

- How compatible/ acceptable will eHealth-based stratified care be to hospital physios and rheumatologists?
- What are the main advantages for clinicians in delivering care via eHealth, compared to usual practice? What are the main disadvantages?

11. What has to be in place for eHealth-based stratified care to be viable to deliver in the hospital setting?

Prompts:

- What are some things that will make this hard/ easy?
- Could this model of care be rolled out in your hospital right now?
- What are some of the barriers?
- What are some of the facilitators?
- Where will the main resistance come from?

12. What kinds of benefits would you anticipate that introducing eHealth-based stratified care would have for patients; physiotherapists; rheumatologists; for hospitals? (Ask about health, service access, cost savings for the hospital).

13. If eHealth-based stratified care was found to be beneficial in a large trial, would you want to provide this intervention in the future? Why, or why not?

14. Is there anything else you would like to say that we have not talked about in this interview?

Thank you so much for your time.

INTERVIEW GUIDE FOR EXTERNAL CLINICIANS AND KEY STAKEHOLDERS

(Questions do not have to be asked in this order, and not all questions have to be covered.)

Hi, my name is [name and background]. Thank you for taking part in this interview. Researchers and health professionals at The University of Sydney and Royal Prince Alfred Hospital want to find out whether a new treatment pathway using telephone and virtual appointments, and App-based exercise programs, helps people receive treatment sooner and get better sooner. We also want to see if the new treatment pathway is acceptable to clinicians.

We would like to ask you questions about the model of care we used in the Back Clinic as part of a trial and the potential of combining stratified care and telehealth to treat various musculoskeletal condition. You can change your mind about talking to me at any time before or during the interview and stop the interview at any time.

Are you happy to continue? [If no, thank them for their time and end interview; if yes continue.]

Thank you [name] for agreeing to take part. We will use your feedback and the feedback of others to write a summary of what people have told us. There will be absolutely no identification of any real names or identification of your professional details.

Are you happy for me to record the interview? Do you have any questions before we start?

CONTEXT: TO UNDERSTAND THE PERCEIVED BARRIERS/ FACILITATORS FOR EVALUATING IN A LARGE, MULTI-SITE TRIAL

Participants will be asked about basic demographic information and other questions to give further background on relevant characteristics (e.g., hospital site, professional experience, years in current position and years since graduated where relevant)

1. Let's first talk about the way your service normally operates.

Prompt:

- How often would you typically see patients? Do you have a waiting list? How long is that waiting list usually?

2. Based on your knowledge, how easy do you think it will be to introduce delivering this model of care in other outpatient musculoskeletal settings?

Prompt:

- *Explanation of the model of care*

3. Has the COVID-19 crisis changed your or your colleagues' attitudes towards delivering rehabilitation remotely?

4. Looking at the approach used to deliver treatment using eHealth in our trial – are there any aspects of the intervention that could have been delivered differently?

Prompts:

- Could participants at high-risk of persistent pain be better managed with face-to-face appointments?
- Could participants with worrisome radicular symptoms be managed equally effectively with virtual appointments?

5. What is the potential for eHealth-based stratified care to provide more patients with treatment sooner? How important is it to cut down waiting lists?

6. Thinking about our model of care – what do you think the pros and cons of using eHealth-based stratified care would be, from patients' perspectives?

Prompts:

- What would be the main advantages for patients compared to usual practice?
- How acceptable would eHealth-based stratified care likely be to those accessing treatment for low back pain in a public hospital? Why or why not?
- What kinds of patients do you think are most suitable for being managed or monitored using eHealth?

7. What are the pros and cons from a clinician's perspective?

Prompts:

- How compatible/ acceptable will eHealth-based stratified care be to hospital physios and rheumatologists?
- What are the main advantages for clinicians in delivering care via eHealth, compared to usual practice? What are the main disadvantages?

8. What has to be in place for eHealth-based stratified care to be viable to deliver in the hospital setting?

Prompts:

- What are some things that will make this hard/ easy?
- Could this model of care be rolled out in your hospital right now?
- What are some of the barriers?
- What are some of the facilitators?
- Where will the main resistance come from?

9. What kinds of benefits would you anticipate that introducing eHealth-based stratified care would have for patients; physiotherapists; rheumatologists; for hospitals? (Ask about health, service access, cost savings for the hospital).

10. If eHealth-based stratified care was found to be beneficial in a large trial, would you want to provide this intervention in the future? Why, or why not?

11. Is there anything else you would like to say that we have not talked about in this interview?

Thank you so much for your time.

COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	14
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	1
Occupation	3	What was their occupation at the time of the study?	14
Gender	4	Was the researcher male or female?	14
Experience and training	5	What experience or training did the researcher have?	14
Relationship with participants			
Relationship established	6	Was a relationship established prior to study commencement?	14
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	14
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	14
Domain 2: Study design			
Theoretical framework			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	14
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	13
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	14
Sample size	12	How many participants were in the study?	16
Non-participation	13	How many people refused to participate or dropped out? Reasons?	16
Setting			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	14
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	14
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	17
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	14
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	23
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	14
Field notes	20	Were field notes made during and/or after the inter view or focus group?	14
Duration	21	What was the duration of the inter views or focus group?	16
Data saturation	22	Was data saturation discussed?	15
Transcripts returned	23	Were transcripts returned to participants for comment and/or	14

Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	14
Description of the coding tree	25	Did authors provide a description of the coding tree?	14
Derivation of themes	26	Were themes identified in advance or derived from the data?	14
Software	27	What software, if applicable, was used to manage the data?	14
Participant checking	28	Did participants provide feedback on the findings?	14
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	16
Data and findings consistent	30	Was there consistency between the data presented and the findings?	23
Clarity of major themes	31	Were major themes clearly presented in the findings?	16,17
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	16

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

Once you have completed this checklist, please save a copy and upload it as part of your submission. DO NOT include this checklist as part of the main manuscript document. It must be uploaded as a separate file.

Supplementary 3: Qualitative interview themes and subthemes from all participant interviews (n=24), example quotes and key changes

Themes	**Subthemes and quotes**
1. Factors impacting the acceptability of our preliminary model of care	Using an initial assessment phone call consistently received high praise for the potential to reduce waiting times for patients by all participant groups. Patients managed with telehealth in the feasibility trial gave mostly positive feedback about convenience and those randomised to usual care frequently suggested they would be open to receiving care remotely. Some patients were apprehensive about the lack of physical human contact in remote appointments. Some health professionals suggested clinic-based examination can be easier, but thought the model of care is safe. The success of observing movement and prescribing exercises was suggested to be dependent on the consultation set up (e.g., screen positioning). One patient suggested exercise prescription would be easy using telehealth, but a diagnosis may be less specific compared to clinic-based assessment. The addition of app-based exercises was frequently rated as necessary to facilitate understanding of exercises and improve compliance, but not an accurate measure of compliance (e.g., decreased use once exercises were learnt). The potential to adapt the model for a variety of musculoskeletal conditions was frequently positive by all participant groups but may require a shift in mindset. The perceived ease of assessment and treatment for

	various musculoskeletal conditions was based on beliefs about the ability to describe or show a symptomatic area, anatomical complexity, pain characteristics, and effectiveness of home-based exercises. Health professionals suggested that not all patients are suitable for telehealth but adults with musculoskeletal conditions significantly affecting mobility were suggested to be particularly appropriate. Health professionals suggested that osteoarthritis, adhesive capsulitis, rotator cuff related pain, tendinopathies, simple strains and sprains, post-surgery or simple fractures are more appropriate for telehealth; but suggested that conditions with neurological involvement (e.g., radiculopathy) and some acute injuries requiring specific hands-on testing may be less appropriate or unsafe for telehealth. One patient thought they needed to wait until their mobility improved until they could go and receive treatment; but suggested that telehealth could have improved their early management. **1.1 Feasibility of our preliminary model of care** *"Overall, I do think telephone consults, telemedicine, to me they're positive things, very positive things and they should remain in health." (F, 61-70 years old, patient)*

	“Instead of people just sitting on a wait list based on how long they’ve had their symptoms or their pain for, it means you can actually stratify them, put them into an appropriate group and know that they will be appropriately managed.” (F, 51-60 years old, Physiotherapist) *“We certainly would support it at a departmental level, and I think it would be something that would be supported up through executive as well.” (M, 31-40 years old Physiotherapist)* **1.2 Effectiveness of delivering exercises remotely** *“It was quite strange initially, but then I got used to it and looked forward to it.” (F, unknown years old, patient).* *“When you’re educating patients on doing exercises in their own environment, you can actually correct the way that they’re doing things in their environment.” (F, 51-60 years old, Physiotherapist)* **1.3 Affordability and convenience of our preliminary model of care** *“There’s no need for people to travel from point A to point B to get that advice if they can receive it via phone.” (M, 51-60 years old, patient)*

	"The convenience of exercising from your own sofa and they don't need to leave the house gets them engaged." (F, 21-30 years old, Physiotherapist) **1.4 Adaptability of our preliminary model of care for other musculoskeletal conditions** *"The ankle seems more complex and could be difficult to assess online compared to the lower back." (F, unknown years old, patient)* *"Other than radiculopathy, I think any MSK issue could be done via telehealth. Because really it is an exercise and education approach." (M, 51 years old, Physiotherapist)*
Key changes: High risk patients will receive clinic-based appointments, and a stringent protocol will not allow flexibility to offer patients more clinic-based appointments.	
2. Barriers and facilitators to telehealth	Patients, health professionals, and key stakeholders suggested pros and cons of using technology to provide care and had mixed views on access to equipment. Poor internet connection and a lack of familiarity with software were identified as barriers, but most participants agreed this could be overcome. Health professionals and patients suggested that a lack of physical touch may be more difficult to overcome, and health professionals suggested that education is needed to shift views about physiotherapy being only a

hands-on profession. Health professionals suggested it may be easier to give real-time feedback using physical touch in clinic-based appointments; but completing exercises in the patient's own environment was suggested by health professionals and key stakeholders to empower patients to become more independent. Providing appropriate support to hospital staff at each individual site was identified by health professionals and key stakeholders as important (e.g., IT support, guidance on using the new model of care, and preparation for unexpected changes in personnel or staff leave).

2.1 Access to appropriate technology and equipment for effective remote care

> *"Because the equipment that I was using is gym-based equipment. There was some things that I could adapt here." (F, 41-50 years old, patient)*

> *"Most people have a camera or a smartphone these days." (F, 41-50 years old, Physiotherapist)*

> *"The technology is there ready to go." (F, 41-50 years old, Physiotherapist)*

2.2 Beliefs about human touch and conducting the physical examination

	"Sometimes it would be okay, but if physio is physical you need to come to the hospital for treatment and if physical is not needed, you can use advice on how to relieve pain, so it depends." (F, 61-70 years old, patient). *"The convenience outweighs the need for personal touch. Personal touch can be good for the soul but isn't always needed." (M, 51-60 years old, patient)* *"Doing a virtual consult for them and getting some advice and education may be absolutely perfect, but other people really have a belief that they need to be touched and felt and have that physical interaction with another human." (M, 51-60 years old, Physiotherapist)* **2.3 Facilitating health professional involvement in a new model of care** *"Focusing down with the clinicians that are actually implementing it, sort of how they're going and follow up calls, whether it be phone, zoom." (F, 51-60 years old, Physiotherapist)* *"What you'll get is probably staff that may not be aware of stratification. So, education to staff that aren't aware of what do I do once they're stratified." (F, 51-60 years old, Physiotherapist)*

	2.4 Relocation or changes in staff personnel *"There is a need to have strategies in place for staff changes." (F, 41-50 years old, Physiotherapist)*
Key changes: Resources will be provided to screening physiotherapists to describe the model of care to potentially eligible patients (e.g. telephone script). Clinical staff will be offered the opportunity to participate in investigator meetings to provide feedback on implementation of the model of care.	
3. Communication and providing quality care	Effective communication between patients and health professionals was suggested to be highly important by all participant groups. Patients frequently suggested they liked that clinic-based appointments provided the opportunity to socialise, but some health professionals suggested small group appointments could potentially satisfy this need. Providing education and sufficient training resources to individual health professionals and departments was identified as important by health professionals and key stakeholders. Health professionals and patients suggested that confident communication of a diagnosis and treatment is influenced by the experience of the health professional, but health professionals suggested this could be partly overcome by providing appropriate support. **3.1 Collaboration between staff and disciplines**

	"I think it also comes down to reinforcing that messaging through medical, through nursing and through allied health. So even though this is obviously a physio led intervention or trial, there's obviously significant medical input as well." (M, 31-40 years old, Physiotherapist) **3.2 Effective communication with patients** *"Communication needs to be clear and honest if any errors occur" (M, 51-60 years old, patient)* *"You need to be able to treat people and understand people and have a good communication and conversation and interview style with patients to then do virtual care very well." (M, 51-60 years old, Physiotherapist)* **3.3 Social interaction for patients** *"One drawback was I missed the comradery." (F, unknown years old, patient)* *"If you've got a group of people with back pain, why can't you have a group education session?" (F, 51-60 years old, Physiotherapist)* **3.4 Education, support, and training about our preliminary model of care**

	“There is potential to have clinician training from a health professional experienced with telehealth to help give guidance on communication strategies that work well.” (F, 21-30 years old, Physiotherapist) *“Personally, I think it comes down to communication and confidence of the therapist.” (M, 51-60 years old, Physiotherapist)* *“And maybe there’s some criteria where you’d kind of want to test whether this would be an appropriate candidate, you know. Yeah, like potentially having a checklist at the start.” (F, 51-60 years old, Psychologist)*
Key Changes: On-going support will be provided to clinical staff at hospital sites involved in the trial as planned.	
4. Access to care and utilisation of health resources	It was frequently suggested by all participant groups that our model has potential to reduce waiting list times, reduce costs, and increase convenience. Various strategies to involve adults of different ages, technology, and communication abilities during virtual consultation (e.g., understand English language or need a translator) were suggested by all participant groups. Health professionals and key stakeholders suggested providing educational material with step-by-step guides on how to access telehealth that can be in multiple languages.

Health professionals and key stakeholders frequently suggested the model has potential to better utilise health care resources by aligning patient management with evidence-based guidelines.

4.1 Reduced waiting times and improving patient access to care

> *"For me, my priority is to actually get someone to look at it rather than sitting and waiting without an answer." (M, 41-50 years old, patient)*

> *"I think this model will help screen some patients off the list and facilitate a fast track of high-risk patients into the service." (F, 41-50 years old, Physiotherapist)*

> *"Yeah, pros. I feel like just being able to get the wait list down would be so much better. I feel like I'd be able to see more patients." (F, 41-50 years old, Physiotherapist)*

4.2 Allowing for the inclusion of language and cultural diversity

> *"My English is not as good but…you can understand me." (which is good) (F, 61-70 years old, patient)*

“There is potential to provide patient information in other languages to improve acceptability.” (M, 61-70 years old, Rheumatologist).

“*A lot of the pain education would make more sense to my clientele if it was in their own language, you would get better uptake and buy in*.” (F, 41-50 years old, Physiotherapist)

4.3 Increasing convenience and saving travel, parking, and time

“I didn’t need to spend an hour to get there and back, it was very convenient.” (F, unknown years old, patient).

“I could catch a train and then I have to catch a bus that all of a sudden it goes from a 30, 60-minute appointment to half my day. So maybe telehealth would be better in that regards.” (M, 21-30 years old, patient)

“I think that there is certainly that convenience and, you know, ultimately that means less cost in time and dollars, whether it’s, you know, parking fees or public transport or taxis or whatever they’re using to, to and fro. The stress of, you know, trying to find parking at the hospital.” (F, 51-60 years old, Psychologist)

<table>
<tr><td></td><td>4.4 Aligning patient management with evidence-based guidelines
<i>“By saying they actually are in this group, you can treat them this way because this is what the evidence says to this group.” (F, 51-60 years old, Physiotherapist)</i>
<i>“I think more broadly it would result in us providing better quality care to patients who need it more.” (M, 31-40 years, Physiotherapist)</i></td></tr>
<tr><td colspan="2">Key changes: We will not include non-English speaking patients in the trial as outcome measures have not been validated for this population.</td></tr>
<tr><td>5. Potential impact of external factors</td><td>COVID-19 was suggested by health professionals to have accelerated the acceptability of remote care and that it had the potential to interrupt service delivery. Some health professionals suggested that communication between referral networks with primary practitioners (e.g., general practitioners) could be strengthened for better utilisation of health resources. An overall increase in primary practitioners and public awareness of the model was frequently suggested by health professionals and key stakeholders to improve adoption. It was suggested by a rheumatologist that evidence-based public education could reduce ‘yellow flags’ and prevent acute cases ending up with chronic pain (e.g., Whiplash education used in Victoria, Australia).</td></tr>
</table>

	5.1 Unanticipated external disruptions *"I think covid, it just highlighted the benefit that it's a tool that we can use, but it's not a tool to replace face-to-face care in my opinion. It's just a tool that suits if it suits." (M, 51-60 years old, Physiotherapist)* **5.2 Partnerships with primary practitioners and referral sources** *"There should be information given to primary care providers which could have the potential to reduce the number of patients referred to ED." (M, 61-70 years old, Rheumatologist)* *"I think is helpful for them because at least they're getting a consistent message and what's being said by the doctors is lining up with what the physios are telling them. So, it's like continuous message." (M, 31-40 years old, Physiotherapist)* **5.3 Public awareness of appropriate management options**

	"I think getting the rolling television things they have in clinics and surgeries; I think that that should be a thing to advertise it." (F, 61-70 years old, patient) *"The holy grail would be public education about low back pain management which could mean less yellow flags and people with acute pain may not end up with chronic pain, like the whip lash education used in Victoria." (M, 61-70 years old, Rheumatologist)* *"The problem is most people see physios as a hands-on only service. That's people just acknowledge the touch, they don't acknowledge the diagnostic treatment, development and the progression that can be done verbally. And our assessment skills are often observational, not hands on, but the community sees us as all hands on." (M, 51-60 years old, Physiotherapist)*
Key changes: We aim to provide information about the study to primary practitioners at the point of referral. For example, general practice clinics can be sent information about our new model to promote recruitment.	
6. Characteristics of staff and patients	There was mixed feedback from patients about trusting health professionals via telehealth. It was frequently suggested by patients that the nature of communication can impact the level of trust between patients and health professionals. One patient suggested the importance of discussions beyond the health condition to

better get to know the health professional. All health professionals could see the potential of the model to increase convenience for patients who wouldn’t need to travel or pay for parking, but some suggested that telehealth appointments can take health professionals similar time to clinic-based appointments. Health professionals and key stakeholders also suggested they may require additional allocated time and assistance from administration staff or IT support (particularly with adults who have difficulty understanding English or need a translator). Health professionals suggested that if the right processes are in place the new model may prevent unnecessary catastrophising of symptoms by patients and reduce administrative time needed to follow up patients who are on waiting lists for extended periods of time.

6.1 Patient assessment and treatment experience

> *“It’s the bed side manner, by talking about things other than just the health condition so you can get to know the health professional and trust them.” (M, 71-80 years old, patient)*

> *“I would trust a health professional even if it was meeting them online.” (F, 61-70 years old, patient)*

> *"You could be negotiating one or two indicators that are important to the patient so that they can see the improvements themselves and that motivates them to do the exercises." (F, 51-60 years old Psychologist)*

6.2 Knowledge and beliefs about our preliminary model of care

> *"I feel like I would still need to see someone face-to-face eventually, but in terms of being seen sooner, better access bridging to that, I think it definitely would've improved it" (M, 21-30 years old, patient)*

> *"You need to sell the benefits of telemedicine and ensure that it is beneficial and a positive experience for that person." (F, 65 years old, patient)*

> *"What would sell it a bit more to clinicians is, I think your low, medium and high-risk patients, in terms of your stratify approach, to explain what each of them specifically entails." (F, 41-50 years old, Physiotherapist)*

6.3 Motivation and capacity to deliver or receive remote care

	"Physiotherapists would spend a similar amount of time treating patients as they would for in person care and it may take longer to explain telehealth." (F, 21-30 years old, Physiotherapist) *"Just outlining those convenience points for them really gets them engaged and want to partake in telehealth I found." (F, 21-30 years old, Physiotherapist)* *"I think some elderly people have embraced technology and then there are others that haven't. And I think you would, that would just have to be one of the things you checked in with people." (F, 51-60 years old, Psychologist)*
Key Changes: Clinical staff will be offered the opportunity to participate in investigator meetings to provide feedback on implementation of the model of care.	
7. Future implementation and delivery of care	Health professionals involved in the feasibility trial suggested sharing data on a common, secure spreadsheet rather than via email to reduce risk of errors. One patient in the feasibility trial who dropped out of the study suggested communication with patients must be clear to maintain patient trust and a chat function using an AI bot may help provided reassurance for patients based on a positive experience with using one to quit smoking. Health professionals in the feasibility trial suggested that difficulties in patients' willingness to

	potentially receive our model of care could be overcome by initially offering clinic-based care that can transition to telehealth after a set number of appointments. Health professionals and stakeholders frequently mentioned training of more full-time staff to stratify patients would also facilitate implementation. **7.1 Planning and execution of delivering preliminary model of care** *"Keep instructions, very straightforward. Just click on this link. And then that's all they do when they wait." (F, 21-30 years old, Physiotherapist)* *"If you get the sense the patient's happy to be involved, you could get that screening going straight away. Whereas the secretary can't do that." (M, 51-60 years old, Physiotherapist)* *"In the telehealth setting you need foundational rules in place for safety so they can only do stairs with a second family member present." (F, 41-50 years old, Physiotherapist)* **7.2 Modifying the preliminary model of care to increase engagement** *"There is potential to recruit patients by offering a set number of in person visits before they are transitioned to telehealth." (F, 21-30 years old, Physiotherapist)*

	High risk patients can be more challenging. To building rapport and compliance then face-to-face can be more valuable." (F, 41-50 years old, Physiotherapist) *"I tend to think radiculopathy patients should be seen face-to-face because at some point they are going to need to do a neurological examination." (M, 51-60 years old, Physiotherapist)* **7.3 Utilisation of technology to promote independence and provide education** *"I'm a great believer in new technologies, just like Zoom." (M, 71-80 years old, patient)* *"Sometimes just allowing people virtual care would allow you to let those patients ask some of those very basic questions, but it relieves their anxiety significantly." (M, 51-60 years old, Physiotherapist)* *"I think giving them a little bit of onus as well to set themselves up is a good thing." (F, 21-30 years old, Physiotherapist)* **7.4 Adaptability of staff roles and evaluating change** *"So even having a collaborative forum can be quite useful, like a user, a forum." (F, 51-60 years old, Physiotherapist)*

	"I'm entrenched in face-to-face treatment because that's what I've always done. So for me, for example, moving to purely a virtual care would probably be, I would find it a clinical challenge." *(M, 51-60 years old, Physiotherapist)*
Key changes: Targeted education strategies highlighting the advantages of the model will be developed to increase the awareness and the need for change due to increasing demand for appointments (e.g., telephone scripts to guide health professionals with the language to use when informing participants of their mode of treatment).	

The views expressed by individuals from professional bodies are their own and do not necessarily reflect the views of the professional b

APPENDIX FIVE

Chapter Six publication metrics

Under review

Impact

Chapter Six led to the development of a new model of care which is currently being evaluated in an adequately-powered randomised controlled trial across multiple public hospital outpatient clinics in Sydney, Australia. It has led to $1.5 million grant funding from the Medical Research Future Fund (MRFF) for the WAIT-less trial.

Supplementary file 1: CONSORT checklist

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	1
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	5
	2b	Specific objectives or research questions for pilot trial	6
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	7
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	10
Participants	4a	Eligibility criteria for participants	8
	4b	Settings and locations where the data were collected	7,8
	4c	How participants were identified and consented	7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	9.10,11
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	12,13

	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	-
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	26
Sample size	7a	Rationale for numbers in the pilot trial	25
	7b	When applicable, explanation of any interim analyses and stopping guidelines	-
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	9
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	9
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	9
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	9
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	9
	11b	If relevant, description of the similarity of interventions	-
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	12,13
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	13
	13b	For each group, losses and exclusions after randomisation, together with reasons	12

Recruitment	14a	Dates defining the periods of recruitment and follow-up	15
	14b	Why the pilot trial ended or was stopped	15
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	1
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	16, 20.21
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	17,18
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	17,18
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	19
	19a	If relevant, other important unintended consequences	-
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	27,28
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	28,29
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	26
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	26, 27
Other information			

Registration	23	Registration number for pilot trial and name of trial registry	3
Protocol	24	Where the pilot trial protocol can be accessed, if available	7
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	3
	26	Ethical approval or approval by research review committee, confirmed with reference number	3

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355. This is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY 3.0) license (http://creativecommons.org/licenses/by/3.0/), which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited.

*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up-to-date references relevant to this checklist, see www.consort-statement.org.

COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	10
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	1
Occupation	3	What was their occupation at the time of the study?	10
Gender	4	Was the researcher male or female?	10
Experience and training	5	What experience or training did the researcher have?	10
Relationship with participants			
Relationship established	6	Was a relationship established prior to study commencement?	10
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	10
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	10
Domain 2: Study design			
Theoretical framework			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	11
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	10
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	10
Sample size	12	How many participants were in the study?	17
Non-participation	13	How many people refused to participate or dropped out? Reasons?	17
Setting			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	10
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	10
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	23
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	23
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	23
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	10
Field notes	20	Were field notes made during and/or after the inter view or focus group?	10
Duration	21	What was the duration of the inter views or focus group?	17
Data saturation	22	Was data saturation discussed?	11
Transcripts returned	23	Were transcripts returned to participants for comment and/or	10

Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	10
Description of the coding tree	25	Did authors provide a description of the coding tree?	18
Derivation of themes	26	Were themes identified in advance or derived from the data?	11
Software	27	What software, if applicable, was used to manage the data?	11
Participant checking	28	Did participants provide feedback on the findings?	11
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	18
Data and findings consistent	30	Was there consistency between the data presented and the findings?	19
Clarity of major themes	31	Were major themes clearly presented in the findings?	19
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	19

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

Once you have completed this checklist, please save a copy and upload it as part of your submission. DO NOT include this checklist as part of the main manuscript document. It must be uploaded as a separate file.

Participant Consent Form

Please complete the survey below.

Thank you!

Rapid Virtual Stratified Care: a feasibility trial comparing two care pathways for people referred to the Back Clinic: Participant Consent Form for Interviews

---

I (Your name), ______
Of (Your full address), ______
Email address

______
and have discussed the study with (name of investigator responsible for conducting informed consent)

______

Please download a copy of the "Participant Information Sheet" for your records.

[Attachment: "PARTICIPANT INFO SHEET.pdf"]

I have read and understood the 'Participant Information Sheet' on the above named research study	○ Yes ○ No

---

If no, please contact the research team to discuss any concerns before proceeding to the survey on agam1165@uni.sydney.edu.au or (02) 8627 7423

I would like to receive a copy of the study results when they become available	○ Yes ○ No

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I have been made aware of the procedures involved in the study, including any known or expected inconvenience, risk, discomfort or potential side effect and of their implications as far as they are currently known by the researchers. I understand that my de-identified data may be used for future research and I agree to this. I understand that, during the course of this study, my medical records may be accessed by Sydney Local Health District by regulatory authorities or by the Ethics Committee approving the research in order to verify results and determine that the study is being carried out correctly. I understand that the SLHD software license for REDCap (Research Electronic Data Capture) will be used to manage the collection and storage of my research data. I have had an opportunity to ask questions and I am satisfied with the answers I have received. I freely choose to participate in this study and understand that I can withdraw at any time. I consent to the future use of any data / samples I provide for research purposes. I understand that before they can use any data I provide, they must seek additional ethics approval. I consent for other research collaborators to use any data / samples I provide for future research purposes. I understand that before they can use my data, they must seek additional ethics approval. I also understand that the research study is strictly confidential. I consent to the storage and use of my information collected from me for use, as described in the relevant section of the Participant Information Sheet, for: This specific research project Other research that is closely related to this research project Any future research I hereby agree to participate in this research study.

○ Yes I would be happy to continue and complete the survey
○ No I would prefer not to complete the survey

Participant signature

____

Date of consent

____

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Rapid Virtual Stratified Care: a feasibility trial comparing two care pathways for people referred to the Back Clinic

PARTICIPANT INFORMATION STATEMENT

1. What is this study about?

You are invited to take part in a research study that will explore a new care pathway for people with back pain and/or leg pain radiating from the back. This Participant Information Statement tells you about the study. Knowing what is involved will help you decide if you want to take part. Please read this sheet carefully and ask questions about anything that you don't understand or want to know more about.

Participation in this research study is voluntary.

By giving your consent to take part in this study you are telling us that you:

- ✓ Understand what you have read
- ✓ Agree to take part in the research study as outlined below
- ✓ Agree to the use of your personal information as described

This Participant Information Statement is yours to keep.

Currently, when you are referred to see a Rheumatologist or Physiotherapist at Royal Prince Alfred Hospital's 'Back Pain Clinic', you are placed on a waiting list. Unfortunately, waiting times for treatment are currently 3 months or longer. This is referred to 'usual care', which is the care you would normally receive when referred to the 'Back Pain Clinic'. Our project involves testing a new pathway using telephone and virtual appointments, and an App-based exercise program. This new pathway is based on 'stratified care'. This involves matching the type and amount of care you receive based on your risk of persisting pain and presence of other symptoms (like leg pain). We want to see whether the new pathway helps people receive treatment sooner and recover sooner.

To find out which pathway is best, we will offer one third of people the current pathway and two-thirds the new pathway. We will monitor the two groups for 6 months and compare what happens between the groups. To ensure the groups are as similar to each other as possible, the group that you will be placed into is by chance. **There is a 67% chance you will be managed according to the new pathway, and a 33% chance you will be managed according to the current pathway.** To make the results of our study fair, we will not tell you which pathway you have been allocated to.

If you decide you would not like to participate in the research study, you will be managed according to the current pathway. However, your decision whether to participate will not affect your current or future relationship with the researchers or anyone else at the University of Sydney or Royal Prince Alfred Hospital. It also won't affect your position on the waiting list or the quality of care you receive.

2. Who is running the study?

This study is funded by the Agency for Clinical Innovation (ACI) New South Wales and the National Health Medical Research Council. Neither funder will benefit commercially from this study. The manufacturers of PhysiTrack, the mobile App you may be provided during the study, do not have any commercial, financial or business interests in this study.

The people conducting this study are:

- Dr Joshua Zadro, NHMRC Postdoctoral Researcher, Institute for Musculoskeletal Health University of Sydney and Sydney Local Health District
- Dr Chris Needs, Staff Specialist Rheumatologist, Royal Prince Alfred Hospital, Sydney Local District Health
- Prof Christopher Maher, Director, Institute for Musculoskeletal Health, University of Sydney and Sydney Local Health District
- Dr David Martens, Rheumatologist Advanced Trainee, Royal Prince Alfred Hospital, Sydney Local District Health
- Ms Danielle Coombs, Physiotherapist, Institute for Musculoskeletal Health University of Sydney and Sydney Local Health District
- Dr Gustavo Machado, NHMRC Postdoctoral Researcher, Institute for Musculoskeletal Health University of Sydney and Sydney Local Health District
- Mrs Charlotte McLennan, Network Manager, Institute for Musculoskeletal Health University of Sydney and Sydney Local Health District
- Dr Cameron Adams, Rheumatologist Advanced Trainee, Royal Prince Alfred Hospital, Sydney Local District Health
- Prof Nadine Foster, Director, Surgical, Treatment and Rehabilitation Service (STARS) Research and Education Alliance, The University of Queensland and Metro North Hospital and Health Service

3. Who can take part in the study?

A person will be allowed to participate in this study if he or she:

- is referred to the 'Back Pain Clinic' at Royal Prince Alfred Hospital
- has low back pain and/or leg pain radiating from the back
- is 18 years or over and able to provide informed consent

4. What does the study involve?

If you agree to participate in our study, we will send you a survey asking questions about you and your low back pain. We kindly ask you to complete these questionnaires and return them back to us via mail (return-paid envelope provided), email, or SMS. After this, you will be randomly allocated (i.e. by chance) to be managed using the new pathway or current pathway. We will send you another questionnaire at 6 weeks, 3 months, and 6 months after joining the study to see how your low back pain has changed. This questionnaire will contain similar questions to the first one you will complete. If you desire any more information at any point of the study, relevant contact details will be provided.

After 6 months, we may contact you to participate in a group interview (with up to 8 other participants) or one-on-one interview if you prefer. This interview may be conducted via telephone or videoconference (e.g. Zoom) or in person at the Institute for Musculoskeletal Health, Level 10 King George V Building, Royal Prince Alfred Hospital. The interview will explore your opinions on the care you received. You will be sent more information about this interview before you agree to participate.

5. How much of my time will the study take?

If you decide to participate, your treatment time is unlikely to be different than if you did not participate and joined the current waiting list. However, by participating in the study, we will ask you to complete one survey when you enter the study, and another at 6 weeks, 3 months, and 6 months. Each survey will take between 10-15 minutes. You may also be asked to participate in a 1-hour group interview or 30 minutes one-on-one interview, but participation is voluntary.

6. Do I have to be in the study? Can I withdraw from the study once I've started?

Participation in this study is entirely voluntary. You are not obliged to participate. If you do participate, you can withdraw at any time without having to give any reason and without any penalty. Whatever your decision, it will not affect your relationship with the Hospital, Local Health District and The University of Sydney, or the standard of care you receive now or in the future.

7. Are there any risks or costs associated with being in the study?

Aside from giving up your time to complete three 5-10 minutes surveys (plus a possible 30-60 minutes for an interview if you’re interested), we do not expect that there will be any risks or costs associated with taking part in this study.

8. Are there any benefits associated with being in the study?

If you are allocated to receive the new care pathway, you may benefit from having faster access to Physiotherapy and Rheumatology care. You may also improve faster because you are seen sooner. If you are allocated to receive the current care pathway, you receive the same treatment as if you had not taken part in the study.

By participating you will be contributing to important research that helps us understand whether our new pathway is potentially beneficial for people with low back pain and worth investigating in a large future study. The results will help us develop better ways to improve the quality of care provided to patients.

9. What will happen to information about me that is collected during the study?

All data collected will be entered electronically and stored on a research database named REDCap (Research Electronic Data Capture). This is a secure, web-based, non-commercial, data management tool designed for research purposes, hosted and backed up on the Sydney Local Health District servers on a daily basis. No personnel other than the researchers will have access to the research documents. The data will be analysed by the researchers at the Royal Prince Alfred Hospital. All data for use in journal publications and presentations will be de-identified. The files will be retained for 15 years from the day the study is completed. Once this retention expires, the files will be disposed of using the Royal Prince Alfred Hospital confidential waste disposal service.

The data may be used for future research purposes; however, Human Research Ethics Committee (HREC) approval will be sought prior to any future use of the data. It will not be shared with local or international collaborators.

If you are allocated to the new pathway, you may be provided with an exercise program delivered via a mobile App (PhysiTrack). No data will be collected through the PhysiTrack App and therefore no data will be sent to the developer. The App will simply be used to show you which exercises to do. PhysiTrack is also not a medical device hence does not require TGA approval. PhysiTrack is simply an App that allows physiotherapists to put together an exercise program to allow you to receive written and video instructions on how to perform the exercises correctly. PhysioTrack is essentially a substitute for drawing an exercise program on a piece of paper. The exercises in PhysiTrack include a range of exercises physiotherapists have been prescribing for patients over many years.

As with any home-exercise program prescribed by a physiotherapist, you are free to stop exercising or using the PhysiTrack app at any time if you experience an increase in your symptoms or are not comfortable performing an exercise.

10. Will I be told the results of the study?

You have a right to receive feedback about the overall results of this study. You can tell us that you wish to receive feedback by ticking a box and leaving your email when you complete the consent form. This feedback will be in the form of a one-page lay summary of the results. You will receive this feedback after the study is finished.

11. What do I do next?

When you have read this information, please store it in a safe place. If you understand what you have read and would like to participant, please sign and return the consent form.

If you would like to know more about the study at any stage and ask questions, please feel free to contact Mr Christopher Han (research assistant) at Christopher.Han@sydney.edu.au or (02) 8627 7423.

12. What if I have a complaint or any concerns about the study?

This study has been approved by the Ethics Review Committee (RPAH Zone) of the Sydney Local Health District.

If you have any complaints or concerns about any aspect of this study, you should call our research team who will do their best to address any issues. If your concerns are not able to be addressed, you can contact the Executive Officer of the Ethics Review Committee on 02 9515 7176 and quote protocol number X21-0221.

13. Complaints and compensation

If you suffer any injuries or complications as a result of the research project, you will be advised to contact the study team and will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

In addition, you may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is sufficiently serious and is caused by unsafe drugs or equipment, or by the negligence of one of the parties involved in the study (for example, the researcher, the hospital, or the treating doctor). You do not give up any legal rights to compensation by participating in this study.

This information sheet is for you to keep.

Supplementary file 5: Participant Information Statements for qualitative interviews

Chief Investigator

Research Fellow

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Rapid Virtual Stratified Care for people with back pain and other musculoskeletal conditions: an interview study

PARTICIPANT INFORMATION STATEMENT - patients

1. What is this study about?

You are invited to take part in a research study that will explore people's opinion on using a screening tool to categorise patients care needs (stratified care) to choose if they are appropriate for telehealth (e.g. Rapid virtual stratified care). This Participant Information Statement tells you about the study. Knowing what is involved will help you decide if you want to take part. Please read this sheet carefully and ask questions about anything that you don't understand or want to know more about.

Participation in this research study is voluntary.

By giving your consent to take part in this study you are telling us that you:

- ✓ Understand what you have read
- ✓ Agree to take part in the research study as outlined below
- ✓ Agree to the use of your personal information as described

This Participant Information Statement is yours to keep.

Your decision whether to participate will not affect your current or future relationship with the researchers or anyone else at the University of Sydney or Royal Prince Alfred Hospital. It also won’t affect the quality of care you receive.

2. Who is running the study?

This study is funded by the Agency for Clinical Innovation (ACI) New South Wales and the National Health Medical Research Council. Neither funder will benefit commercially from this study.

The people conducting this study are:

- Dr Joshua Zadro, NHMRC Postdoctoral Researcher, Institute for Musculoskeletal Health University of Sydney and Sydney Local Health District
- Dr Chris Needs, Staff Specialist Rheumatologist, Royal Prince Alfred Hospital, Sydney Local District Health
- Prof Christopher Maher, Director, Institute for Musculoskeletal Health, University of Sydney and Sydney Local Health District

- Dr David Martens, Rheumatologist Advanced Trainee, Royal Prince Alfred Hospital, Sydney Local District Health
- Ms Danielle Coombs, Physiotherapist, Institute for Musculoskeletal Health University of Sydney and Sydney Local Health District
- Dr Gustavo Machado, NHMRC Postdoctoral Researcher, Institute for Musculoskeletal Health University of Sydney and Sydney Local Health District
- Mrs Charlotte McLennan, Network Manager, Institute for Musculoskeletal Health University of Sydney and Sydney Local Health District
- Dr Cameron Adams, Rheumatologist Advanced Trainee, Royal Prince Alfred Hospital, Sydney Local District Health
- Prof Nadine Foster, Director, Surgical, Treatment and Rehabilitation Service (STARS) Research and Education Alliance, The University of Queensland and Metro North Hospital and Health Service
- Mr Andrew Gamble, Physiotherapist, Institute for Musculoskeletal Health, Sydney School of Public Health, University of Sydney & Sydney Local Health District

3. Who can take part in the study?

A person will be allowed to participate in this study if he or she participated in our study comparing two care pathways for people with back pain and/or leg pain radiating from the back and completed the 6 month follow up. People who require treatment for any musculoskeletal condition and are interested in our new model of care are also eligible.

4. What does the study involve?

If you agree to participate in our study, we will arrange a time for you to participate in a group interview (with up to 8 other participants who took part in the study) or a one-on-one interview if you prefer. This interview may be conducted via telephone or videoconference (e.g. Zoom) or in person at the Institute for Musculoskeletal Health, Level 10 King George V Building, Royal Prince Alfred Hospital. The interview will explore your opinion on combining the use of stratified care and telehealth (e.g. Rapid virtual stratified care) to manage back pain or other musculoskeletal conditions. The interviews will be audio-recorded and transcribed verbatim for analysis. The recordings will be deleted after they have been transcribed.

5. How much of my time will the study take?

If you decide to participate, you will need to participate in a 1 hour group interview or 30-minute one-on-one interview. If you would like the interview to be face-to-face, there may be travel time to get to the Institute for Musculoskeletal Health.

6. Do I have to be in the study? Can I withdraw from the study once I've started?

Participation in this study is entirely voluntary. You are not obliged to participate. If you do participate, you can withdraw at any time without having to give any reason and without any penalty. Whatever your decision, it will not affect your relationship with the Hospital, Local Health District and The University of Sydney, or the standard of care you receive now or in the future.

7. Are there any risks or costs associated with being in the study?

Aside from giving up your time to participate in an interview, we do not expect that there will be any risks or costs associated with taking part in this study.

8. Are there any benefits associated with being in the study?

By participating, you will be contributing to important research that helps us understand whether the new care pathway that we are testing is acceptable to patients with back pain and other musculoskeletal conditions. The results may help us refine the care pathway before testing it in large research study.

9. What will happen to information about me that is collected during the study?

By providing your consent, you are agreeing to us collecting personal information about you for the purposes of this research study. Your information will only be used for the purposes outlined in this Participant Information Statement, unless you consent otherwise.

Your information will be stored and analysed securely on a research database within the Institute for Musculoskeletal Health, Sydney Local Health District, and your identity/information will be kept strictly confidential, except as required by law. Study findings may be published, but you will not be individually identifiable in these publications.

We will keep the information we collect for this study, and we may use it in future project. By providing your consent you are allowing us to use your information in future projects, however all identifying data will remain strictly confidential. We don’t know at this stage what these other projects may involve. We will seek ethical approval before using the information in these future projects.

10. Will I be told the results of the study?

You have a right to receive feedback about the overall results of this study. You can tell us that you wish to receive feedback by ticking a box and leaving your email when you complete the questionnaires. This feedback will be in the form of a one-page lay summary of the results. You will receive this feedback after the study is finished.

11. What do I do next?

When you have read this information, please store it in a safe place. If you understand what you have read and would like to participant, please complete the online consent form, or sign and return the paper consent form.

If you would like to know more about the study at any stage and ask questions, please feel free to contact Mr Andrew Gamble (PhD student and research assistant) at agam1165@uni.sydney.edu.au or (02) 8627 7423.

12. What if I have a complaint or any concerns about the study?

This study has been approved by the Ethics Review Committee (RPAH Zone) of the Sydney Local Health District.

If you have any complaints or concerns about any aspect of this study, you should call our research team who will do their best to address any issues. If your concerns are not able to be addressed, you can contact the Executive Officer of the Ethics Review Committee on 02 9515 6766 and quote protocol number **X21-0221**.

This information sheet is for you to keep.

School of Public Health

ABN 15 211 513 464

Dr Joshua Zadro

Chief Investigator

Research Fellow

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Rapid Virtual Stratified Care for people with back pain and other musculoskeletal conditions: an interview study

PARTICIPANT INFORMATION STATEMENT – clinicians and key stakeholders

1. What is this study about?

You are invited to take part in a research study that will explore clinicians' opinion on combining stratified care and telehealth (e.g. Rapid virtual stratified care). This Participant Information Statement tells you about the study. Knowing what is involved will help you decide if you want to take part. Please read this sheet carefully and ask questions about anything that you don't understand or want to know more about.

Participation in this research study is voluntary.

By giving your consent to take part in this study you are telling us that you:

- ✓ Understand what you have read
- ✓ Agree to take part in the research study as outlined below
- ✓ Agree to the use of your personal information as described

This Participant Information Statement is yours to keep.

Your decision whether to participate will not affect your current or future relationship with the researchers or anyone else at the University of Sydney or Royal Prince Alfred Hospital.

2. Who is running the study?

This study is funded by the Agency for Clinical Innovation (ACI) New South Wales and the National Health Medical Research Council. Neither funder will benefit commercially from this study.

The people conducting this study are:

- Dr Joshua Zadro, NHMRC Postdoctoral Researcher, Institute for Musculoskeletal Health University of Sydney and Sydney Local Health District
- Dr Chris Needs, Staff Specialist Rheumatologist, Royal Prince Alfred Hospital, Sydney Local District Health
- Prof Christopher Maher, Director, Institute for Musculoskeletal Health, University of Sydney and Sydney Local Health District
- Dr David Martens, Rheumatologist Advanced Trainee, Royal Prince Alfred Hospital, Sydney Local District Health

- Ms Danielle Coombs, Physiotherapist, Institute for Musculoskeletal Health University of Sydney and Sydney Local Health District
- Dr Gustavo Machado, NHMRC Postdoctoral Researcher, Institute for Musculoskeletal Health University of Sydney and Sydney Local Health District
- Mrs Charlotte McLennan, Network Manager, Institute for Musculoskeletal Health University of Sydney and Sydney Local Health District
- Dr Cameron Adams, Rheumatologist Advanced Trainee, Royal Prince Alfred Hospital, Sydney Local District Health
- Prof Nadine Foster, Director, Surgical, Treatment and Rehabilitation Service (STARS) Research and Education Alliance, The University of Queensland and Metro North Hospital and Health Service
- Mr Andrew Gamble, Physiotherapist, Institute for Musculoskeletal Health, Sydney School of Public Health, University of Sydney & Sydney Local Health District

This study is funded by the Agency for Clinical Innovation (ACI) New South Wales and the National Health Medical Research Council. Neither funder will benefit commercially from this study.

3. Who can take part in the study?

A person will be allowed to participate in this study if he or she is a physiotherapist or rheumatologist who provided care as part of our study comparing two care pathways for people with back pain and/or leg pain radiating from the back. Physiotherapists or rheumatologists who were not involved in the study and key stakeholders that may be interested in the new model of care are also eligible.

4. What does the study involve?

If you agree to participate in our study, we will arrange a time for you to participate in a one-on-one interview with a member of the research team. This interview may be conducted via telephone or videoconference (e.g. Zoom) or in person at the Institute for Musculoskeletal Health, Level 10 King George V Building, Royal Prince Alfred Hospital. The interview will explore your opinion on barriers, facilitators and acceptability of combining stratified care and telehealth (e.g. Rapid virtual stratified care). The interviews will be audio-recorded and transcribed verbatim for analysis. The recordings will be deleted after they have been transcribed.

5. How much of my time will the study take?

If you decide to participate, you will need to participate in a 30-minute one-on-one interview. If you would like the interview to be face-to-face, there may be travel time to get to the Institute for Musculoskeletal Health.

6. Do I have to be in the study? Can I withdraw from the study once I've started?

Participation in this study is entirely voluntary. You are not obliged to participate. If you do participate, you can withdraw at any time without having to give any reason and without any penalty. Whatever your decision, it will not affect your relationship with the Hospital, Local Health District and The University of Sydney.

7. Are there any risks or costs associated with being in the study?

Aside from giving up your time to participate in an interview, we do not expect that there will be any risks or costs associated with taking part in this study.

8. Are there any benefits associated with being in the study?

By participating, you will be contributing to important research that helps us understand whether the new care pathway that we are testing is acceptable for patients with back pain and/or leg pain radiating from the back, other musculoskeletal conditions, and clinicians providing care to these patients. The results may help us refine the care pathway before testing it in large research study.

9. What will happen to information about me that is collected during the study?

By providing your consent, you are agreeing to us collecting personal information about you for the purposes of this research study. Your information will only be used for the purposes outlined in this Participant Information Statement, unless you consent otherwise.

Your information will be stored and analysed securely on a research database within the Institute for Musculoskeletal Health, Sydney Local Health District, and your identity/information will be kept strictly confidential, except as required by law. Study findings may be published, but you will not be individually identifiable in these publications.

We will keep the information we collect for this study, and we may use it in future projects. By providing your consent you are allowing us to use your information in future projects, however all identifying data will remain strictly confidential. We don't know at this stage what these other projects may involve. We will seek ethical approval before using the information in these future projects.

10. Will I be told the results of the study?

You have a right to receive feedback about the overall results of this study. You can tell us that you wish to receive feedback by ticking a box and leaving your email when you complete the questionnaires. This feedback will be in the form of a one-page lay summary of the results. You will receive this feedback after the study is finished.

11. What do I do next?

When you have read this information, please store it in a safe place. If you understand what you have read and would like to participant, please complete the online consent form, or sign and return the paper consent form.

If you would like to know more about the study at any stage and ask questions, please feel free to contact Mr Andrew Gamble (PhD student and research assistant) at agam1165@uni.sydney.edu.au or (02) 8627 7423.

12. What if I have a complaint or any concerns about the study?

This study has been approved by the Ethics Review Committee (RPAH Zone) of the Sydney Local Health District.

If you have any complaints or concerns about any aspect of this study, you should call our research team who will do their best to address any issues. If your concerns are not able to be addressed, you can contact the Executive Officer of the Ethics Review Committee on 02 9515 7176 and quote protocol number **X21-0221**.

This information sheet is for you to keep.

Supplementary file 6: Participant consent forms for qualitative interviews

Rapid Virtual Stratified Care for people with back pain and other musculoskeletal conditions: an interview study

PARTICIPANT CONSENT FORM - patients

I, ... [print name], agree to take part in the research project: In giving my consent I acknowledge that:

Please tick/initial boxes

☐ I have read the Participant Information Statement and have been given the opportunity to discuss the study and my involvement in it with the researcher/s.

☐ The procedures required and time involved (including any inconvenience, risk, discomfort or side effect, and their implications) have been explained to me, and my questions about the project have been answered to my satisfaction.

☐ I understand that participation is voluntary. I am under no obligation to consent.

☐ I understand that I can withdraw from the study at any time, without providing a reason and without suffering any penalty. This will not affect my relationship with the researcher/s, university, Sydney Local District Health, or RPA Hospital.

☐ The interview I participate in will be audio-recorded and transcribed verbatim. I understand that I can stop my participation at any time and select to erase the interview to that point.

☐ I understand that my involvement is strictly confidential and no information about me will be used in any way that reveals my identity.

☐ I understand that data from this study may be used again for future research purposes, but that all data is strictly confidential and no information about me will be used in any way that reveals my identity.

☐ I would like the researchers to contact me to inform me about the results of the study.

Signature:____

Date:____

You have a right to receive feedback about the overall results of this study. This feedback will be a one-page summary regarding the overall findings of the study.

Would you like to receive feedback about the overall results of this study?

○ Yes
○ No

If yes, please provide your email address ____________________________

This study has been approved by the Ethics Review Committee (RPAH Zone) of the Sydney Local Health District. Any person with concerns or complaints about the conduct of this study should contact the Executive Officer on 02 9515 6766 and quote protocol number X21-0221.

THE UNIVERSITY OF SYDNEY

ABN 15 211 513 464

School of Public Health

Dr Joshua Zadro

Chief Investigator

Research Fellow

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Rapid Virtual Stratified Care for people with back pain and other musculoskeletal conditions: an interview study

PARTICIPANT CONSENT FORM - clinicians and key stakeholders

I,____ *[full name]*

Of____ *[address]* have read and understood the Participant Information Sheet on the abovenamed research study

and have discussed the study with ____

[investigator responsible for conducting informed consent].

- I have been made aware of the procedures involved in the study, including any known or expected inconvenience, risk, discomfort or potential side effect and of their implications as far as they are currently known by the researchers.

- I understand that the interview discussion will be audio-recorded and will then be transcribed and be kept in a manner in which I cannot be identified for analysis and I agree to this.

- I understand that my de-identified data may be used for future research and I agree to this.

  I would like to receive a copy of the study results when they become available. My email address

  is: ____

- I understand that, during the course of this study, my medical records may be accessed by Sydney Local Health District by regulatory authorities or by the Ethics Committee approving the research in order to verify results and determine that the study is being carried out correctly.
- I understand that the SLHD software license for REDCap (Research Electronic Data Capture) will be used to manage the collection and storage of my research data.

- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I freely choose to participate in this study and understand that I can withdraw at any time.
- I consent to the future use of any data / samples I provide for research purposes. I understand that before they can use any data I provide, they must seek additional ethics approval. YES/ NO
- I consent for other research collaborators to use any data / samples I provide for future research purposes. I understand that before they can use my data, they must seek additional ethics approval. YES/NO
- I also understand that the research study is strictly confidential.
- I hereby agree to participate in this research study.
- I consent to the storage and use of my information collected from me for use, as described in the relevant section of the Participant Information Sheet, for:

  -This specific research project

  -Other research that is closely related to this research project

  - Any future research

Participant Name:____

Participant Signature:____

Date:____

Name of Person conducting informed consent:____________________________

Signature of Person conducting informed consent: __________________________

Date:____
_

Supplementary file 7: Semi-structured interview guides

INTERVIEW GUIDE FOR PATIENTS INCLUDED IN TRIAL

Questions do not have to be asked in this order, and not all questions have to be covered

Introduction

Hi, my name is [name]. Thank you for taking part in this interview. Researchers and health professionals at The University of Sydney and Royal Prince Alfred Hospital want to find out whether a new treatment pathway using telephone and virtual appointments, and App-based exercise programs, helps people receive treatment sooner and get better sooner.

We would like to ask you questions about the treatment you received in the Back Clinic. If at any time you would like to stop the interview, please let us know and we will stop. You can change your mind about talking to me at any time before or during the interview and stop the interview at any time. You can choose not to answer a question.

Are you happy to continue? [If no, thank them for their time and end the interview; if yes, continue].

Thank you [name] for agreeing to take part. We will use your feedback and the feedback of others to write a summary of what people have told us. There will be absolutely no identification of any real names or identification of where you live or which hospitals or health professionals you have seen.

Are you happy for me to record the interview? Do you have any questions before we start?

CONTEXT: TO UNDERSTAND WHAT WORKED, WHAT DIDN'T WORK, AND WHY/ WHY NOT FOR THE TWO METHODS OF SERVICE DELIVERY.

I am interested in exploring your experiences with the care you received in greater detail. Please feel free to be honest about what it was like for you.

All participants

1. Please tell me about your experiences overall of [face-to-face care, virtual consultation, App, pain education program, telephone consultation].

Prompts:

- What aspects of the experience do you like most, and why?
- What do you like least, and why?

2. Was your treatment convenient?

Prompts:

- How convenient was it for you to receive [face-to-face care, virtual consultation, App, pain education program, telephone consultation]?
- How do you feel about not having to attend the hospital for treatment (for low-, medium-, and high-risk participants)?
- How do you feel about having to attend the hospital for treatment (for participants with worrisome radicular symptoms and the usual care group)?

Low-risk participants

3. Next, I'd like to get your views about the virtual/telephone call you received (or why you did not receive it).

Prompts:

- How did you find the call? What was helpful? What wasn't?
- Do you feel as though you got any benefit from the phone call?
- What kinds of things did you talk about with the rheumatologist?
- Would you recommend this method of delivering for others? What kinds of people would this approach suit? Who wouldn't it suit?
- What else would you liked to have received as part of your treatment during the trial?

Medium- and high risk participants

4. Next, I'd like to get your views about the virtual consultation(s) you received (or why you did not receive them).

Prompts:

- How did you find the consultation(s)? What was helpful? What wasn't?
- Do you feel as though you got any benefit from the virtual consultation(s)?
- Do you feel the benefit was similar to what you would have got with face-to-face appointment(s)?
- Would you recommend this method of delivering treatment for others? What kinds of people would this approach suit? Who wouldn't it suit?
- What else would you liked to have received as part of your treatment during the trial?
- Can you comment on the frequency of your appointments?

5. Next, I want to discuss the PhysiTrack App.

- Did you ever use the App?
- If no, why was that?
- If yes, how easy was it to use the App? Did it get easier over time?
- Did you need help to use it? If yes, explore.
- What do you think about the physio using the App to monitor your compliance with the rehabilitation exercises? Why do you say that?
- Did your recording of exercises match what exercise you did?
- How long did you use the App?
- How long did you do the rehabilitation exercises? Why or why not?

6. Next, I want to discuss the self-directed pain education program. **(High risk participants)**

- Did you access the program?
- If no, why was that?
- If yes, how easy was it to navigate? Did it get easier over time?
- Did you need help to access it? If yes, explore.
- How did you find the information in the program?
- Did you watch all the videos? Explore

Participants with worrisome radicular pain (and people in the usual-care group)

7. Next, I'd like to get your views about the face-to-face appointments you received (or why you did not receive them).

Prompts:

- How did you find the appointment(s)? What was helpful? What wasn't?
- Can you tell me about the process of scheduling appointments? What was the availability of your rheumatologist and physiotherapist?
- Did you always have the same person?
- What is it about seeing a rheumatologist or physiotherapist in person that you like or don't like?
- How convenient was it for you to travel to and attend a face-to-face appointment(s) at the hospital?
- Can you comment on the frequency of your appointments? Is that what you expected? Why or why not?
- Do you feel as though you got any benefit from the appointment(s)?
- Would you recommend this method of delivering treatment for others? What kinds of people would this approach suit? Who wouldn't it suit?
- Do you feel you could have a got a similar benefit from a telephone or virtual consultation(s)?
- What else would you liked to have received as part of your treatment during the trial?

8. Is there anything else you would like to say that we have not talked about in this interview?

Thank you so much for your time.

INTERVIEW GUIDE FOR EXTERNAL PATIENTS

Questions do not have to be asked in this order, and not all questions have to be covered

Introduction

Hi, my name is [name]. Thank you for taking part in this interview. Researchers and health professionals at The University of Sydney and Royal Prince Alfred Hospital want to find out whether a new treatment pathway using telephone and virtual appointments, and App-based exercise programs, helps people receive treatment sooner and get better sooner.

We would like to ask you questions about your thoughts on the model of care (rapid virtual care) and our trial testing this model. If at any time you would like to stop the interview, please let us know and we will stop. You can change your mind about talking to me at any time before or during the interview and stop the interview at any time. You can choose not to answer a question.

Are you happy to continue? [If no, thank them for their time and end the interview; if yes, continue].

Thank you [name] for agreeing to take part. We will use your feedback and the feedback of others to write a summary of what people have told us. There will be absolutely no identification of any real names or identification of where you live or which hospitals or health professionals you have seen.

Are you happy for me to record the interview? Do you have any questions before we start?

All participants

Participants will be asked about basic demographic information and other questions to give further background on relevant characteristics (e.g., what is their current musculoskeletal condition).

1. What are your thoughts on the positives and negatives of this model of care?

2. What reason or reasons would (did) you decide to not participate in the trial testing this model?

3. What reason or reasons would (did) you not provide follow-up data (or stop providing data)?

Prompts

- *Explanation of the model of care*
- *Ask participants on their thoughts on what could be improved to make the model more suitable for them and more likely to participate*
- *Ask participants what information they would need to hear during the recruitment phone call to increase the likelihood they would participate and complete follow up data*

4. Do you have any other musculoskeletal pain?

- *If yes, do you think this model of care will be beneficial for this pain if you would otherwise see a physiotherapist or rheumatologist?*

5. Is there anything else you would like to say that we have not talked about in this interview?

Thank you so much for your time.

INTERVIEW GUIDE FOR CLINICIANS INCLUDED IN THE TRIAL

(Questions do not have to be asked in this order, and not all questions have to be covered.)

Hi, my name is [name and background]. Thank you for taking part in this interview. Researchers and health professionals at The University of Sydney and Royal Prince Alfred Hospital want to find out whether a new treatment pathway using telephone and virtual appointments, and App-based exercise programs, helps people receive treatment sooner and get better sooner. We also want to see if the new treatment pathway is acceptable to clinicians.

We would like to ask you questions about the treatment you provided in the Back Clinic as part of the trial. You can change your mind about talking to me at any time before or during the interview and stop the interview at any time.

Are you happy to continue? [If no, thank them for their time and end interview; if yes continue.]

Thank you [name] for agreeing to take part. We will use your feedback and the feedback of others to write a summary of what people have told us. There will be absolutely no identification of any real names or identification of your professional details.

Are you happy for me to record the interview? Do you have any questions before we start?

CONTEXT: TO UNDERSTAND WHAT WORKED, WHAT DIDN'T WORK, AND WHY/ WHY NOT FOR THE TWO METHODS OF SERVICE DELIVERY

Participants will be asked about basic demographic information and other questions to give further background on relevant characteristics (e.g., hospital site, professional experience, years in current position and years since graduated).

1. Let’s first talk about the way your service normally operates.

Prompt:

- How often would you typically see patients? Do you have a waiting list? How long is that waiting list usually?

2. Please tell me about your overall experiences coordinating the Rapid Virtual Stratified Care trial.

Prompts:

- What pleased you about the trial?
- What surprised you?
- What were your concerns?
- What would you do differently?

3. How did the clinicians and patients involved in the trial respond to being involved?

4. Please tell us about the recruitment process for the trial.

Prompts:

- How did you manage the logistics of recruitment?
- Was there any difficulty in recruiting participants? If so, please describe.

CONTEXT: TO UNDERSTAND THE PERCEIVED BARRIERS/ FACILITATORS FOR EVALUATING IN A LARGE, MULTI-SITE TRIAL

5. On the basis of your experience in the trial, how easy do you think it will be to introduce delivering this model of care in other outpatient musculoskeletal settings?

6. Has the COVID-19 crisis changed your or your colleagues' attitudes towards delivering rehabilitation remotely?

7. Looking back on the approach used to deliver treatment using eHealth in the trial – are there any aspects of the intervention that could have been delivered differently?

Prompts:

- Could participants at high-risk of persistent pain be better managed with face-to-face appointments?
- Could participants with worrisome radicular symptoms be managed equally effectively with virtual appointments?

8. What is the potential for eHealth-based stratified care to provide more patients with treatment sooner? How important is it to cut down waiting lists?

9. Thinking about what you have learnt from your experiences in the trial – what are the pros and cons of using eHealth-based stratified care, from patients' perspectives?

Prompts:

- What are the main advantages for patients compared to usual practice?
- How acceptable is eHealth-based stratified care likely to be to those accessing treatment for low back pain in a public hospital? Why or why not?
- What kinds of patients do you think are most suitable for being managed or monitored using eHealth?

10. What are the pros and cons from a clinician's perspective?

Prompts:

- How compatible/ acceptable will eHealth-based stratified care be to hospital physios and rheumatologists?
- What are the main advantages for clinicians in delivering care via eHealth, compared to usual practice? What are the main disadvantages?

11. What has to be in place for eHealth-based stratified care to be viable to deliver in the hospital setting?

Prompts:

- What are some things that will make this hard/ easy?
- Could this model of care be rolled out in your hospital right now?
- What are some of the barriers?
- What are some of the facilitators?
- Where will the main resistance come from?

12. What kinds of benefits would you anticipate that introducing eHealth-based stratified care would have for patients; physiotherapists; rheumatologists; for hospitals? (Ask about health, service access, cost savings for the hospital).

13. If eHealth-based stratified care was found to be beneficial in a large trial, would you want to provide this intervention in the future? Why, or why not?

14. Is there anything else you would like to say that we have not talked about in this interview?

Thank you so much for your time.

INTERVIEW GUIDE FOR EXTERNAL CLINICIANS AND KEY STAKEHOLDERS

(Questions do not have to be asked in this order, and not all questions have to be covered.)

Hi, my name is [name and background]. Thank you for taking part in this interview. Researchers and health professionals at The University of Sydney and Royal Prince Alfred Hospital want to find out whether a new treatment pathway using telephone and virtual appointments, and App-based exercise programs, helps people receive treatment sooner and get better sooner. We also want to see if the new treatment pathway is acceptable to clinicians.

We would like to ask you questions about the model of care we used in the Back Clinic as part of a trial and the potential of combining stratified care and telehealth to treat various musculoskeletal condition. You can change your mind about talking to me at any time before or during the interview and stop the interview at any time.

Are you happy to continue? [If no, thank them for their time and end interview; if yes continue.]

Thank you [name] for agreeing to take part. We will use your feedback and the feedback of others to write a summary of what people have told us. There will be absolutely no identification of any real names or identification of your professional details.

Are you happy for me to record the interview? Do you have any questions before we start?

CONTEXT: TO UNDERSTAND THE PERCEIVED BARRIERS/ FACILITATORS FOR EVALUATING IN A LARGE, MULTI-SITE TRIAL

Participants will be asked about basic demographic information and other questions to give further background on relevant characteristics (e.g., hospital site, professional experience, years in current position and years since graduated where relevant)

1. Let’s first talk about the way your service normally operates.

Prompt:

- How often would you typically see patients? Do you have a waiting list? How long is that waiting list usually?

2. Based on your knowledge, how easy do you think it will be to introduce delivering this model of care in other outpatient musculoskeletal settings?

Prompt:

- *Explanation of the model of care*

3. Has the COVID-19 crisis changed your or your colleagues’ attitudes towards delivering rehabilitation remotely?

4. Looking at the approach used to deliver treatment using eHealth in our trial – are there any aspects of the intervention that could have been delivered differently?

Prompts:

- Could participants at high-risk of persistent pain be better managed with face-to-face appointments?

- Could participants with worrisome radicular symptoms be managed equally effectively with virtual appointments?

5. What is the potential for eHealth-based stratified care to provide more patients with treatment sooner? How important is it to cut down waiting lists?

6. Thinking about our model of care – what do you think the pros and cons of using eHealth-based stratified care would be, from patients' perspectives?

Prompts:

- What would be the main advantages for patients compared to usual practice?
- How acceptable would eHealth-based stratified care likely be to those accessing treatment for low back pain in a public hospital? Why or why not?
- What kinds of patients do you think are most suitable for being managed or monitored using eHealth?

7. What are the pros and cons from a clinician's perspective?

Prompts:

- How compatible/ acceptable will eHealth-based stratified care be to hospital physios and rheumatologists?
- What are the main advantages for clinicians in delivering care via eHealth, compared to usual practice? What are the main disadvantages?

8. What has to be in place for eHealth-based stratified care to be viable to deliver in the hospital setting?

Prompts:

- What are some things that will make this hard/ easy?
- Could this model of care be rolled out in your hospital right now?
- What are some of the barriers?
- What are some of the facilitators?
- Where will the main resistance come from?

9. What kinds of benefits would you anticipate that introducing eHealth-based stratified care would have for patients; physiotherapists; rheumatologists; for hospitals? (Ask about health, service access, cost savings for the hospital).

10. If eHealth-based stratified care was found to be beneficial in a large trial, would you want to provide this intervention in the future? Why, or why not?

11. Is there anything else you would like to say that we have not talked about in this interview?

Thank you so much for your time.

Supplementary file 8: Characteristics of interviewed participants

Patients	Total sample (n=11)	Intervention (n=7)	Usual care (n=4)
Age, median (IQR)[a]	60 (50 to 66) [b]	63 (59 to 66)[d]	50 (25 to 70) [c]
Female, n (%)	7 (64)	4 (57)	3 (75)
Language other than English spoken at home, n (%)	4 (36)	3 (43)	1 (25)
Employment, n (%)			
Currently employed	3 (27)	3 (43)	2 (50)
Not currently employed	6 (55)	4 (57)	0 (0)
Student	2 (18)	0 (0)	2 (5)
Unpaid carer	0 (0)	0 (0)	0 (0)
Education, n (%)			
High school (not completed)	2 (18)	2 (29)	0 (0)
High school (completed)	1 (9)	0 (0)	1 (25)
TAFE/Trade	3 (27)	1 (14)	2 (50)
University – postgraduate degree	1 (9)	1 (14)	0 (0)
University – undergraduate degree	4 (36)	3 (43)	1 (25)

Other	0 (0)	0 (0)	0 (0)
Symptom duration of 12 weeks or longer, n (%)	11 (100)	7 (100)	4 (100)
Taken sick leave, n (%)	6 (55)	5 (71)	1 (25)
Risk subgroup, n (%)			
Low risk	1 (9)	0 (0)	1 (25)
Medium risk	2 (18)	1 (14)	1 (25)
High risk	2 (29)	2 (29)	0 (0)
Keele STarT MSK score (0-12), median (IQR)	9 (7 to 10)	10 (9 to 11)	5 (3 to 7)
Potential radiculopathy	6 (55)	4 (57)	2 (50)
Clinicians	**Total** (n=2)		
Age, median (IQR)	50 (40 to 60)		
Female, n (%)	1 (50%)		
Hospital			
Royal Prince Alfred	2 (100)		
Type of Health profession			
Rheumatologist	1 (50)		

Physiotherapist	1 (50)
Years experience, median (IQR)	20 (12 to 28)
Years in current position, median (IQR)	5 (3 to 6)

[a,b,c] Data missing for two participants age (one from each group). N, Number of participants; IQR, interquartile range; TAFE, Technical and Further Education, MSK, Musculoskeletal.

APPENDIX SIX

Additional publication forming part of this thesis (n=1)

1. Hutton JM, **Gamble AR**, Maher CG, De Campos TF, Han CS, Coombs D, Halliday M, Harvey LA, Foster NE, Machado G, Anderson DB, Billot L, Richards B, Swain M, McKay MJ, Needs C, Chu J, Shaw T, Lung T, Harris IA, Zadro JR. Effectiveness of a physiotherapist-led triage and treatment service on WAITing time for adults with musculoskeletal pain referred to Australian public hospital physiotherapy clinics: a protocol for the WAIT-less trial. *BMJ Open* (2025) https://doi:10.1136/bmjopen-2024-091293

BMJ Open

Effectiveness of a physiotherapist-led triage and treatment service on WAITing time for adults with musculoskeletal pain referred to Australian public hospital physiotherapy clinics: a protocol for the WAIT-less trial

Joshua M Hutton ,[1,2,3] Andrew R Gamble ,[1,2] Chris G Maher,[1,2] Tarcisio F de Campos ,[1,2,4] Christopher S Han ,[1,2] Danielle Coombs ,[1,2] Mark Halliday,[5] Lisa A Harvey,[6,7] Nadine E Foster,[8] Gustavo Machado ,[1,2] David Anderson,[9,10] Laurent Billot ,[11] Bethan Richards ,[1,2,3] Michael Swain,[4] Marnee McKay,[2] Chris Needs,[1,2,3] Jackie Chu ,[6,7] Timothy Shaw,[12] Tom Lung,[2] Ian A Harris,[1,2,3,13] Joshua R Zadro ,[1,2] WAIT-less TRIAL INVESTIGATORS

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ABSTRACT

Introduction Musculoskeletal pain is the second leading cause of disease burden in Australia, and there is a need to investigate new models of care to cope with the increasing demand for health services. This paper describes the protocol for a randomised controlled trial investigating whether a physiotherapist-led triage and treatment service is non-inferior for improving function at 6 months and superior for reducing treatment waiting times, compared with usual care for patients with musculoskeletal pain referred to public hospital outpatient physiotherapy clinics.

Methods and analysis A total of 368 participants (184 per arm) will be recruited from six public hospitals located in metropolitan Sydney, Australia. We will recruit adult patients newly referred to a public hospital physiotherapy outpatient clinic with a musculoskeletal condition that is typically managed by a physiotherapist (eg, back or neck pain, osteoarthritis, rehabilitation postorthopaedic surgery and sporting injuries). Participants will be randomised 1:1 to the physiotherapist-led triage and treatment service or usual care. A physiotherapist will telephone participants in the intervention group and match them to different modes and types of care based on baseline characteristics. Participants at low risk of poor outcomes (assessed by the Keele STarT MSK tool) will be given simple advice and education during this call and instructed to call back if their symptoms do not improve in 6 weeks. Participants at medium risk of poor outcomes or requiring postoperative rehabilitation will be offered a course of telehealth (videoconference) physiotherapy targeting exercise-based self-management. Participants at high risk of poor outcomes and/or with potential nonprogressive radiculopathy will be offered a course of usual clinic-based physiotherapy as per all participants in the usual care group. Physical function (Patient Specific Functional Scale) at 6 months postrandomisation and waiting time (time from randomisation to first treatment) are coprimary outcomes. Secondary outcomes include other patient outcomes (eg, pain), health resource use, adverse events, process measures (eg, adherence) and costs.

Ethics and dissemination This trial has approval from the Sydney Local Health District Human Research Ethics Committee (RPAH Zone; X24-0090 and 2024/ETH00585). Recruitment will commence in September 2024 and is expected to be completed by December 2025 with follow-ups completed by December 2026. The results of the trial will be submitted for publication in reputable international journals and presented at relevant national and international conferences.

Trial registration number ANZCTR (ACTRN12624000947505).

STRENGTH AND LIMITATIONS OF THIS STUDY

- ⇒ This is a multicentre, two-arm, parallel-group randomised controlled trial with nested process and economic evaluation.
- ⇒ Findings may provide information on the implementation of a physiotherapist-led triage and treatment service that could improve access to care within outpatient hospital physiotherapy departments.
- ⇒ Participants will be blinded to the study hypothesis.
- ⇒ Physiotherapists delivering the interventions will not be blinded.
- ⇒ All study sites will be in metropolitan Sydney, so the findings might not be applied to rural and remote parts of Australia or other countries.

INTRODUCTION

Musculoskeletal pain is the second leading cause of disease burden in Australia, and there is a need to investigate new models of care to cope with the increasing demand placed on health services.[1 2] Many Australians seeking care for musculoskeletal pain do not have private health insurance[3] and join increasingly long waiting lists for clinic-based physiotherapy in publicly funded hospitals (where there is no cost to the patient). Long waiting times of up to 12 months[4] for physiotherapy in public hospitals likely delay recovery for some patients with musculoskeletal pain and lead some to develop persistent disabling symptoms that are costly and complex to manage.[5–7] A potential solution to reduce treatment waiting times is a model of care that can identify patients with simple musculoskeletal problems that can be managed with less resources (eg, brief telephone appointments and App-based home exercise programmes), thereby freeing up clinic-based resources for patients with more complex presentations.

A promising model of care that reduced treatment waiting times without compromising clinical outcomes in a large randomised controlled trial (RCT; n=2256) was the UK PhysioDirect telephone assessment and advice service for patients with musculoskeletal pain.[8] PhysioDirect used an innovative clinical algorithm that supported physiotherapists to triage patients who needed clinic-based care while managing patients they judged to be able to self-manage via telephone consultation (exercise advice and advice leaflets).[8] PhysioDirect reduced treatment waiting times compared with usual clinic-based care (median of 7 days vs 34 days, arm time ratio of 0.32, 95% CI 0.29 to 0.35) and was deemed equally clinically effective and seemingly safe.[8] It was also acceptable to patients and physiotherapists in the UK.[8]

The PhysioDirect model of care inspired us to develop and evaluate a similar model of care to tackle the long waiting times in many outpatient physiotherapy clinics in Australia. Our initial 'triage and treatment service' was developed for a multidisciplinary rheumatology and physiotherapy clinic where it was later evaluated in a pilot and feasibility RCT for people with low back pain.[9] In this trial, a rheumatologist called participants in the intervention group soon after they joined the clinic waiting list and matched them to different modes and types of care based on a baseline screening assessment. Participants at low risk of poor outcomes (assessed by the Keele STarT MSK tool)[10] were given simple advice and education during this call and instructed to call back if their symptoms did not improve in 6 weeks. Participants at medium and high risk of poor outcomes were offered a course of telehealth (videoconference) physiotherapy targeting exercise-based self-management. High-risk participants were additionally encouraged to complete an online self-directed pain education programme. Participants with potential nonprogressive radiculopathy were offered a clinic-based rheumatology appointment with the option of clinic-based physiotherapy. Findings from the pilot and feasibility RCT and additional qualitative interviews were used to refine our new model of care and adapt it for use in outpatient physiotherapy clinics ('physiotherapist-led triage and treatment service') that manage a range of musculoskeletal conditions. A more detailed description of the development and refinement of our physiotherapist-led triage and treatment service is described elsewhere.[11]

This paper describes the protocol for an RCT (WAIT-less trial) investigating whether our new physiotherapist-led triage and treatment service is noninferior for improving function at 6 months and superior for reducing treatment waiting times (coprimary outcomes) compared with usual clinic-based physiotherapy care for patients with musculoskeletal pain referred to public hospital outpatient physiotherapy clinics.

METHODS AND ANALYSIS

Design

The WAIT-less trial is a pragmatic multicentre, two-arm, parallel-group RCT with nested process and economic evaluation. This protocol follows the Standard Protocol Items: Recommendations for Interventional Trials statement (https://www.spirit-statement.org/). The trial is registered with the Australian and New Zealand Clinical Trials Registry—trial registration number ACTRN12624000947505.

Setting

The WAIT-less trial will be conducted in several public hospital outpatient physiotherapy clinics across Sydney Local Health District (SLHD) and South Eastern Sydney Local Health District (SESLHD) in NSW, Australia, and compare the physiotherapist-led triage and treatment service with usual clinic-based care. The participating hospitals provide diversity with respect to patient demographic characteristics, ethnicity, hospital setting and outpatient clinic staffing models. We will randomise, across all sites, 368 participants to this trial (ie, 184 per arm). Participants in the physiotherapist-led triage and treatment service group and usual care group will be treated at the hospital they are referred to.

Eligibility criteria

Patients referred to participating outpatient physiotherapy clinics are referred from Hospital Emergency Departments, inpatient units, outpatient hospital clinics and local General Practices. Occasionally, patients can self-refer but only at some hospitals and in extenuating circumstances. Potentially eligible newly referred patients will be contacted by a screening physiotherapist from either an SLHD or SESLHD site to determine if the patient is eligible and interested in participating in the trial. Figure 1 illustrates the trial design. Box 1 below describes the eligibility criteria for the trial.

Participant recruitment

Initial contact with patients referred to the outpatient physiotherapy clinic will be made as soon as possible after

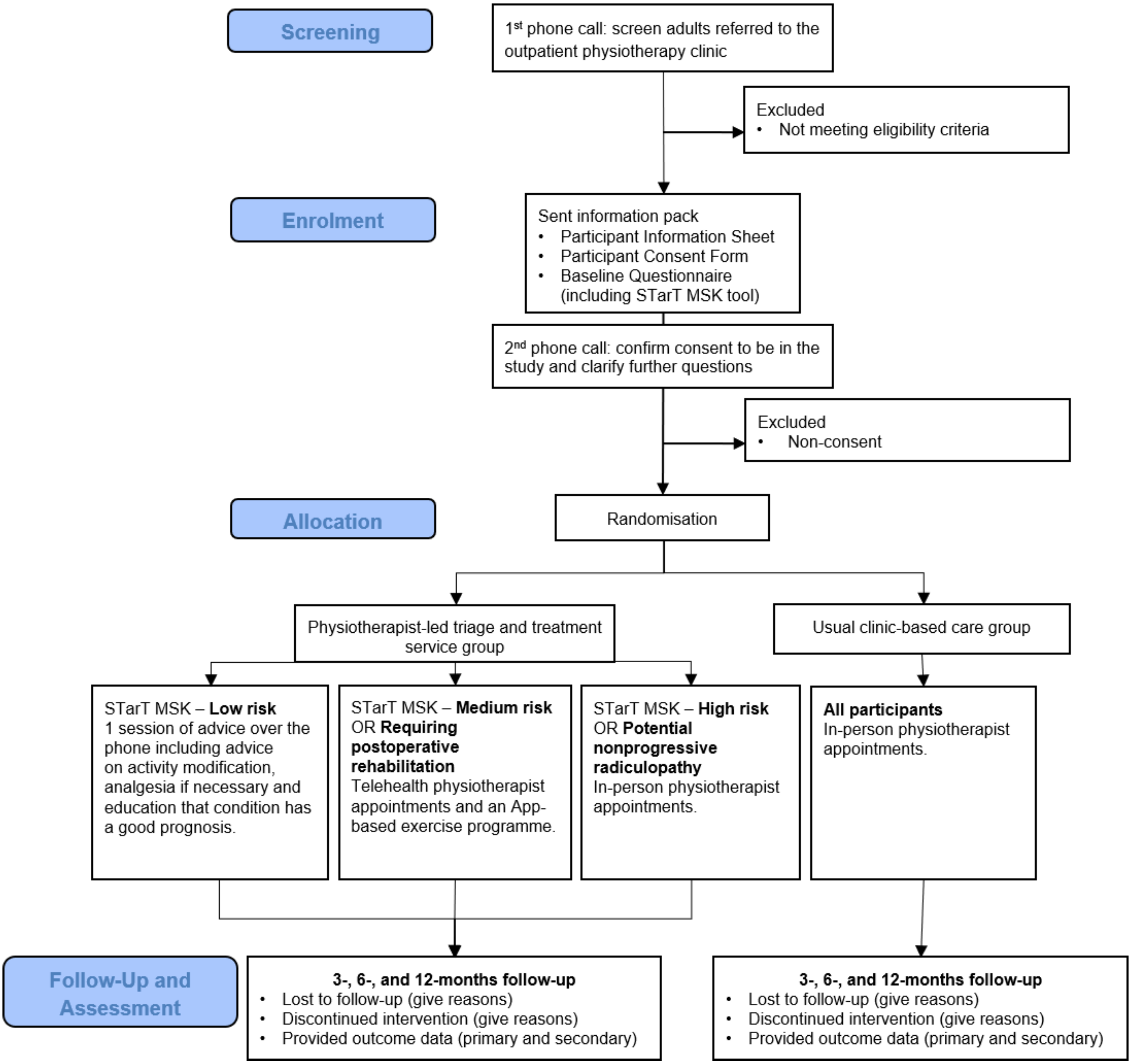

Figure 1 Trial design.

a referral is received by a screening physiotherapist via telephone. During this call, patients will be invited to participate in the trial. If patients demonstrate interest, the screening physiotherapist will explain the trial and determine their eligibility using a screening form that contains the eligibility criteria. For all patients interested and eligible to be involved, the screening physiotherapist will send an email, SMS or mail out of the trial information pack that includes the Participant Information Statement Form (online supplemental appendix 1), Participant Consent Form (PCF—online supplemental appendix 2) and the baseline assessment questionnaire. Participants will be made aware that participation is voluntary, and they are free to withdraw at any time with no repercussions. Participants who receive the information pack via email or SMS will provide consent by 'checking' a radio button in an online survey through Research Electronic Data Capture (REDCap) and then proceed to the baseline assessment questionnaire online. For all interested and eligible patients who are not able to complete the PCF and baseline assessment questionnaire via SMS or email, they will be sent the trial information pack via post. Patients who receive the trial information pack via post will be provided with a pen and a postage-paid return envelope, so they can post their signed PCF and completed baseline assessment questionnaire to the screening physiotherapist.

Box 1 Eligibility criteria

Inclusion criteria

- Adult patient (≥18 years)
- New referral (defined as being referred within the last 6 weeks) to a public hospital physiotherapy outpatient clinic with a musculoskeletal condition or musculoskeletal pain (hereafter referred to as ‘musculoskeletal pain’) that would usually be managed by a physiotherapist. Examples include but are not limited to:
  - Back/neck pain
  - Osteoarthritis
  - Whiplash-associated disorders
  - Ankle sprains
  - Postfracture
  - Sporting injury (eg, ankle sprains)
  - Postorthopaedic surgery (eg, hip or knee replacement, rotator cuff repair)
- Willing to participate and provide follow-up data
- Can speak and read English to provide informed consent

Exclusion criteria

- Suspected serious underlying pathology or musculoskeletal conditions requiring urgent medical care (eg, malignancy, fracture, infection, inflammatory arthritis and joint dislocation)
- New referral strongly suggestive of concerning neurological features (eg, progressive radiculopathy or upper motor neuron lesion)
- Is on a postoperative exercise regimen prescribed by a surgeon which specifies the mode of care delivery (eg, needs to be provided in a clinic supervised by a physiotherapist)
- Requiring mobility progression or assistance weaning from a walking aid(s) whereby the person is at an increased fall risk and needs to be seen in the clinic
- Pregnant women.

The screening physiotherapist will offer all participants a telephone call if they need assistance completing the PCF or baseline assessment questionnaire. Participant consent will be documented in the REDCap trial database and the participant’s hospital medical record. This is as per normal practice and a medico-legal requirement. All patients deciding not to be involved in the trial will receive care from a health practitioner as per the standard of care in the clinic they were referred to. At any time during the study if the treating physiotherapist determines serious pathology must be excluded (suspicion of red flag pathology via assessment and screening questions), the participant will be referred to their general practitioner or referring doctor (eg, orthopaedic surgeon, rheumatologist or within hospital specialty) to obtain medical clearance before resuming physiotherapy as per best practice.

Randomisation procedure

The 1:1 random allocation sequence will be independently generated in Stata by the team’s biostatistician and uploaded to REDCap. Allocation will be concealed as the biostatistician generating the sequence will not be involved in the recruitment of participants and the screening physiotherapist will not know the participant’s group allocation until their baseline data are entered into REDCap. The allocation sequence will also be concealed from potential participants and all on-site staff associated with the trial. The randomisation sequence will use randomly permuted blocks of variable sizes (2 and 4) to ensure equal numbers in both groups. Stratification variables for the randomisation sequence include trial sites and the three treatment subgroups. This will ensure that the intervention and control groups have a similar proportion of participants across different trial sites. The screening physiotherapist will telephone participants who consent (via completing the PCF—online supplemental appendix 2) and complete their baseline assessment to inform them of their group allocation. Table 1 describes the physiotherapist-led triage and treatment service and usual care group.

Outcomes

The coprimary outcomes are physical function as assessed by the Patient Specific Functional Scale (PSFS) at 6 months postrandomisation and treatment waiting time (from randomisation to first treatment). PSFS scores at 3 and 12 months are secondary outcomes. Participants completing the PSFS list up to five functional tasks currently limited by their musculoskeletal condition and score each task based on their current level of ability—0 (unable to perform activity) to 10 (able to perform activity at the same level as before the complaint). Scores for each activity will be summed and calculated as an average of the total possible score for the participants (determined by the number of identified activities). This generic measure will be used as patients with a wide range of musculoskeletal pain presentations will be included in the trial, and it compares well with disease-specific measures in terms of reliability and validity.[10 12 13] Treatment waiting time will be assessed as the number of days from randomisation to the first appointment with a physiotherapist (either telephone, video conference or clinic-based). It will also be expressed as the number of days from the referral date to the first appointment with a physiotherapist to understand treatment waiting times across sites before, during and at the end of the trial recruitment period; this will be a secondary outcome.

Secondary outcomes (eg, pain and quality of life), health resource measures (eg, number of clinic-based appointments and number of telehealth appointments), potential mediators (eg, pain self-efficacy and recovery expectations), process measures (eg, adherence and usability of PT eXercises App) and adverse events are outlined in online supplemental appendix 3.

Data collection methods

Participants will receive a unique link via email or SMS to complete their surveys directly in REDCap. Participants will receive an email or SMS 2 days prior to each time point, reminding them to complete their respective surveys. Two reminders followed by a phone call will be provided to patients who do not complete their surveys at a particular time point. The treating clinicians may remind participants to complete their surveys during

Table 1 Physiotherapist-led triage and treatment service and usual care protocol.

Treatment group and subgroup	Intervention protocol
Physiotherapist-led triage and treatment service	
All participants	For participants randomised to the physiotherapist-led triage and treatment service, the screening physiotherapist will match them to different modes and types of care during the call informing participants of their group allocation.
Low risk of poor outcomes	Participants at low risk of poor outcomes (Keele STarT MSK tool score 0–4)[28] will be offered brief advice and education (via one telephone call with a physiotherapist) including advice on activity modification, analgesia if necessary and education that their condition has a good prognosis. This advice and education will be provided during the phone call where participants are informed of their trial arm allocation. Participants in this treatment subgroup will be asked to call the screening physiotherapist back if their symptoms have not improved in 6 weeks. If nil contact is received after 6 weeks, participants will be discharged from the physiotherapy service.
Medium risk of poor outcomes or requiring postoperative rehabilitation	Participants at medium risk of poor outcomes (Keele STarT MSK tool score 5–8) or requiring postoperative rehabilitation will be offered physiotherapy via telehealth. An appointment with a telehealth physiotherapist will be organised by the screening physiotherapist during the phone call where participants are informed of their trial arm allocation. Telehealth physiotherapy will consist of assessment, advice, education to support self-management and a tailored home-exercise programme delivered via the PhysioTherapy Exercise App (freely available online exercise prescribing software created by some of the study authors: www.physiotherapyexercises.com). The number of appointments offered will be at the discretion of the treating physiotherapist.
High risk of poor outcomes and/or with potential nonprogressive radiculopathy	Participants at high risk of poor outcomes (Keele STarT MSK tool score 9–12) and/or with potential nonprogressive radiculopathy will be offered a course of clinic-based (in-person) physiotherapy as is usually provided at the participating public hospital clinics. An appointment with a clinic-based physiotherapist will be organised by the screening physiotherapist during the phone call where participants are informed of their trial arm allocation. Participants will be offered clinic-based care but will not be told they are at high risk of poor outcomes (according to the Keele STarT MSK tool). Clinic-based physiotherapy may include a combination of any advice and education to support self-management (eg, advice to exercise, modify activities, lose weight or take simple pain medications if needed), exercise tailored to patients' activity goals and level of function, graded activity, graded exposure and manual therapy. The number of appointments offered will be at the discretion of the treating physiotherapist.
Usual care	
All participants	Participants randomised to the usual care group will be offered a course of clinic-based (in-person) physiotherapy as is usually provided at the participating public hospital clinics and an initial appointment commensurate with the usual clinic waiting time. An appointment with a clinic-based physiotherapist will be organised by the screening physiotherapist during the phone call where participants are informed of their trial arm allocation. Participants will be offered clinic-based physiotherapy which may include a combination of any advice and education to support self-management (eg, advice to exercise, modify activities, lose weight or take simple pain medications if needed), exercise tailored to patients' activity goals and level of function, graded activity, graded exposure and manual therapy. The number of clinic-based appointments will be at the discretion of the treating physiotherapist.

Participants in either group can be referred to a specialist pain clinic or to see a psychologist if the treating physiotherapist believes it would be valuable. All treatment for participants in both trial arms will be conducted within weekday business hours (Monday to Friday from 7.30 a.m. to 4.30 p.m.). Waiting time includes weekends and public holidays when the clinics are closed as it is the normal approach to reporting waiting time in participating clinics.

appointments. If requested, paper copies of the surveys will be posted (including a pen and a postage-paid return envelope) to participants with their responses entered directly into REDCap by an assessor blind to group allocation. If required, a study investigator may contact participants to assist them in completing their surveys, so they can post their survey responses to the screening physiotherapist via a postage-paid return envelope.

Sample size

A total sample of 368 participants will provide 90% power to exclude a noninferiority margin of 0.7 points on the 11-point PSFS with a 15% loss to follow-up,[8] an SD of 1.9, two-sided α of 5% and PSFS at 6 months in the control arm participants of 5.8—based on a recent trial conducted in the same setting.[14] A between-group difference of ≤0.7 points will indicate that the new physiotherapy model of care is noninferior (as good as or better) compared with usual clinic-based care. We chose an SD of 1.9 as it is between the mean value of the SD for the PSFS at follow-up in published studies of similar patient populations with the SDs of 1.7,[15] 2.0[12] and 2.1[16]. The minimal important difference (MID) for the PSFS ranges from 1.3 (small change) to 2.7 (large change).[17] Guidelines suggest using a noninferiority margin of 50% (or less preferably) of the expected treatment effect.[18] Thus, we chose a conservative between-group noninferior margin of 0.7 (50% of the MID of 1.3).

If our physiotherapist-led triage and treatment service is noninferior for improving function at 6 months compared with usual care, we will interpret the findings for treatment waiting time as a coprimary outcome. This hierarchical approach to our coprimary outcomes was selected because consumer feedback suggested that reducing waiting times is not valuable if patient outcomes are adversely affected. Our sample size of 368 participants will provide >80% power to determine a conservative 14-day mean reduction in waiting time (approximately half of the reduction found in the PhysioDirect trial[8]), calculated from medians and interquartile ranges with this formula,[19] using an SD of 43 (conservative SD from participating public hospital outpatient clinics over the past 5 years), two-sided α of 5% and 15% loss to follow-up.

Process evaluation: qualitative interviews

A process evaluation, informed by the RE-AIM[20] framework, will be conducted to better understand the views and experiences of clinicians and patients regarding the two treatment paths in the trial. This information would be useful regardless of the trial result, allowing a better understanding of trial outcomes and assisting in identifying potential barriers and facilitators to future implementation. RE-AIM considers the target population (*Reach* (eg, representativeness), *Effectiveness* of the service, whether clinicians, patients and key stakeholders are willing to *Adopt* the service, fidelity (eg, clinician and patient adherence), barriers and facilitators to *Implementation* and the extent to which the service can become part of practice or policy (Maintenance)). RE-AIM will use quantitative data sources (eg, health resource use, patient adherence to the intervention and clinician fidelity to the protocol) and qualitative data sources (eg, interviews with physiotherapists, patients and key stakeholders). A more detailed outline of the process evaluation will be published a priori. All qualitative aspects of this study will be reported according to the consolidated criteria for reporting qualitative research (COREQ).[21]

We will attempt to interview 10 physiotherapists involved in delivering the physiotherapist-led triage and treatment service, 20 participants from the usual care group and 20 from the physiotherapist-led triage and treatment service (with a similar number of participants from the three treatment subgroups). The anticipated sample size was informed by the concept of information power that considers the study aim, specificity, theory, dialogue and analysis to guide planning for sample size in qualitative research.[22] The actual sample size may vary based on the saturation of elicited themes. We will attempt to purposively sample physiotherapists involved in delivering the physiotherapist-led rapid triage phone service by age, gender, familiarity with telehealth and years of experience. We will attempt to purposively sample patient participants to achieve diversity in presenting musculoskeletal condition, age, gender, ethnicity, trial arm, treatment subgroup (if in the intervention group) and response to the intervention.

To gain an in-depth understanding of potential barriers to broader implementation, we will also aim to interview 10 physiotherapists who may be interested in this new model of care but were not involved in the trial, 10 patients who dropped out of this trial or chose to not participate, 10 patients who did not attend their appointments and 10 key stakeholders (n=10) (eg, heads of allied health, physiotherapy departments at hospital sites in NSW, representatives from Sydney Health Partners and government-funded insurance authorities), with the anticipated sample size calculated as per earlier.

An experienced researcher and physiotherapist will conduct all qualitative interviews. The role of the interviewer as an active participant in the research process will be critically acknowledged through reflexivity. The interviewer will take field notes to document personal assumptions and biases, and the research team will critically evaluate how their interactions with participants may be shaped by their prior experiences and beliefs through regular reflective practice and peer debriefing.

In this study, the assumed research paradigm is pragmatism as our trial focuses on evaluating the practicality and effectiveness of a physiotherapist-led triage and treatment service in Australian public health physiotherapy clinics. This approach will allow us to make a practice, actionable critique of our new model of care, drawing on the experiences of patients, their health professionals and other key stakeholders.[23] The paradigm is appropriate for person-centred research as it focuses on applying different research methods, forms and value hierarchies to gain knowledge, asserting that optimal definitions for social problems emanate from the people experiencing them.[23]

Blinding

Therapists and assessors will not be blinded. The surveys administered during this trial are self-assessments completed by participants who will be blind to the study hypothesis (ie, will not be aware of what the new model of care involves). Blinding participants to the study hypothesis will be achieved by providing participant information sheets that do not mention the study hypothesis and state that the study is comparing two models of care (without specifying which model is the intervention of interest).

Statistical methods

A detailed Statistical Analysis Plan and Health Economics Analysis Plan (HEAP) including mock tables will be developed before unblinding and shared with the Data Monitoring and Safety Board (DMSB). Prespecified analyses will be programmed using randomly scrambled treatment allocations. Unblinded results will be presented to the study team once all analyses have been programmed and validated.

Primary analysis

The purpose of our trial is to assess whether the physiotherapist-led triage and treatment service is as good as or better than usual clinic-based care for improving function and better than usual care in terms of reducing treatment waiting time. The between-arm difference in PSFS scores at 6 months postrandomisation is a coprimary outcome and we have prospectively defined a noninferiority margin of −0.7 points for this analysis. This is the maximal compromise on the outcome we are prepared to tolerate (based on guidelines[18] and consumer feedback) and still consider the physiotherapist-led triage and treatment service to be clinically noninferior to usual clinic-based care. We will test the null hypothesis that the mean difference in PSFS scores (intervention − usual care) is no greater than −0.7 (H0: mean difference ≤−0.7). To declare noninferiority for the new model of care when compared with usual clinic-based care, the 95% CI around the mean difference should be entirely above the noninferiority margin, that is, the lower bound of the 95% CI must be higher than −0.7. A repeated-measure linear mixed model including all postrandomisation PSFS measurements will be used to generate an adjusted mean difference and 95% CI representing the comparison of PSFS scores between the intervention and usual care arms at each time point. The model will be adjusted for the baseline PSFS value (to improve statistical precision), hospital site and treatment subgroup allocation.

The between-arm difference in treatment waiting time is the other coprimary outcome, provided the physiotherapist-led triage and treatment service is as good or better than usual clinic-based care for improving function (hierarchical approach). We have prospectively defined an effect size of 14 days or greater to be clinically important (approximately half the reduction found in the PhysioDirect trial).[8] This is the difference that our consumers and clinician partners consider meaningful. A generalised linear model will be used to generate an adjusted mean difference and 95% CI representing the comparison of treatment waiting times between the intervention and usual care groups. The model will be adjusted for hospital site and treatment subgroup allocation.

Imputation techniques may be considered if more than 5% of any outcome data are missing, depending on patterns within missing data.

Secondary analysis

Similar linear models will be used to analyse between-group differences in other continuous outcomes, while logistic regression will be used to estimate the treatment effect for binary outcomes. All analyses of secondary outcomes will be adjusted for baseline values (if applicable), hospital site and treatment subgroup allocation as per the primary analysis.

Cost-effectiveness analysis

Costs will be measured using a combination of trial records, administratively linked data, healthcare diaries and published data: healthcare costs (based on local costing models) and intervention costs (clinician time and wage, and other resources required to deliver the interventions). Comparisons made between the new model of care and usual care arms will be generated through the economic evaluation which will estimate the difference in the cost and benefits between the arms of the trial. The economic assessment method will adhere to best practice guidelines for economic evaluations alongside noninferiority trials.[24]

Wherever possible, the costs will be standardised to current prices. Quality-adjusted life-years (QALYs) will be generated through the utilisation of the EuroQolEQ-5D-5L questionnaire outcomes which will be compared with the national Australian value set.[25] To avoid biases associated with complete case analysis, multiple imputation methods may be employed to impute missing data as described in more detail in the HEAP. Incremental cost per QALY gained will demonstrate the results of the economic evaluation.

Predefined equivalence margins for costs and QALYs will be chosen as recommended by guidelines.[24] Incremental costs and QALYs will be calculated in terms of the difference between those in the physiotherapist-led triage and treatment service group and the usual care group. Bootstrapping will be used to estimate a distribution around costs and QALYs and will be plotted on a cost-effectiveness plane. The cost-effectiveness plane and the predefined equivalence margins will be used to determine the probability of the physiotherapist-led triage and treatment service being noninferior to usual care. One-way sensitivity analyses will be conducted around key cost variables, and a probabilistic sensitivity analysis will be conducted to estimate the uncertainty in all parameters.

Qualitative interview analysis

All interview data will be analysed using thematic analysis, a method for identifying, analysing and reporting patterns within qualitative data.[26] We will employ the Braun and Clarke six-step framework for thematic analysis, which includes familiarisation with the data (Step 1), generating initial codes (Step 2), searching for themes (Step 3), reviewing themes (Step 4), defining and naming themes (Step 5) and producing the report (Step 6).[27] In practice, two researchers will independently familiarise themselves with the interviews (via audio-recording or transcribed interviews using the Otter AI software), record initial observations and identify concepts relevant to the questions asked. The two researchers will then organise concepts into broader themes and subthemes in NVivo that will be discussed with the other co-investigators. Any disagreements in categorising concepts into themes and subthemes will be discussed and resolved. The mapping of themes and subthemes will be iterative as new data emerges. Interview themes and subthemes will be matched to the appropriate five dimensions of the RE-AIM[20] framework (Reach, Effectiveness, Adoption, Implementation and Maintenance) to further understand contextual factors. Interviews will stop after three consecutive interviews where no new themes have emerged (data saturation).

Data monitoring

A Data Safety and Monitoring Board (DSMB) charter will be developed to define the roles and responsibilities of an independent DSMB. The independent DSMB will be convened to oversee this trial. The Trial Steering Committee will appoint three members to the DSMB. This will include a member with scientific expertise in the management of musculoskeletal pain in the physiotherapy outpatient department, a member with experience and expertise in clinical trial conduct and methodology and an experienced biostatistician. One of the DSMB members will be the Chair. The Chair will provide DMSB members with a quarterly report that identifies all AEs and SAEs reported during that period. If the quarterly review of AE data does not raise any concerns, the Chair will report this to the other members of the DSMB and to the study team. However, if these reviews suggest any significant risk of harm or unknown or uncertain risks to the trial participants, the Chair will convene a full meeting of the DSMB to review the AE data to make recommendations about whether the trial should continue, continue with modifications or be stopped. Any unintended consequences or AEs will be compared between groups and will be reported at the end of the trial. There will be no interim analyses of outcome data.

Auditing

Internal audits may be conducted quarterly to carry out data validation for all data entered into the REDCap database manually. A random sample of 10% of all survey data entered into REDCap manually by a member of the research team will be reviewed by a second team member to ensure that data have been entered and recorded accurately. If errors are detected, corrections will be made. In the event of greater than 10% of data being incorrect, a further sample of 10% will be drawn. The new acceptable error rate will then reduce to 9%, and if the observed error rate is greater than the new acceptable error rate then a further 10% sample will be tested (new acceptable error rate of 8%). This process will continue reducing the acceptable error rate by 1% until the error rate drops below the acceptable threshold. Audits will also be conducted to ensure that correct procedures are being followed for patient invitation, screening procedure, eligibility criteria, consent and intervention delivery.

Access to data

Study data will be stored within The University of Sydney's secure REDCap server. This web-based software will be managed by a member of the research team. This server is secure, stable and backed up daily in compliance with national, state and district privacy and confidentiality obligations. This database will be username and password-protected and can only be accessed by personnel named on the ethics application. Only the screening physiotherapists will have access to identified data. All other study investigators will only have access to deidentified data. All study data and documents will be retained for a minimum of 15 years after the completion of the study. Following this period, destruction of the data and documents will occur in a secure manner as per the privacy act.

Consumer involvement

We have engaged with consumers and clinician-researchers from study conception (including when writing our Medical Research Future Fund grant funding application for this project) and have formed a trial Consumer Advisory Committee that will provide ongoing feedback on trial design, conduct and reporting. We have also sought feedback from physiotherapists at our hospital sites, and consumers with lived experience of musculoskeletal pain who have presented to these sites, to ensure that our new model of care is as relevant and acceptable as possible.

Ethics and dissemination

The Human Research Ethics Committee (RPAH Zone) of the Sydney Local Health District has approved this trial (protocol number X24-0090 and 2024/ETH00585). Approval must be sought from the trial's Steering Committee and the ethics committee for any amendments prior to implementation.

Findings from this trial will be published in peer-reviewed journals and presented at national and international conferences. There will be no identifiable information related to trial participants in any published report or conference presentation. Deidentified individual data will be made available via consultation with the trial team and the approving ethics committee. Deidentified data will be stored on the University of Sydney's secure digital data servers as outlined in the trial's research data management plan. We will offer a plain language summary of the findings from the study to all consenting participants.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, and conduct, and reporting, and dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer-reviewed.

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APPENDIX SEVEN

Related publications not forming part of this thesis (n=11)

A systemetic review comparing intensitve supervisied rehabiltation versus less supervised rehabilitation following anterior cruciate ligament reconstruction:

1. **Gamble AR**, Pappas E, O'Keeffe M, Ferreira G, Maher CG, Zadro JR. Intensive supervised rehabilitation versus less supervised rehabilitation following anterior cruciate ligament reconstruction? A systematic review and meta-analysis. J *Sci Med Sport*. 2021;24(9):862-870. https://doi.org/10.1016/j.jsams.2021.03.003

Development and early evaluation of a patient decision aid for adults with Femoracetabular Impingement Syndrome:

2. Yonan FH, Anderson DB, Rhon DI, Foster K, **Gamble AR**, McKay MJ, Parsons NA, Hoffmann T, Zadro JR. Developing a Patient Decision Aid for Femoroacetabular Impingement Syndrome: A Mixed-methods Study (2025) (under review)

Review of the use of guidelines by physiotherapist on using imaging and electrotherapy for patients with low back pain:

3. Kharel P, Maher CG, **Gamble AR,** Ferreira GE, Zadro JR. (2025) Effectiveness of Choosing Wisely recommendations in reducing physiotherapists' intentions to refer for imaging and use electrotherapy for low back pain: a randomised controlled

experiment. *BMJ Open*. 2025;15:e097202. https://doi.org/10.1136/bmjopen-2024-097202

Use of infographics, development of a checklist and guide for infographics and reporting of inforgraphics:

4. Muller R, Ferreira GE, Bejarano G, **Gamble AR**, Kirk J, Sindone J, Zadro JR. Do infographics 'spin' the findings of health and medical research? *BMJ Evid Based* Med. 2025;30:84-90. https://doi.org/0.1136/bmjebm-2024-113033
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Work related musculoskeletal conditions (disorders) in endoscopic sinus and skull based surgeons:

7. Campbell RG, Zadro JR, **Gamble AR**, Chan CL, Mackey MG, Osie G, Hui Png L, Douglas RG, Pappas E. Work-related musculoskeletal disorders in endoscopic sinus and skull base surgery: a systematic review with meta-analysis. *OHNS*. 2024;171(6):1650-1669. https://doi.org/10.1002/ohn.892

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9. Campbell RG, Zadro JR, Chan CL, Mackey MG, Nettel-Aguirre A, Douglas RG, **Gamble AR**, Pappas E. Work-related musculoskeletal disorders in endoscopic sinus and skull base surgeons. Results of an international survey (2025) (under review)

Management advice and use of diagnostic labels for people with rotator cuff disease:

10. Zadro JR, Michaleff ZA, O'Keeffe M, Ferreira GE, Trager AC, **Gamble AR**, Afeaki F, Li Y, Wen E, Yao J, Zhu K, Page R, Harris IA, Maher CG. How do people perceive different advice for rotator cuff disease? A content analysis of qualitative data collected in a randomised experiment. *BMJ Open.* 2023;13(5):e069779. https://doi.org/10.1136/bmjopen-2022-069779
11. Zadro JR, O'Keeffe M, Ferreira GE, Trager AC, **Gamble AR**, Page R, Herbert RD, Harris IA, Maher CG. Diagnostic labels and advice for rotator cuff disease influence perceived need for shoulder surgery: an online randomised experiment. *J. Physiother*. 2022;68(4):269-276. https://doi.org/https://doi.org/10.1016/j.jphys.2022.09.005

APPENDIX EIGHT

Research Dissemination

Conference presentations- International (n=9)

1. International Forum for Back and Neck Pain Research in Primary Care, Davos, Switzerland (2025)
   - *9-minute oral presentation and 3 minutes of questions (Chapter 6)*
2. International Forum for Back and Neck Pain Research in Primary Care, Davos, Switzerland (2025)
   - *Poster presentation (Chapter 4)*
3. World Physiotherapy Conference, Tokyo, Japan. (2025)
   - *Poster presentation (Chapter 4)*
4. World Physiotherapy Conference, Tokyo, Japan. (2025)
   - *E-Poster presentation with 5-minute oral presentation and questions (Chapter 6)*
5. Wiser Health Care International Conference, Sydney, Australia. (2024)
   - 9*-minute oral presentation and 2 minutes questions (Chapter 4)*
6. Global Spine Congress, Bangkok, Thailand (2024)
   - *Poster presentation (Chapter 4)*
7. The 4th World Congress of Sports Physical Therapy (WCSPT), Nyborg, Denmark (2022)
   - *Poster presentations (Chapter 2)*
8. *The 4th World Congress of Sports Physical Therapy (WCSPT),* Nyborg*, Denmark (2022)*
   - *Poster presentations (Additional paper 1)*
9. Sydney MSK Bone & Joint Health Alliance Annual Scientific (Virtual) Meeting (2020)
   - *10-minute oral presentation via Zoom (Additional paper 1)*

Conference presentations- National (n=15)

1. Sydney Musculoskeletal Health Annual Scientific meeting (2024)
    - *7-minute oral presentation and 2-minute questions (Chapter 6)*
    - ***Awarded the top presentation in the 'clinical trials' oral abstract session***
2. Institute for Musculoskeletal Health, Sydney Local Health District Meeting, Sydney, Australia (2024)
    - *10-minute oral presentation and 5-minute questions (Chapter 4)*
3. Australian Shared Decision-Making Symposium, Gold Coast, Australia (2024)
    - *Presentation of research related to shared decision making (Chapters 3 and 4)*
4. Sydney Pain Consortium, Optimising Pain Management across the Lifespan (2024)
    - *9-Minute oral presentation and 2-minute questions (Chapter 6)*
5. Faculty of Medicine and Health HDR conference (2024)
    - *12-minute oral presentation and 3-minute questions (Chapter 4)*
6. Southeast Sydney Local Health District Physiotherapy Leadership meeting (2024)
    - *10-minute oral presentation (Chapters 5 and 6)*
7. Early Mid-Career Researcher SSPH Research Pitch Awards (2024)
    - *5-minute oral presentation (Chapter 3)*
8. Australian Physiotherapy Association (APA) 'IGNITE' conference, Brisbane, Australia. (2023)
    - *15-minute oral presentation (Chapter 2)*
9. Australian Physiotherapy Association (APA) 'IGNITE' conference, Brisbane, Australia. (2023)
    - *5-minute oral presentation (Chapter 3)*
10. 15th National Allied Health Conference, Perth, Australia (2023)
    - *15-minute oral presentation, unable to attend (Chapter 2)*

11. Sydney Musculoskeletal Health Annual Scientific meeting (2023)
    - *5-minute oral presentation and 2-minute questions (First Author paper 1)*
12. Syd MSK Health Annual Scientific Meeting (2022)
    - *10-minute Oral presentation (Chapter 2)*
13. The University of Sydney 3MT Faculty of Medicine and Health semi-final (2022)
    - *3-minute Oral presentation (Chapter 3)*
14. The University of Sydney NMSK Research Collaborative meeting (2022)
    - *15-minute Oral presentation (Additional paper 1)*
15. Institute for Musculoskeletal Health, Sydney Local Health District Meeting (2021)
    - *15-minute oral presentation and 15-minute questions (Additional paper 1)*

Invited media engagement (n=5)

1. Inside the Science MSK Podcast, Jason Ward, 2024 *(Chapter 3)*
2. Inside the Science MSK Podcast, Jason Ward, 2024 *(Additional paper 1)*
3. Dr Karen Litzy 'Healthy, Wealthy & Smart Podcast, 2024 *(Chapter 3)*
4. E3 Rehab Podcast, 2024 *(Additional paper 1)*
5. Sydney Morning Herald (SMH) online, ACL injury research by Deakin University's Patrick Owen suggests benefits of rehabilitation exercise over surgery, smh.com.au, and in the newspaper 'ACL studies shift focus from surgical solutions to physio', 2022 *(Chapter 2)*

Example images from media engagement

Funding via Scholarships and Grants

- $5, 000 The University of Sydney Travel scholarship (2025)
- $3, 000 Travel scholarship (ANZMUSC) for the IBNPF, Switzerland, Davos (2025)
- $15, 000 (3x$5000) University of Sydney Graduate Research School events (2024)
- $1,000 Travel bursary, ANZMUSC Annual Scientific Meeting, Adelaide, Australia (2024)
- $1,000 Sydney Health Partners Emerging Perioperative Clinician Researcher Career Development Award (2023)
- $42,967 plus $2,000 per annum for up to 3 years (total: $134,901) Postgraduate Research Scholarship in Care for Musculoskeletal Conditions and research allowance
- $2000 (2x $1000) University of Sydney PRSS funding (2023, 2024)

Research Awards

- The University of Sydney, Sydney Musculoskeletal Health Annual Scientific meeting top presentation award in the ‘clinical trials’ oral abstract session (2024)
- Emerging Perioperative Clinician Researcher Career Development Award from Sydney Health Partners (2023)
- The University of Sydney, Sydney School of Health Science Teachers Award for ‘Fostering a sense of belonging and motivating students to learn’ (2022)