Remotely delivered physiotherapy for musculoskeletal conditions

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Doctor of Philosophy

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Supervisor's statement

As supervisor of Hannah Withers' doctoral work, I certify that I consider her thesis "Remotely delivered physiotherapy for musculoskeletal conditions" to be suitable for examination.

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Statement of originality

This is to certify that to the best of my knowledge; the content of this thesis is my own work. This thesis has not been submitted for any degree or other purposes.

I, **Hannah Withers**, certify that the intellectual content of this thesis is the product of my own work and that all the assistance received in preparing this thesis and sources have been acknowledged.

Hannah Withers Date: 17/12/2024

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Published Papers

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ABSTRACT

Musculoskeletal (MSK) conditions are common, and physiotherapy treatment is traditionally provided in an outpatient setting with face-to-face sessions. Accessing this treatment can be difficult and inconvenient with long waitlists and significant costs to both the health system and patients. Current evidence suggests that it may be possible to move some patients with specific MSK conditions away from face-to-face treatment and replace it with more flexible and accessible treatment delivered remotely. However, there is a lack of evidence clearly indicating that remotely delivered physiotherapy for MSK conditions can achieve good patient outcomes, increase patient access to treatment and be cost effective from both the health system and patient perspective. The content of this thesis aims to investigate these areas where evidence is lacking.

Chapter 2 of this thesis presents the protocol of the REFORM trial – a non-inferiority, randomised controlled trial with pragmatic inclusion criteria, designed to determine whether or not a remotely delivered exercise programme could achieve outcomes as good or better than usual care physiotherapy.

To supplement the main trial, a Process Evaluation was conducted alongside the trial. **Chapter 3** presents the protocol of the process evaluation which aims to determine whether the intervention was delivered as intended and to identify the barriers and facilitators of rolling out this intervention.

Chapter 4 of this thesis presents one component of the process evaluation: a qualitative study investigating the attitudes and perceptions of patients, physiotherapists and other stakeholders of remotely delivered physiotherapy. The results of the full process evaluation are not included in this thesis.

Chapter 5 of this thesis presents the results of a randomised controlled, non-inferiority trial – the REFORM trial. The results of this trial revealed that remotely delivered physiotherapy is as good as usual face-to-face care that is typically provided in a public hospital outpatient setting. The secondary results showed no significant between group differences which support the results of the primary outcome.

Chapter 6 presents the results of the health economics analysis that was embedded within the REFORM trial. In keeping with the results of the primary outcome, a cost minimisation was completed and showed that when taking uncertainty into account the probability of remotely delivered physiotherapy being cost saving and effective for the PSFS outcome was 88%. The cost utility analysis also showed that for the Quality Adjusted Life Years (QALY) outcome, the probability of the intervention being cost-effective at a $50,000/QALY threshold was 51%.

The studies within this thesis have identified an intervention for MSK conditions that is cost effective without compromising patient outcomes. This intervention has the potential to increase access to physiotherapy and decrease wait times in an outpatient setting.

PREFACE

This thesis is organised into 7 chapters, each written so it can be read independently. **Chapter 1** is an introduction to this thesis and presents an overview of the current burden of the treatment of musculoskeletal conditions, and the difficulties some people have accessing timely and affordable physiotherapy. This chapter draws attention to the gaps in the literature which are addressed by the studies presented in the following chapters. **Chapters 2 and 3** are published study protocols and **Chapters 4 and 5** consist of studies that have been published in peer-reviewed journals. These studies have been presented in the format in which they have been published. **Chapter 6** consists of a draft of a study that has been prepared for submission to a journal for peer review. This study is presented in the format in which it will be submitted. **Chapter 7** presents a discussion about the key findings from this body of work, and the clinical implications and recommendations for future research based on these findings. The complete reference list is at the end of this thesis. Any additional appendices or supplementary material not included in the individual chapters are included in **Appendices** at the end of the thesis.

CHAPTER ONE: Introduction

1.1 Musculoskeletal conditions

1.1.1 Defining Musculoskeletal conditions

Musculoskeletal (MSK) conditions are a diverse group of disorders comprising up to 150 acute and chronic conditions that affect connective tissues in the body including bones, joints, ligaments, tendons and muscles [1]. They affect a person's ability to move and cause pain. MSK conditions are caused by inflammation, trauma, or ageing and lifestyle [2]. MSK conditions can have a sudden onset, be a short-term problem, recurrent, or can become chronic disorders [3].

1.1.2 Prevalence and burden of MSK conditions on health systems

Musculoskeletal conditions make up the second highest cause of disability and affect up to 1.7 billion people worldwide [4]. This number is forecasted to increase due to population growth and ageing; and changes in prevalence [1]. The diversity of MSK conditions places significant strain on health systems both in Australia and globally [4]. In Australia, up to 25% of the total disease burden is due to MSK conditions which is greater than that of mental health disorders [4]. Approximately 4 million Australians are living with back problems including low back pain and intervertebral disc disorders, and up to 90% of people will experience low back pain in their lifetime [4]. Additionally, 2.1 million Australians are affected by osteoarthritis [5]. This condition is a leading cause of pain and disability, particularly among older adults, and its prevalence is projected to rise by 31% to 5.39 million by 2040, due to population growth and aging [5].

MSK conditions are a leading cause of disability in Australia, placing a significant strain on the healthcare system, and impacting an individual's ability to work and carry out everyday activities due to pain, stiffness, and reduced mobility [6]. Chronic conditions such as arthritis, and back pain can limit physical function, making it difficult to perform tasks that require standing, lifting, or repetitive movements. This can lead to decreased productivity,

absenteeism, or even early retirement in severe cases [7]. Everyday activities, such as walking, cooking, cleaning, and self-care, may become challenging due to pain and fatigue. Individuals with severe MSK conditions may require assistive devices, modifications to their living spaces, or help from caregivers to maintain independence. Mental health can also be affected, as persistent pain and physical limitations can lead to stress, anxiety, or depression [6]. The high prevalence of these conditions leads to increased demand for medical consultations, diagnostic services, and therapeutic interventions, including surgeries and rehabilitation. Musculoskeletal conditions also create a large economic burden from both direct and indirect costs. Direct costs result from health care utilisation where services are sought to diagnose, treat or prevent a condition. In 2012, the total direct health expenditure for arthritis and other MSK conditions was estimated at $9.2 billion [8]. Arthritis alone accounted for $5.5 billion in healthcare costs, with projections indicating an increase to $7.6 billion by 2030. Indirect costs are also significant and include the cost of absenteeism or reduced productivity at work, or early retirement from work [9]. In a study from the United States of America it was estimated that MSK conditions have a combined direct and indirect costs of over $200 Billion, and this figure will only increase with the growing and ageing population [10].

The economic burden of MSK conditions is substantial, and contributes to lost work hours, increased healthcare costs, and reduced quality of life. Effective management, including early intervention, public health initiatives, and improved treatment options are essential to decreasing the burden on individuals, workplaces, and the healthcare system as a whole.

1.2 Exercise, support and advice for the management of MSK conditions

MSK conditions, such as arthritis, osteoporosis, and chronic back pain, are typically managed through a combination of medical, physical, and lifestyle interventions. The primary management strategies include pharmacological treatment, physiotherapy, lifestyle

modifications and surgery. In Australia, individuals with back problems predominantly seek care from General Practitioners (GPs), who serve as the initial point of contact for diagnosis, management, and referrals to specialists [11]. Patients with lower limb MSK conditions, most commonly present to a physiotherapist as their primary care provider [11]. Additionally, both public and private hospitals, are critical in delivering care, particularly for advanced imaging, surgeries, and emergency interventions. In 2020–21, hospital services represented 68% ($10 billion) of MSK expenditure [12].

With such a large economic burden and vast number of people suffering from MSK conditions, it is important that high value care, which is accessible and cost effective, with good patient outcomes is provided by healthcare systems [13]. Evidence shows that patients who have access to physiotherapy treatment have better and more cost effective outcomes than those who seek care from a (GP) [10] making access to physiotherapy important for the management of MSK conditions [14,15]. Access to care often depends on factors such as the severity of the condition, personal preference, financial situation, and private health insurance coverage.

Physiotherapy is typically provided through regular face-to-face sessions with a physiotherapist [16]. The key aspects of physiotherapy management are informed by evidence-based guidelines, which recommend treatment consisting of exercise, support and advice for some common MSK conditions such as low back pain, knee osteoarthritis and some shoulder injuries [17-19]. In addition, it is important that physiotherapy treatment is equitable, patient-centred and consistent [13]. Without appropriate management, MSK conditions can lead to loss of independence, frailty and more expensive health care needs [4]. However, up to 63% of people with a MSK condition are not receiving optimal treatment [18].

In addition to limited access to care in Australia, one major issue that leads to suboptimal treatment is delayed diagnosis of MSK conditions. Many individuals experience long wait times for consultations with health professionals and people in rural and remote areas face even

greater challenges due to a lack of local healthcare providers. Many patients often only seek treatment when their condition has progressed to a severe stage, making management more complex and expensive [20].

Despite evidence supporting the effectiveness of physiotherapy in the management of MSK conditions, one study reported that in an audit of over 1000 GPs, less than 20% of patients with MSK conditions were referred to a physiotherapist [11]. High costs and out-of-pocket expenses often prevent individuals from seeking physiotherapy, exercise programs, and specialised treatments. Many services are not fully covered by Medicare or private health insurance, placing financial strain on patients [11].

As a result, there is a clear need for a new treatment approach which improves accessibility, is low cost, and is based on clinical guideline recommendations. In order to address this healthcare need, this thesis tests the REFORM intervention - a remotely delivered model of physiotherapy for people with some MSK conditions which can be treated with exercise, support and advice, which is accessible, cost effective and based on clinical guidelines.

1.2.1 Defining remotely delivered physiotherapy

The World Health Organisation (WHO) (2024) defines rehabilitation as '*a set of interventions designed to optimise functioning and reduce disability in individuals with health conditions in interaction with their environment'* [21]. When interventions are delivered via communication technology at a distance it can be described with the term 'telerehabilitation' [22]. Another common term that is sometimes used is 'telehealth' - defined as '*the provision of health care at a distance.... using different sources of technology and is inclusive of all health professions*' [23]. These terminologies are commonly used interchangeably in the current literature to describe physiotherapy provided at a distance and can be confusing. There are no agreed upon classifications, and the terminology often tries to describe the healthcare profession involved

and the modality of technology that is being used e.g. telerehabilitation which is particularly common for physiotherapy [24].

In addition to terminologies describing the type of distance interactions, the use of different technologies can be categorised into two types: synchronous and asynchronous. Synchronous modalities describe care that is provided in real time such as telephone calls and videoconferencing. Asynchronous modalities describe the provision of care that does not occur simultaneously and could consist of digital images (as in an app) or text messages [24,25]. A hybrid model of care includes in person, synchronous and asynchronous forms of treatment [26].

The REFORM trial involved providing care (the intervention) using different modes of technology at a distance, by a physiotherapist. Therefore the term 'remotely delivered physiotherapy' is used throughout the thesis to describe the intervention.

1.2.2 Effectiveness of remotely delivered physiotherapy for MSK conditions

Remotely delivered treatment for MSK conditions can be implemented through various modalities, each offering unique benefits in terms of accessibility, convenience, and engagement. A number of systematic reviews have examined the effectiveness of providing physiotherapy in different ways [26-31]. In addition, there are many studies looking at the benefits of videoconferencing [25,32-37] or telephone calls to increase physical activity [38-42]. One study compared face-to-face physiotherapy with one session of face-to-face physiotherapy and regular telephone calls, finding no between group differences for any outcomes including the primary outcome of pain intensity [42]. Another study compared face-to-face treatment with an App. The results indicated there was no significant difference between the groups for the primary outcome which was pain measured on a visual analogue scale (0-10) at three months, 0.1 (-0.53 to 0.33) [41] (reported in Corso et al, 2022 [29]). Both studies were investigating the effectiveness of management options for low back pain and were superiority

trials that failed to indicate that one method of physiotherapy delivery was superior to the other. In addition, they were very small trials done within the African context.

Although studies have claimed to have demonstrated that remotely delivered physiotherapy achieves similar outcomes to a face-to-face intervention, these studies have many limitations. For example, the results of a systematic review by Cottrell et al, (2017) demonstrated that synchronous telehealth was moderately effective compared to usual care post-intervention (SMD 0.45, 95% CI 0.20 to 0.70) with moderate heterogeneity (I^2 56%) [43]. The two main modalities of synchronous telehealth were video conferencing and telephone calls. However only a very small number of studies were included (n=8) and the outcome favouring telehealth was attributed to the fact that the majority of the included studies investigated telehealth in addition to usual care compared to usual care alone. Several of the studies also delivered the same physiotherapist led exercise programs to both groups, only changing the method of the treatment delivery. The remaining included studies favoured the use of synchronous telehealth in the form of video conferencing. Only two of the included studies were non-inferiority trials and the study population was patients following total knee replacement. One of the most commonly used modes of synchronous telehealth delivery is videoconferencing because this method allows for visual cues when monitoring patient progress [44]. However, videoconferencing also requires a hosting platform, equipment and education to use. The possibility for visual cues also increases its similarity to traditional face-to-face physiotherapy, increasing the likelihood of effectiveness if used to deliver physiotherapy interventions.

One large trial (PhysioDirect) from the UK examined the effectiveness of moving people off a waiting list onto a home-supported program. The participants in the control group were not provided with physiotherapy at the same time but instead were placed on a waiting list to receive physiotherapy assessment and treatment as it became available [45]. In addition, the initial assessment and advice was provided by telephone with some participants then being

seen by a physiotherapist as required. The authors reported equivalence on the primary outcome measure, the physical component summary measure of SF36 at 6 months with a between group difference of -0.01(-0.80 to 0.79). However, it is not known from this trial whether patients would have done as well or better if the control participants received face-to-face physiotherapy at the same time that the intervention participants received the telephone support.

Another recent high quality pragmatic non-inferiority trial - The PEAK trial [44] investigated whether a physiotherapist-led, digitally supported exercise and education program delivered via videoconferencing, for individuals with knee osteoarthritis was as effective as traditional in-person physiotherapy. The between-group difference for the primary outcome measure, which was the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC),of -0.3 (95% CI, -0.6 to 0.0) indicated that participants in the digital intervention group achieved non inferior results compared to those receiving face-to-face physiotherapy [44]. However, in this trial, the intervention group received physiotherapy delivered via videoconferencing, which is face-to-face, synchronous and very similar to in-person face-to-face physiotherapy sessions. Videoconferencing allows clinicians to observe visual cues, such as body posture, movement patterns, and range of motion, which assist when assessing MSK conditions and guiding exercises [46]. For this reason, studies which used videoconferencing to deliver the intervention were considered to be too similar to face-to-face physiotherapy and were therefore not relevant to the REFORM trial.

There are also many studies that have looked at various ways of providing physiotherapy services and ongoing support to people with osteoarthritis (OA) to help them manage their disease. For example, studies have looked at the added benefit of regular telephone calls provided in combination with face-to-face physiotherapy or group sessions [47-49]. Or they have examined the benefits of telephone calls instead of face-to-face physiotherapy [40]. Then

other studies have compared the effectiveness of telephone calls to no intervention [50], or internet-based educational programs with or in addition to face-to-face physiotherapy [51,52]. Most of these studies however involve providing comprehensive and overall management support for arthritis, and do not test the effectiveness of providing physiotherapy per se.

When reviewing the literature, three main criteria were used to determine whether or not the evidence was relevant, somewhat relevant or not relevant to the REFORM trial. If the study used text messages, Apps or telephone calls to deliver a physiotherapy intervention then it was relevant to the REFORM trial. If the study used videoconferencing, then it was not relevant because while videoconferencing is not 'in-person' physiotherapy, it does enable face-to-face physiotherapy. Studies that did not include a physiotherapy treatment but did use text messages, Apps or telephone calls were considered to be somewhat relevant. Similarly, studies that focussed on outcomes unrelated to MSK conditions, (such as obesity or physical activity levels), were also considered to be only somewhat relevant. These studies are summarised in **Table 1**, ranked in order of relevance to the REFORM trial.

To date, there has not been enough high-quality evidence to draw definite conclusions about the effectiveness of remotely delivered physiotherapy for the treatment of various MSK conditions. There are notable gaps in the current body of evidence, including a lack of high quality trials that specifically evaluate the effects of remotely delivered physiotherapy on functional outcomes for patients using readily available technology other than videoconferencing [18]. To address these gaps, the design of the REFORM trial was pragmatic, with a focus on real-world applicability and feasibility, to reflect how remotely delivered physiotherapy would be delivered outside the controlled trial settings. To ensure that the intervention was as accessible and affordable for as many people as possible, a hybrid asynchronous/synchronous approach was adopted, using a freely available App, text messages and phone calls. The intervention design was based on the assumption that most people had

access to a smart device and the internet, making the intervention feasible and accessible in a real-world setting. This approach was compared to usual care as typically provided in a hospital outpatient setting.

1.3 Apps and text messages for adherence

Even though exercise is frequently claimed to be an effective treatment for MSK conditions, many studies report low levels of adherence [53]. To increase the effectiveness of exercise, it is necessary to improve adherence by removing any barriers to patients' abilities to adhere to their exercise programs. Barriers such as previous low levels of physical activity, poor social support and helplessness are common factors leading to poor adherence [53]. Strategies such as the provision of verbal and written instructions, support, motivation, education, positive feedback and goal setting may be helpful in improving patients' adherence to exercises [54]. Therefore, when designing a model of care for the treatment of MSK conditions it is appropriate to include strategies which will help to optimise exercise adherence. We incorporated these principles into the REFORM trial. For example, text messages were pre-programmed and sent weekly to offer motivation and support. Text messages are an easy and accessible way to provide motivational messages and support because of the minimal costs involved, the widespread accessibility of text messaging and the low level of technological knowledge required to receive and send information via text messages [55]. Many studies point to the motivating effects of regular text messages for people trying to cease smoking, lose weight or increase physical activity [39,56,57]. The current available evidence has conflicting results regarding the effects of text messaging interventions for MSK populations, however, one recent study with good methodological quality showed that text messages designed to provide encouragement and support for the treatment of MSK conditions can increase participants' adherence to their home exercise programs. The results of this trial found a mean between group difference of 1.3 on a 11-point scale (95% CI 0.2 to 2.3) [58] where patients self-reported their adherence on a

numerical rating scale ranging from 0 = ‘never performed my exercises’ to 10 = ‘always performed my exercises’.

Similarly, Apps provide a way to encourage adherence and are readily accessible because of widespread mobile phone use. To encourage patients’ adherence to their home exercise program in REFORM, the prescribed exercises were delivered via an App which contained individualised exercises with pictures and written descriptions of each exercise. It was possible to include the required number of repetitions for each exercise and there was an option to record adherence once per day when an exercise was completed. Patients were taught to use the App during the initial face-to-face session with the trial physiotherapist, who also encouraged goal setting, delivered education and advice; and informed the patients that their adherence would be monitored. Additionally, each patient received a follow up telephone call at 2 and 4 weeks where they received positive feedback, encouragement and advice about their exercise adherence. Providing an App can lead to greater exercise adherence than providing home exercises on pieces of paper particularly when the therapist can review patients’ progress and adherence [58]. Despite this finding, a recent systematic review on the use of Apps for the treatment of MSK conditions found that due to mixed results from very low quality studies it was not possible to determine whether the use of Apps was beneficial for improving exercise adherence [58].

It is essential to incorporate effective, accessible and low-cost approaches to delivering physiotherapy that increase the likelihood of patients’ adhering to their exercise programs in addition to being convenient and accessible. These principles were incorporated into the design of the intervention that was tested as part of the REFORM trial.

1.4 Increasing access to physiotherapy services

There are several barriers which prevent some people from accessing healthcare services. Living in rural and remote areas presents a considerable barrier to accessing health services

due to distance and travel costs. Equally, travel time or an inability to travel are also barriers to accessing treatment [59]. Further, a shortage of rurally based physiotherapists contributes to the difficulties of accessing treatment in rural or remote areas [60].

Financial barriers such as patient out of pocket costs may mean that some people can't afford to pay for physiotherapy treatment for their MSK condition. MSK conditions are common, which in turn leads to long waitlists in public hospital outpatient departments. Patients who wait longer for physiotherapy treatment for their MSK conditions may experience greater healthcare utilisation and costs, compared to those who are able to access physiotherapy sooner [61].

Innovative use of technology, such as text messaging and Apps, have the potential to help physiotherapists provide support and advice to patients who are geographically isolated, and who need cost effective options for treatment [60,61]. Moving appropriate patients with MSK conditions across to a remotely delivered model of care could increase access to physiotherapy [43] and reduce the burden on the healthcare system [14,62].

Overall, a lot of work has been done over recent years looking at different ways to provide physiotherapy services for people with MSK conditions, particularly utilising videoconferencing as a delivery modality which is similar to traditional face-to-face physiotherapy. However, very little work has looked at a model of care that consists of one initial face-to-face session, and then a remotely delivered package designed to reduce dependency on face to-face-care.

Chapter 2 of this thesis addresses the current lack of good quality studies investigating the effectiveness of remotely delivered physiotherapy, by presenting the Protocol of a non-inferiority, randomised, controlled trial comparing remotely delivered physiotherapy to usual care physiotherapy (The REFORM trial). The REFORM trial was designed to test a model of care that consists of an initial face-to-face session with the remaining treatments delivered via telephone, text messages and an App. This was compared to the usual care that patients typically receive in a public hospital outpatient setting, to determine whether patients with

some MSK conditions can achieve outcomes as good (or better), than patients who receive usual face-to-face outpatient physiotherapy.

The overarching aim of the trial was to determine whether appropriate patients could be moved away from face-to-face physiotherapy to remotely delivered physiotherapy without compromising patient outcomes. In addition, the trial had several specific aims including increasing accessibility to physiotherapy services, identifying patients', physiotherapists', and stakeholders' perceptions about remotely delivered physiotherapy and providing cost effective treatment for MSK conditions. **Chapter 5** presents the rationale, methods and primary and secondary results from this trial.

1.5 Perceptions and attitudes towards remotely delivered physiotherapy – different perspectives

There are differing perceptions and attitudes towards remotely delivered physiotherapy. And of course, even within different interest groups attitudes vary. For example, some physiotherapists welcome the opportunity to reduce patients' reliance on face-to-face physiotherapy. However, others are more reluctant to embrace this model of care. Some physiotherapists commonly believe that an important component in achieving good patient outcomes is the development of a therapeutic relationship between the patient and physiotherapist. They also believe that establishing a positive relationship can lead to greater patient satisfaction and adherence with treatment than when there is no positive relationship [63].

There is currently a lack of research looking at what fosters therapeutic relationships in physiotherapy, but one recent study attempted to identify the four necessary conditions [63]. The first condition the study identified was that the physiotherapist needed to be *present* in the moment, and engaging fully with the patient. Second, the physiotherapist needed to be *receptive* and demonstrate an open attitude to listening and acknowledging the patient. Third,

the physiotherapist must be *genuine* by being honest, being themselves and invested in the person. Fourth, the physiotherapist must be *committed* to understanding the condition and the patient, and to actioning continuous care. It is a commonly held belief by many physiotherapists that a positive patient/physiotherapist relationship cannot be fostered remotely, creating a barrier to the acceptance of remotely delivered physiotherapy [64]. However, studies have found that using remote modalities to deliver physiotherapy treatments can result in more positive relationships than face-to face treatments for both MSK patients and their physiotherapists [59,65].

There are qualitative studies that report some patients simply perceive in the superior nature of face-to-face treatment due to the need for manual therapy in order to improve [66,67]. Conversely, some patients place a lot of importance on ready access to services and the increased convenience that comes with remotely delivered physiotherapy. These people often welcome the opportunity to receive remotely delivered physiotherapy. Some argue that remotely delivered physiotherapy can help patients to take control of their own health and wellbeing, by enabling interactions with health professionals, increasing access to health education and providing the ability to share information easily [68].

To provide high quality care and achieve good patient outcomes, it is important to include shared decision making and deliver patient centred care [69,70]. There has been a recent shift in patients', physiotherapists' and other stakeholders' attitudes toward remotely delivered physiotherapy, to acknowledge that most likely a hybrid approach to physiotherapy service delivery is the way forward, where patients can opt for face-to-face or remotely delivered treatments or a combination of both [71].

Prior to COVID-19 there was a lack of policy, payment structure, training and a willingness to embrace a remote mode of service delivery from both the provider and patient [72]. Uptake of remotely delivered physiotherapy was slow [24] and physiotherapists did not feel they were

adequately trained to deliver treatments remotely [73]. However, during the COVID-19 global pandemic, social distancing protocols increased the demand for different models of care [74], making remotely delivered models of care potentially more appealing. There was also a growing acceptance of remotely delivered interventions by patients with demand for remotely delivered health care increasing by up to 64% by the end of 2020 [74].

Remotely delivered physiotherapy has the potential to increase communication, decrease wait times, increase access to care, empower patients to self-manage, and improve outcomes [16]. Remotely delivered physiotherapy may have many advantages for patients, physiotherapists and stakeholders compared to face-to-face physiotherapy. For example, patients may find it more convenient, and stakeholders may welcome the possible decrease in waiting times. Other advantages may include increased communication, access to care and patient empowerment. In order to investigate some of these possible advantages from the perspective of the patient, physiotherapist and stakeholder, semi structured interviews formed the basis of a qualitative study embedded within the REFORM trial. Themes were extracted and these results are presented in **Chapter 4** of this thesis. This qualitative study is part of the Process Evaluation conducted alongside the REFORM trial. The protocol for the Process Evaluation is presented in **Chapter 3.** There were many purposes to the Process Evaluation. They included an examination of the fidelity of the REFORM trial and its processes. All of the results of the Process Evaluation are yet to be published and will not be presented in this thesis. The Process Evaluation paper has been prepared and submitted to a journal for peer review.

1.6 The cost of remotely delivered interventions

The economic impact of MSK conditions must be considered from two perspectives. There is the cost from a health system perspective arising from the cost to provide a healthcare service, and then there is a personal cost arising from what the patient must pay to access these services [2]. There are very few studies investigating the cost effectiveness of remotely delivered

physiotherapy treatments for MSK conditions despite initial studies in this area suggesting that remotely delivered physiotherapy may improve quality of life and function [26]. One recent study found physiotherapy treatment delivered remotely for low back pain when compared with clinic-based treatments from a health system perspective was cost saving [62].

Several studies have investigated ways to deliver care to patients that are less costly without compromising on patient outcomes. Specifically, there are a number of studies comparing remotely delivered physiotherapy treatments with usual in-person care, which found that the main factor contributing to cost efficiency was reducing the number of in-person treatments [75-79]. Furthermore, studies that tested interventions that reduced the need for patients to travel for their treatments also significantly contributed to cost efficiency [62,80].

A study comparing virtual exercise rehabilitation in home therapy (VERITAS) with traditional care following total knee arthroplasty found lower post operative costs in the virtual physiotherapy group at 12 weeks, and similar outcomes in knee function [77]. These results are partially supported by another trial comparing a remote approach to physiotherapy for hip and knee osteoarthritis. Remotely delivered physiotherapy consisted of providing the 'e-Exercises' protocol for 12 weeks. The e-Exercises protocol consisted of accessing a website which delivered an online program of graded activities, exercises and education. Five 30-minute sessions were delivered in-person throughout the 12-week intervention period to discuss patient progress. In addition, each patient was provided with online assignments for a self-chosen activity from the physiotherapist to complete each week. This was compared to usual care consisting of face-to-face treatment determined by the physiotherapist with no restrictions on the number of treatments. When comparing 12 face-to-face sessions in the usual care group with the 5 face-to-sessions plus e-Exercises in the intervention group, there was no clinically

significant difference between the groups in effectiveness when measuring physical function and physical activity [76].

The health economic evaluation determined that the intervention costs of the e-Exercise group were significantly lower than the usual care group who received on average 12 face-to-face sessions in the 12-week treatment period. Interestingly though, the e-exercise group was not cost effective as there were no significant differences in the total health care and societal costs. These results are encouraging for empowering patients to make informed choices about physiotherapy service delivery, as patients can expect to achieve good outcomes with either remotely delivered physiotherapy, face-to-face physiotherapy or a hybrid approach to treatment.

Most available health economics analyses involve different health conditions, such as childhood obesity, hip and knee osteoarthritis or back pain. Additionally, most also do not investigate the cost effectiveness of a remotely delivered physiotherapy intervention for a population with a range of MSK conditions from a health system plus patient perspective. A cost effectiveness analysis of the PhysioDirect study did include a large population of patients with a range of MSK conditions [81]. The intervention involved remotely delivered physiotherapy and the probability that the intervention was cost effective at a £20,000 willingness to pay threshold was 88%. However, this trial was carried out in a UK setting and may not be generalisable to an Australian context.

In order to investigate the cost effectiveness of the REFORM intervention, health economics questions were included in the data collection for each participant at 6 weeks. Participants were asked to answer questions relating to healthcare utilisation and health related costs from a health system plus patient perspective. These data were self-reported and collected over the

telephone. **Chapter 6** of this thesis presents the results of the economic analysis that was embedded within the main REFORM trial.

1.7 Aims of the thesis

The overarching aim of this thesis was to investigate whether remotely delivered physiotherapy could achieve outcomes that were as good or better than usual care physiotherapy for people with MSK conditions that can be treated with exercise support and advice.

The specific aims of thesis are to:

1. Determine whether a model of care that reduced dependency on face-to-face physiotherapy was as good as or better than face-to-face physiotherapy as delivered in a public hospital outpatient department (**Chapter 2 and Chapter 5**).
2. Describe the rationale for a process evaluation investigating trial fidelity, explaining the context in which the trial was conducted and identify the barriers and facilitators to rolling out the intervention (**Chapter 3**).
3. Identify patients', physiotherapists', and stakeholders' perceptions and attitudes towards remotely delivered physiotherapy for some patients with MSK conditions (**Chapter 4**).
4. Describe the cost effectiveness of remotely delivered physiotherapy through a cost effectiveness analysis from a health system plus patient perspective (**Chapter 6**).

Table 1: Summary of studies and systematic reviews reporting on the effectiveness of remotely delivered physiotherapy for MSK conditions.

Date	Author	Title	Study type	Participants	Intervention	Relevant to REFORM	Purpose of intervention	Main Findings
2021	Dadarkh et al [42]	Remote Versus in-Person Exercise Instruction for Chronic Nonspecific Low Back Pain Lasting 12 Weeks or Longer: A Randomized Clinical Trial.	RCT	Back pain	Phone + 1 face-to-face vs 12 Face-to-face sessions	YES	Physiotherapy	Very small treatment effect size of 0.01 for pain intensity and 0.05 for disability. There was no between group difference for changes in pain scores or disability. Primary outcome measure was pain intensity at 3 months 0.1 (-0.53 to 0.33) [22]
2019	Mbada et al [41]	Comparative efficacy of clinic-based and telerehabilitation application of Mckenzie therapy in chronic low-back pain. International Journal of Telerehabilitation	RCT	Back pain	Mckenzie exercises delivered by App vs Mckenzie exercises delivered face-to-face	YES	Physiotherapy	The between group difference was ($p>0.05$) for changes in the treatment outcome which is not significant.
2014	Odole et al [40]	Is telephysiotherapy an option for improved quality of life in patients with osteoarthritis of the knee?	RCT	OA knee	Phone vs Face -to -face	YES	Physiotherapy	There was no significant difference between the groups after 6 weeks. Quality of life health domain at 6 weeks -4.1 (95% CI -8.84 to 0.6) [22]
2017	Bennell et a l [49]	Telephone Coaching to Enhance a Home-Based Physical	RCT	OA knee	6-12 Telephone calls + 5 F2F	YES	Behavioural change for	For the primary outcome there was no significant between group difference

Date	Author	Title	Study type	Participants	Intervention	Relevant to REFORM	Purpose of intervention	Main Findings
		Activity Program for Knee Osteoarthritis: A Randomized Clinical Trial			sessions vs 5 F2F sessions		exercise and physical activity	in pain, with a mean difference in pain of 0.4 units (95% CI -0.4 to 1.3 units)
2023	Thompson et al [82]	Mobile app use to support therapeutic exercise for musculoskeletal pain conditions may help improve pain intensity and self-reported physical function: a systematic review	SR	MSK conditions	Exercises delivered by App vs Exercises not delivered by an app	YES	Exercise prescription; Behaviour change	Reported there was low certainty evidence that using an App to support exercise interventions can achieve greater improvement in pain intensity SMD -0.60, (95% CI -0.93 to -0.27) or physical function SMD -0.92, (95% CI -1.57 to -0.27)
2014	Salisbury et al [45]	Effectiveness of PhysioDirect telephone assessment and advice services for patients with musculoskeletal problems.	RCT	MSK conditions	Phone + face-to-face, if necessary, vs nothing	YES	Early Triage	The PhysioDirect intervention is equally as effective as usual care at 6 months for the primary outcome of the SF-36v2 physical component score with adjusted difference in means -0.01 (95% CI -0.80 to 0.79).
2020	Fritsch et al [55]	Effects of using text message interventions for the management of musculoskeletal pain: a systematic review.	SR	MSK pain	Text messages vs usual care, in addition to usual care, in addition to mobile app.	YES	Adherence	The addition of text messages increased self-reporting about adherence MD 13.0/100, (95% CI 2.9 to 23.1) for patients with upper or lower limb MSK conditions.

Date	Author	Title	Study type	Participants	Intervention	Relevant to REFORM	Purpose of intervention	Main Findings
2017	Dario et al [27]	Effectiveness of telehealth-based interventions in the management of non-specific low back pain: a systematic review with meta-analysis.	SR	Low Back pain	Any telehealth – phone, text, App, internet vs Face-to-face or nothing	SOME-WHAT	Improving quality of life and reducing pain and disability for low back pain.	Limited evidence supported telehealth for LBP but findings indicated it is not superior to usual care for improving pain or disability after less than three months or from 3 months to 1 year. 95% CI for pain at 3 months to 1 year -0.9 (-5.3 to 3.6, I^2 40%)disability at 3 months to 1 year 0.2 (-4.1 to 4.4, I^2 0%).
2020	Hewitt et al [28]	The Effectiveness of Digital Health Interventions in the Management of Musculoskeletal Conditions: Systematic Literature Review.	SR	MSK conditions	Any telehealth – phone, text, App, internet vs Face-to-face, nothing, leaflets	SOME-WHAT	Reduce pain and functional disability	Found there were clinical benefits to manage pain and functional disability with digital health (web and app based). Not specifically physiotherapy. No meta-analysis was reported in this SR.
2022	Corso et al [29]	Are Nonpharmacologic Interventions Delivered Through Synchronous Telehealth as Effective and Safe as In-Person	SR	MSK conditions	Videoconferencing or phone calls vs Face-to-face	SOME-WHAT	Non-pharmacologic interventions from multiple health care providers.	This SR summaries the results of included trial and concludes that synchronous telehealth is as effective as in-person care for MSK conditions (including chronic headaches, back pain

Date	Author	Title	Study type	Participants	Intervention	Relevant to REFORM	Purpose of intervention	Main Findings
		Interventions for the Management of Patients With Nonacute Musculoskeletal Conditions? A Systematic Rapid Review.						and OA) as a stand-alone treatment or when combined with usual care.
2011	Iles et al [83]	Telephone coaching can increase activity levels for people with non-chronic low back pain: a randomised trial	RCT	Back pain	Phone + face-to-face vs Face-to -face	NO	Increasing activity levels	Usual physiotherapy plus telephone coaching can increase physical activity levels for patients with low back pain. The between group difference for the primary outcome measure of the patient specific functional scale (0 to10) at week 12 was 3.0 (0.7 to 5.4)
2017	Allen et al [51]	Patient and Provider and combined interventions for managing Osteoarthritis in primary care: A cluster randomised trial.	CRT	OA hip/knee	Phone + emails +internet vs internet	NO	Self-management for weight management, and physical activity	The primary outcome measure was the Western Ontario and McMaster Universities osteoarthritis index (WOMAC). The patient-provider group did not have greater improvement than the usual care group in mean WOMAC scores at 12 months, -1.6 (95% CI, -6.6 to 3.3)

Date	Author	Title	Study type	Participants	Intervention	Relevant to REFORM	Purpose of intervention	Main Findings
2015	Cuperus et al [47]	Randomized trial of the effectiveness of a non-pharmacological multidisciplinary face-to-face treatment program on daily function compared to a telephone-based treatment program in patients with generalized osteoarthritis.	RCT	OA	6 face-to-face group sessions vs 2 face-to-face group session + 4 phone calls	NO	Self-management	There was no significant between group difference for the primary outcome measuring daily function with the HAQ-DI (Dutch consensus) -0.03 (95% CI, -0.14 to 0.07)
2005	Pariser et al [48]	Effects of telephone intervention on arthritis self-efficacy, depression, pain, and fatigue in older adults with arthritis.	RCT	OA	Phone + usual care vs Usual care	NO	Self-Management - arthritis self-efficacy (ASE)	Quantitative results indicate that the primary outcome measure (ASE) at 12 weeks for the intervention group was 253.4 ± 58.9 compared to 248.2 ± 59.2 for the control group. Qualitative results suggest telephone calls increased access to care for some patients and helped them work towards a goal.
2017	Cottrell et al [43]	Real-time telerehabilitation for the treatment of	SR	MSK conditions	Videoconferencing vs Face-to-face	NO	Rehabilitation	Subgroup meta-analyses of telerehabilitation plus usual care indicated neither group was more

Date	Author	Title	Study type	Participants	Intervention	Relevant to REFORM	Purpose of intervention	Main Findings
		musculoskeletal conditions is effective and comparable to standard practice: a systematic review and meta-analysis						favourable when compared to usual care for function and disability outcomes, 0.66 (-0.27 to 1.60).
2024	Hinman et al [44]	Telerehabilitation consultations with a physiotherapist for chronic knee pain versus in-person consultations in Australia: the PEAK non-inferiority randomised controlled trial	RCT non-inferiority trial	Chronic knee Pain	Video conferencing vs face-to-face	NO	Physiotherapy	The mean between group difference for the primary outcome of pain was 0.16. (95% CI -0.26 to 0.57) and for function was 1.65,(95% CI, -0.23 to 3.53) indicating non-inferiority.
2018	Jiang et al [31]	The comparison of telerehabilitation and face-to-face rehabilitation after total knee arthroplasty: A systematic review and meta-analysis.	SR	Total knee replacement	Videoconferencing vs Face-to-face	NO	Rehabilitation	Meta analysis suggests that both groups had comparable results for pain relief, mean difference 0.52, (95% CI -0.20 to 1.24) and for WOMAC mean difference 1.13, (95% CI 0.23 to 2.02)
2020	Wong et al [14]	How is telehealth being utilised in the context of rehabilitation for lower limb musculoskeletal	Scoping Review	MSK conditions	Videoconferencing vs face -to-face	NO	Physiotherapy – assessment and treatment	Videoconferencing for assessment is comparable to face-to-face assessment. Standard exercise programs and education

Date	Author	Title	Study type	Participants	Intervention	Relevant to REFORM	Purpose of intervention	Main Findings
		disorders: a scoping review.						delivered via videoconferencing were also comparable to face-to-face treatment.
2017	Bini et al [25]	Clinical outcomes of remote asynchronous telerehabilitation are equivalent to traditional therapy following total knee arthroplasty: A randomized control study.	RCT	Total knee replacement	Videoconferencing + more vs Face-to-face	NO	Physiotherapy	Asynchronous telerehabilitation was not inferior to traditional care for the treatment of total knee arthroplasty. There was no difference in the percentage of people that improved more than the Minimal clinically significant improvement (p=0.17)for VAS (p=0.35) for pain.
2009	Eriksson et al [32]	Physiotherapy at a distance: A controlled study of rehabilitation at home after a shoulder joint operation.	RCT	Shoulder	Videoconferencing vs Face-to-face	NO	Physiotherapy	Significantly more improvement in pain for the telemedicine group (p=0.004).
2010	Kosterink et al [33]	The clinical effectiveness of a myofeedback-based teletreatment service in patients with non-specific neck and shoulder pain: a	RCT	Neck and shoulder pain	Videoconferencing vs Usual care (package)	NO	myofeedback	The primary outcome measures were pain measured with a VAS (0-10) and disability (pain disability index) No significant between group differences with both groups effectively reducing pain and

Date	Author	Title	Study type	Participants	Intervention	Relevant to REFORM	Purpose of intervention	Main Findings
		randomized controlled trial.						disability. By 3 months the disability scores had returned to baseline values.
2015	Moffett et al [34]	In-Home Telerehabilitation Compared with Face-to-Face Rehabilitation After Total Knee Arthroplasty: A Noninferiority Randomized Controlled Trial.	RCT non-inferiority	Total knee replacement	Videoconferencing vs Usual care (package)	NO	Rehabilitation	In-home rehabilitation and support for total knee arthroplasty was non inferior to face-to-face treatment for the primary outcome measure (WOMAC) -1.6% (95% CI, -5.6% to 2.3%) for the total score. The non inferiority margin was -15%
2013	Piqueras et al [35]	Effectiveness of an interactive virtual telerehabilitation system in patients after total knee arthroplasty: a randomized controlled trial.	RCT	Total knee replacement	Videoconferencing vs Face-to-face	NO	Physiotherapy	The main significant finding was that quadriceps strength was greater in the telerehabilitation group (p=0.011) at baseline and at three months (p=0.018)
2011	Russell et al [36]	Internet-based outpatient telerehabilitation for patients following total knee arthroplasty: a randomized controlled trial.	RCT	Total knee replacement	Videoconferencing vs Usual care	NO	Physiotherapy	Results from both groups were comparable but better outcomes at six weeks for the patient specific functional scale and the stiffness component of the WOMAC for the telerehabilitation group.

Date	Author	Title	Study type	Participants	Intervention	Relevant to REFORM	Purpose of intervention	Main Findings
2011	Tousignant et al [37]	A randomized controlled trial of home telerehabilitation for post-knee arthroplasty.	RCT	Total knee replacement	Videoconferencing vs Face-to-face	NO	Physiotherapy	Home telerehabilitation is at least as effective as usual care for total knee replacement – (intergroup difference was tested with Mann-Whitney test)
2013	Bossen et al [50]	Effectiveness of a web-based physical activity intervention in patients with knee and/or hip osteoarthritis: randomized controlled trial.	RCT	OA	Internet vs none	NO	Behavioural change – increasing activity levels	Significantly improved Physical Activity in the intervention group mean difference 6.5 points, (95% CI 1.8 to 11.2) Secondary outcomes of pain, tiredness, self-efficacy for pain also improved.
2018	Bennell et al [84]	Effects of internet-based pain coping skills training before home exercise for individuals with hip osteoarthritis (HOPE trial): a randomised controlled trial.	RCT	OA Hip	Internet + face-to-face vs Face-to-face	NO	Self-management	The primary outcomes were a numerical rating scale for pain (0-10) and the WOMAC at 24 weeks. There was no between group difference for pain 0.5, (95% CI, -0.3 to 1.3) or WOMAC function -9, (95% CI, -4.8 to 2.9)
2017	Bennell et al [85]	Effectiveness of an internet-delivered exercise and pain-coping skills training intervention for persons with chronic	RCT	Chronic Knee pain	Internet plus videoconferencing vs Internet based educational material	NO	Pain coping skills	The intervention group made clinically meaningful improvements in pain (NRS 0-10) 1.6. (95% CI, 0.9 to 2.3) and function 9.3 (95% CI , 5.9 to 12.7) compared to the internet-based education group.

Date	Author	Title	Study type	Participants	Intervention	Relevant to REFORM	Purpose of intervention	Main Findings
		knee pain: A randomised trial.						
2021	Bennell et al [86]	Comparing Video-Based, Telehealth-Delivered Exercise and Weight Loss Programs With Online Education on Outcomes of Knee Osteoarthritis: A Randomized Trial.	RCT	OA knee	Videoconferencing plus exercise equipment and resources vs diet and exercise program vs electronic OA information	NO	Physiotherapy,	Telehealth delivered exercise and diet improved the primary outcome measures at 6 months of pain NRS (0-10) (mean between group difference on exercise -0.8,(95% CI, -1.5 to -0.2)and function (WOMAC) on exercise -0.7, (95% CI, -9.7 to -4.2) for people who had knee OA and were obese.
2020	Hinman et al [87]	Does telephone-delivered exercise advice and support by physiotherapists improve pain and/or function in people with knee osteoarthritis? Telecare randomised controlled trial	RCT	OA Knee	Telephone (with a nurse) vs exercise, support advice (from a physiotherapist trained in behavioural change) plus usual care	NO	Behaviour change	Modest improvement in primary outcome measures of pain (NRS 0-10) and physical function (WOMAC) at 6 months for the telephone delivered physiotherapy led exercise advice and support group. The mean between group difference for exercise advice and support was 4.7 (95% CI, 1.0 to 8.4) for improving function.
2021	Deslauriers et al [61]	Effects of waiting for outpatient physiotherapy services in persons with musculoskeletal	SR	MSK conditions	Early physiotherapy vs delayed physiotherapy	NO	Decreasing wait list times.	Negative effect or no significant effect of waiting time before receiving outpatient physiotherapy on pain, disability and range of motion. No

Date	Author	Title	Study type	Participants	Intervention	Relevant to REFORM	Purpose of intervention	Main Findings
		disorders: a systematic review.						positive effects on waiting were reported.
2020	Lin et al [88]	What does best practice care for musculoskeletal pain look like? Eleven consistent recommendations from high-quality clinical practice guidelines: systematic review	SR	MSK pain	No intervention	NO	Management recommendations	Identified 11 consistent recommendations for MSK care from clinical practice guidelines.
2022	Lara-Palermo et al [89]	Efficacy of e-health interventions in patients with chronic low-back pain: a systematic review with meta-analysis.	SR	Low back pain	e-Health (App based treatments OR internet website OR activity tracker) vs No intervention OR Placebo OR Advice and information OR other therapies	NO	Physiotherapy	Moderate evidence suggests that e-health is as effective as physical therapy intervention for short term pain and back-specific function SMD= -0.20, (95% CI, -0.81 to 0.41)
2022	Tsang et al [90]	The effectiveness of telerehabilitation in patients after total knee replacement: A systematic review and meta-analysis of randomized controlled trials.	SR	Total knee replacement	Telerehabilitation (telephone follow up OR videoconferencing OR virtual telerehabilitation OR app based) vs usual care	NO	Rehabilitation	No significant between group difference for pain and physical function SMD -0.15, (95% CI, -0.47 to 0.16) and SMD -0.04, (95% CI, -0.19 to 0.12) respectively
2023	Wang et al [91]	The effectiveness of internet-based telerehabilitation among patients after	SR	Total joint Arthroplasty	Internet based telerehabilitation (app based OR videoconferencing	NO	Physiotherapy	No significant between group differences for any outcomes, including pain SMD -0.11, (95% CI -0.32

Date	Author	Title	Study type	Participants	Intervention	Relevant to REFORM	Purpose of intervention	Main Findings
		total joint arthroplasty: A systematic review and meta-analysis of randomised controlled trials			vs usual face-to-face care			to 0.10) and physical function SMD 0.01, (95% CI -0.15 to 0.17)

CRT: cluster randomised trial; RCT: randomised controlled trial; SR: Systematic Review; OA: Osteoarthritis; LBP: Low Back Pain, HAQ -DI: Dutch health assessment questionnaire; NRS: numerical rating scale; VAS: visual analogue scale; SMD: Standardised mean difference; CI: confidence interval; WOMAC: Western Ontario and McMaster Universities osteoarthritis index; MD: mean difference.

Dark grey cells are deemed to be the most relevant to REFORM, light grey somewhat relevant and white are the least relevant to the REFORM trial.

CHAPTER TWO: Face-to-face physiotherapy compared to a supported home exercise program for the management of musculoskeletal conditions: Protocol of a multicentre, randomised controlled trial - the REFORM trial

2.1 Authorship attribution statement

This statement is to outline the authorship contribution made by **Hannah Withers** to the following manuscript:

*"***Withers HG**, Glinsky JV, Chu, Jennings M, Hayes AJ, Starkey I, Palmer B, Szymanek L, Cruwys J, Wong D, Duong K, Barnett A, Tindall M, Lucas B, Lambert TE, Sherrington C, Maher CG, Ferreira M, Taylor D, Harvey LA. Face-to -face physiotherapy compared with a supported home exercise programme for the management of musculoskeletal conditions: protocol of a multicentre, randomised controlled trial – the REFORM trial. *BMJ Open* 2021; doi:10.1136/bmjopen-2020-041242"

During her PhD candidature Hannah Withers has contributed to:

- the conception and design of this study protocol
- securing funding for the trial
- site recruitment, site management and training of trial personnel
- participant recruitment
- drafting the manuscript
- responding to reviewers' comments

Hannah Withers Date: 17/12/2024

As supervisor for the candidature upon which this thesis is based, I can confirm that the authorship attribution statements above are correct.

Professor Lisa Harvey Date: 17/12/2024

BMJ Open

Face-to-face physiotherapy compared with a supported home exercise programme for the management of musculoskeletal conditions: protocol of a multicentre, randomised controlled trial—the REFORM trial

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ABSTRACT

Introduction Exercise, support and advice are considered core components of management for most musculoskeletal conditions and are typically provided by physiotherapists through regular face-to-face treatments. However, exercise can be provided remotely as part of a home exercise programme, while support and advice can be provided over the telephone. There is initial evidence from trials and systematic reviews to suggest that remotely provided physiotherapy can be used to manage a variety of musculoskeletal conditions safely and effectively.

Methods and analysis The aim of this single-blind randomised controlled non-inferiority trial is to determine whether a supported home exercise programme is as good as or better than face-to-face physiotherapy for the treatment of musculoskeletal conditions. Two hundred and ten participants will be recruited from five public hospitals in Sydney, Australia. Participants will be randomised to either the supported home exercise group or the face-to-face physiotherapy group. Participants allocated to the supported home exercise group will initially receive one face-to-face session with the trial physiotherapist and will then be managed remotely for the next 6 weeks. Participants allocated to the face-to-face physiotherapy group will receive a course of physiotherapy as typically provided in Sydney government hospitals. The primary outcome is function measured by the Patient Specific Functional Scale at 6 weeks. There will be nine secondary outcomes measured at 6 and 26 weeks. Separate analyses will be conducted on each outcome, and all analyses will be conducted on an intention-to-treat basis. A health economic evaluation will be conducted from a health funder plus patient perspective.

Ethics and dissemination Ethical approval was obtained on the 17 March 2017 from the Northern Sydney Local Health District HREC, trial number HREC/16HAWKE/431-RESP/16/287. The results of this study will be submitted for publication to peer-reviewed journals and be presented at national and international conferences. Recruitment commenced in March 2019, and it is anticipated that the trial will be completed by December 2021. This trial will investigate two different models of physiotherapy care for people with musculoskeletal conditions.

Trial registration number CPMP/ICH-135/95.

Protocol version The most recent version of the protocol is V.1.2 dated November 2019.

Strengths and limitations of this study

- The intervention that is being investigated minimises reliance on face-to-face treatments and as such is highly relevant to the current COVID-19 pandemic.
- The trial has many design features important for minimising bias including concealed allocation, blinded assessors and intention-to-treat analysis.
- This trial is highly pragmatic involving five public hospitals in Sydney, which increases its external validity.
- Although the 6-week and 26-week assessments are blinded, it is not possible to blind the clinicians or the participants.
- The results of this trial will be most applicable to the provision of physiotherapy in public hospitals as no participants from the private physiotherapy sector will be included.

INTRODUCTION

Musculoskeletal conditions are common and include back pain, hip and knee osteoarthritis, whiplash-associated disorders and ankle sprains. Together musculoskeletal conditions cause 21% of the total years lived with disability (second only to mental illness),

placing a great burden on world health.[1] In 2015, an estimated 30% of all people had at least one musculoskeletal condition in Australia.[2] This figure is reported to be as high as 72% for people aged over 75 years.[3] In 2008–2009, costs attributed to musculoskeletal conditions were an estimated $5.7 billion.[4 5]

Exercise, support and advice are considered core components of management for many musculoskeletal conditions.[6–9] Exercise, support and advice are typically provided by physiotherapists through regular face-to-face treatments. However, exercise can be provided remotely as part of a home exercise programme while support and advice can be provided via the telephone. There is initial evidence from trials and systematic reviews to suggest that different forms of remotely provided physiotherapy can be used to manage a variety of musculoskeletal conditions safely and effectively.[6 10–18] A move away from reliance on face-to-face physiotherapy has many potential benefits. Adopting new technologies and strategies into physiotherapy management will allow for the delivery of timely and accessible care to those who are in remote or rural locations and those who have significant mobility issues. Another benefit for this method of physiotherapy is its low cost, which might enhance cost-effectiveness from a funder and patient perspective. Increasing remote access and decreasing the cost of physiotherapy may have the added benefit of decreasing the burden on the public health system by decreasing waiting times for publicly funded outpatient physiotherapy.[19]

This model of care is particularly relevant given the global COVID-19 pandemic, although it was developed prepandemic. In Sydney, Australia, and elsewhere, the pandemic has meant that telerehabilitation strategies have been rapidly adopted by many hospital outpatient clinics. This has allowed physiotherapists to support the social isolation policies in place to reduce the spread of COVID-19. Telerehabilitation has enabled physiotherapists to continue to provide services to some of the many patients requiring physiotherapy thereby potentially preventing the escalation of symptoms and presentation to emergency departments at a time of burden for the health system.[20]

The trial will be highly pragmatic with broad inclusion criteria to capture a range of musculoskeletal conditions for which exercise, support and advice are the basis of evidence-based care. The aim is to determine whether a supported home exercise programme is as effective or better than a course of face-to-face physiotherapy. This will be determined with one primary outcome and nine secondary outcomes. An economic analysis will be run alongside the trial to assess the affordability and value for money of this model of care from a health funder plus patient perspective. A process evaluation will also be completed in order to understand the feasibility of delivering physiotherapy through supported home exercise programmes and to explore the perspectives of patients, healthcare professionals and key stakeholders about different models of delivering physiotherapy.

METHODS AND ANALYSIS

Design

A single-blind randomised controlled non-inferiority trial will be undertaken to compare a course of physiotherapy as typically provided in Sydney government hospitals with a supported home exercise programme administered through a smartphone/tablet application (an 'app') and supplemented with text messages and two telephone calls. Cost-effectiveness will be evaluated from a health funder and patient perspective.

Participants will be recruited from five tertiary public teaching hospitals in Sydney, Australia: Bankstown Lidcombe Hospital, Blacktown-Mt Druitt Hospital, Campbelltown Hospital, Hornsby Hospital and Liverpool Hospital.

Participants

Two hundred and ten adults with a musculoskeletal condition presenting for a course of physiotherapy or on a waiting list for physiotherapy at one of the five participating hospitals will be recruited.

A person will be eligible to participate if he or she:

- Is 18 years or over and able to provide informed consent in writing.
- Has a musculoskeletal condition. Examples include:
  - Back/neck pain.
  - Hip or knee osteoarthritis.
  - Whiplash-associated disorders.
  - Ankle sprains.
  - Postfracture.
  - Sporting injury.
  - Post hip or knee replacement.
- Is seeking physiotherapy treatment at the participating hospital.
- Can speak and read English to provide informed consent.
- Is able to participate for 6 weeks and will be available for 6-week and 26-week follow-up assessments.
- Has access to a smartphone with internet connection.
- Is identified by the hospital physiotherapists or trial physiotherapist (study coordinator) to have a condition appropriate for treatment with exercise, support and advice.

A person will be excluded if he or she:

- Is pregnant.
- Has a mental illness that may affect adherence to the trial protocol. This will be determined in consultation with the treating physiotherapists and a review of medical history.
- Is deemed to be at a high risk of falling with home exercises.
- Is at a clinical risk without face-to-face physiotherapy.
- Is on a postoperative exercise regimen prescribed by a surgeon.

Public and patient involvement

Over a 20-year period, patients and the public were involved in the development of the exercise app (www.

physiotherapyexercises.com) on which this trial is based. The primary outcome measure was developed in 1995[18] with input from patients. All participants for this trial are patients on a waiting list for outpatient physiotherapy in one of the five public hospitals involved in this trial. All participants will be asked to give written informed consent before being randomised. In order to include the participants' perspective in the results of this trial, an outcome measure asking the participants to self-report their satisfaction with service delivery will be included. A secondary process evaluation will also explore participants' opinions and experiences of the intervention and trial. A separate manuscript is being prepared to explain the protocol for the process evaluation. Participants will be able to access the published results of this trial.

Recruitment strategy and time frame

Recruitment started in March 2019, and currently, 141 participants have been randomised. Recruitment was however temporarily ceased on 9 March 2020 because of the COVID-19 pandemic. It recommenced gradually from July 2020, once it was considered safe and appropriate by the investigators and participating sites and will continue until 210 participants have been recruited (see online supplemental appendix table 1 for the timeline of study).

Potential participants will be screened according to the inclusion/exclusion criteria from the waiting list of each outpatient physiotherapy department. This process will be completed by either the treating physiotherapists or administrative staff of the department over the telephone. If appropriate, patients will be given an appointment to attend the outpatient department to complete the consent, baseline assessment and randomisation.

Assignment of intervention

A secure random allocation schedule has been computer generated by an independent researcher and is stored off site on a REDcap database. Randomisation is blocked and stratified by site and duration since onset of injury (less than 12 weeks vs more than 12 weeks). The allocation schedule is concealed from potential participants and from all staff associated with the trial. Randomisation will occur once a participant has been screened, provided consent and completed the baseline assessment. A trial staff member responsible for coordinating the treatments will log onto REDcap to retrieve the participant's allocation. Participants' assignments will not be disclosed to the blinded assessors or all but two investigators. Eligible participants are randomised into one of two groups namely:

The supported home exercise group

Participants initially receive one face-to-face session with the trial physiotherapist but are then managed remotely for the next 6 weeks.

The face-to-face physiotherapy group

Participants receive a course of face-to-face physiotherapy by a hospital physiotherapist.

Interventions

Supported home exercise group

Participants allocated to the supported home exercise group initially receive one face-to-face session with the trial physiotherapist and then will be managed remotely for the next 6 weeks. During the initial session, the trial physiotherapist will assess the patient and then prescribe an individualised 6-week home exercise programme consisting of a battery of 5–10 exercises. This will be delivered to patients' mobile devices using a freely available exercise-prescribing app that authors LAH, JVG and colleagues have developed (www.physiotherapyexercises.com). The number of repetitions and sets of exercises will be determined by the trial physiotherapist. Participants will be asked to complete their exercises at least once every day for the intervention period of 6 weeks. Participants will record exercise adherence on their app. These data will be automatically transferred to a password-protected section of the website, which is accessed by the trial physiotherapist to remotely monitor exercise adherence. The trial physiotherapist will provide ongoing support through weekly text messages. The purpose of these text messages is to encourage adherence to the prescribed exercises and provide the participants with encouragement and support. These text messages are generated from a prepaid website and are scheduled to be sent each week to the participants in the supported home exercise group. The messages are not individualised but are designed to be motivating and to remind participants to continue their exercises. Participants cannot respond to these text messages (see online supplemental appendix table 2 for examples of the text messages). The participants will also receive a telephone call from the trial physiotherapist at 2 and 4 weeks to ensure adherence and provide feedback, support and advice. Participants will be telephoned more frequently if their exercise adherence is poor. Participants are also able to contact the trial physiotherapist on a study mobile phone number or via email at any time. The trial physiotherapist has the option of providing an additional face-to-face physiotherapy session if she has any concerns about a participant's progress, safety or well-being that she may become aware of from conversations with the participant over the telephone or from any other trial or hospital staff. Details about all additional text and phone calls with the intervention participants will be recorded including the number of text messages and the number and duration of telephone calls. In addition, the number of failed attempts to contact participants by telephone will be recorded. Detailed notes will also be kept regarding participants' adherence to their exercise programmes and any advice and support given. Participants will also be asked to report on whether or not they received the weekly autogenerated text messages.

Face-to-face physiotherapy group

Participants allocated to the face-to-face physiotherapy group will receive a course of physiotherapy as typically provided

in Sydney government hospitals. This will be provided by the hospital physiotherapists and could involve up to three sessions per week for up to 6 weeks or group classes. The number of sessions per week and duration of the course of physiotherapy for each participant will be determined by the hospital physiotherapist and may be gradually decreased and completed during the intervention period if a participant recovers. This approach has been adopted to mimic usual practice. The type of physiotherapy provided during the face-to-face sessions will be determined by the hospital physiotherapist and may include any combination of manual therapy, advice, exercise and occasional electrotherapy. In this way, the trial will be pragmatic and will provide a real-life comparison of the two models of care. The number of sessions and type of therapy provided will be recorded and reported (see online supplemental appendix table 3 for a detailed description of the intervention as per the Template for Intervention Description and Replicaton (TIDieR) checklist).

Participants in both groups are permitted to continue with any concomitant treatments for any comorbidities. Participants in both groups will be asked not to pursue other sources of physiotherapy for their current musculoskeletal conditions over the 6-week intervention period.

Outcome measures

All outcomes will be collected at baseline, 6 weeks and 26 weeks except one outcome (participant satisfaction with healthcare service delivery), which will only be collected at 6 and 26 weeks (see online supplemental appendix table 4 for the trial visit schedule). Site, duration since onset of injury (less than 12 weeks vs more than 12 weeks) and baseline measurements will be used as covariates in the analyses to increase the precision of the estimates.

The primary outcome will be:

Function as measured by the patient-specific functional scale at 6 weeks

This outcome measure is sensitive to changes that are important to patients and is used across many different types of musculoskeletal conditions including cervical spine, knee and lower back pain.[18] Participants are asked at baseline to identify up to five functional activities that are most important to them and which they find difficult to perform. Participants are then asked to rate each activity at baseline and 6 weeks on an 11-point scale. The scale ranges from 0 to 10 and indicates the level of difficulty participants have with each activity due to their condition. Zero indicates that they are unable to perform the activity and 10 indicates that they are able to perform the activity at preinjury level. Scores for each activity are summed and expressed as a percentage of the total possible score for the participant (determined by the number of identified activities).[18 21]

The secondary outcomes will be:

The patient-specific functional scale at 26 weeks

See previous information for details.

Fear of movement and reinjury measured using the Tampa Scale for Kinesiophobia (TSK) at 6 and 26 weeks

The TSK is a multi-item instrument that quantifies fear of movement and reinjury. Participants are asked to score 17 items on a scale of 1–4, where a score of 1 indicates '*strongly disagree*' and a score of 4 indicates '*strongly agree*'. Items 4, 8, 12 and 16 are reversed where 1 indicates '*strongly agree*' and 4 indicates '*strongly disagree*'. This instrument has high reliability.[22 23]

Pain measured using a 0–10 Numerical Rating Scale (NRS) at 6 and 26 weeks

Participants are asked to rate their average pain over the past 24 hours on a 0–10 NRS anchored at each end with '*no pain*' and '*worst pain imaginable*'. The NRS for pain measurement is a valid and reliable tool for measuring acute and chronic pain.[24]

Patient global impression of change at 6 and 26 weeks

Participants are asked to rate the change in their condition on a numerical scale. This scale ranges from negative seven to positive seven anchored in the middle and at each end with '*no change*', '*very much worse*' and '*very much better*', respectively.

Patient satisfaction with healthcare service delivery at 6 weeks

Participants are asked to rate their satisfaction with the care they have received for their musculoskeletal condition on an 11-point numerical scale. This scale ranges from 0 to 10 anchored at each end with '*complete dissatisfaction*' and '*complete satisfaction*' with the delivery of healthcare service.

Health-related quality of life measured using the EuroQol-5D at 6 and 26 weeks

This validated questionnaire has been used in a wide range of musculoskeletal conditions and requires the participant to rate their level of problems in five dimensions including mobility, self-care, usual activities, pain and anxiety/depression. Utility-based quality of life will be derived from the Australian valuation of this instrument for use in the cost–utility analysis.

Functional performance measured with the function component of the later life function and disability instrument at 6 and 26 weeks

This standardised 32-item instrument captures participants' perceptions about their abilities to perform discrete actions or activities (eg, unscrew the lid of a jar and put on and take off a coat or jacket). It is suitable for adults of all ages even though it was specifically designed for adults in later life. This instrument has good validity and has been recommended for self-reported data collection.[25] The full assessment also captures life performing tasks and limitations on performing life performance tasks but only the functional performance aspect of the assessment will be used. Participants are asked to rate their difficulties performing each of the 32 actions or activities on a five-point scale ranging from '*none*' (ie, no difficulties performing the activity) to '*can't do*'. Scores will be

transformed into a 0–100 summary score where a high score indicates a higher level of functioning.[26]

Frequency of performing life tasks measured with the disability component of the later life function and disability instrument at 6 and 26 weeks

This standardised 16-item instrument captures participants' perceptions about the frequency with which they perform socially defined life tasks such as visiting friends and family in their homes, taking part in recreational activities and travelling with overnight stays.[25 26] Participants are asked '*to what extent they feel limited in doing a particular task*'. They are provided with the following options: '*completely*', '*a lot*', '*somewhat*', '*a little*' and '*not at all*'. Scores will be transformed into a 0–100 summary score where a high score indicates a higher level of functioning.[26]

Limitations in capability of performing life tasks measured with the disability component of the later life function and disability instrument at 6 and 26 weeks

This standardised 16-item instrument captures participants' perceptions about their limitations in performing socially defined life tasks such as visiting friends and family in their homes, taking part in recreational activities and travelling with overnight stays.[25] Participants are asked '*how often do they do a particular task*'. They are provided with the following options: '*very often*', '*often*', '*once in a while*', '*almost never*' and '*never*'. Scores will be transformed into a 0–100 summary score where a high score indicates a higher level of functioning.[26]

Sample size

A sample size of 210 people is required to provide 80% power for a non-inferiority margin (delta) of −1.5 points on the primary outcome Patient Specific Functional Scale (PSFS) where a positive between-group difference favours the supported home exercise group assuming a 15% loss to follow-up, an SD of 2,[21] a 15% treatment dropout rate, a correlation between baseline and final scores of 0.5 and a conservative estimate that the between-group difference favours the face-to-face group by 0.75 points.

Data analysis

Statistical plan

Data analysis and dissemination of results will occur after the database has been cleaned and locked. All analyses will be conducted on an intention-to-treat basis with these performed and interpreted blinded to treatment group according to a prespecified statistical analysis plan. Separate analyses will be conducted on each outcome.

Non-inferiority analysis

The supported home exercise group will be considered non-inferior to the face-to-face physiotherapy group if the upper limit of the 95% CI associated with the mean between group difference on the PSFS at 6 weeks indicates that supported home exercise versus face-to-face physiotherapy is either better or no worse than 1.5 points out of 10. The non-inferiority cut-off point of 1.5 was decided by the investigators after taking into consideration the likely implications of this amount of difference on function and the cost of the intervention.

Other analyses

The results of all other analyses will be presented as point estimates (with 95% CI) and will not be interpreted with respect to non-inferiority margins (deltas) or statistical significance but instead used to aid the interpretation of the results of the non-inferiority analysis of the primary outcome at 6 weeks. We will not make any adjustments for multiple comparisons; however, we will interpret these findings cautiously taking into account the number of outcomes and the two endpoints. Between-group comparisons of each outcome will be conducted using regression models in which the outcome will be a linear function of a dummy-coded variable representing group membership (supported home exercise group or face-to-face physiotherapy group) and a dummy-coded variable for stratum, specifically site and duration since onset of injury (less than 12 weeks vs more than 12 weeks). Baseline scores will be included in the model to increase statistical precision. If more than 5% of data are missing for a particular analysis, multiple imputation will be used to account for missing data provided the missing at random assumption appears plausible.

Economic evaluation

The economic evaluation will compare the supported home exercise programme with face-to-face physiotherapy and will be conducted from a health funder plus patient perspective, since patients will contribute time and money to the treatments. If supported home exercise is statistically non-inferior to face-to-face physiotherapy, then a cost minimisation analysis will be conducted; otherwise, a cost-effectiveness analysis for the primary and secondary outcomes (patient function at 6 weeks and 26 weeks) will be conducted. A trial-based cost–utility analysis for quality of life outcomes at 26 weeks will also be conducted. The cost of delivering the physiotherapy intervention in the two arms of the trial will be determined using standard microcosting methods. All costs will be collected during the trial period and valued in 2021 Australian dollars. Health funder costs will include physiotherapists' time and materials where appropriate. Other healthcare utilisation (eg, visits to doctors, exercise physiologists and masseurs) will be determined by patient self-report. Patient costs will include the costs associated with the time to: attend the face-to-face sessions with the physiotherapist (including travel time), receive the telephone calls from the trial physiotherapist and to complete the prescribed home exercise programme. The cost of any equipment purchased will also be included. As in all economic evaluations, the costs captured in this study are likely to be skewed, so nonparametric bootstrap methods will be used for hypothesis testing and interval estimation. In the cost–utility analysis, patient outcomes will be measured in quality-adjusted life years (QALYs)

at 26 weeks, using a standard instrument, the Euro-Quol quality of life questionnaire, the EQ-5D-5L. The incremental cost-effectiveness ratio (ICER) will be determined in Australian Dollars (AUD) per QALY gained. Bootstrapped cost-effect pairs will be plotted on an incremental cost-effectiveness plane and a cost-effectiveness acceptability curve will be generated for the probability of being cost-effective at different thresholds. The robustness of the ICERs will be tested through multiple one-way sensitivity analyses.

Data collection

Baseline data will be collected on paper case report forms (CRFs) and then entered into an electronic database (REDcap) by the trial physiotherapist. The data at 6 and 26 weeks will be collected in one of four ways. Most participants will be guided while they use an online data collection form or the assessor will take responses from participants over the telephone and enter them into the online data collection form for the participant. If the participant prefers a paper copy to be sent in the mail, then the assessor will take responses from the participant over the telephone and enter them into the database while the participants read the questions from the paper copy. Participants will also be given the option to complete the assessment on paper and return the completed forms via an included prepaid envelope. The final option of data collection will allow the participant to complete the online assessment independently by receiving a link via email and completing the questions online without any assistance from the assessor. Regardless of the method used to collect the data, the assessor responsible for interacting with the participant and/or collecting the data over the telephone will be blinded to the treatment. In addition, participants will be reminded at the time of the assessment not to reveal any details regarding their physiotherapy treatments to the assessor. If unblinding occurs, a new blinded assessor will complete the next assessment for that participant. Data for the economic evaluation will be collected over the telephone by an unblinded trial physiotherapist after the 6-week blinded assessment has been completed.

Data storage

All information collected for this trial will have identifying information removed and will be kept confidential and secure. All files containing participants' personal details will remain at the site where they are collected. The original CRFs will be stored centrally on completion of the trial and will only contain the participants' ID code. Electronically transcribed data will be stored on the REDcap system managed by the University of Sydney. Access to data will only be granted to the principal investigators and other research staff directly involved in the study. All source documents and trial documentation will be kept in a secure location by the investigators for 15 years or the appropriate retention period according to local regulations.

Data confidentiality

Consent forms, baseline assessments and all files containing participants' personal details will remain at the site where the participant was recruited. Compulsory medical notes will be completed on the electronic medical record system used in public hospitals in Sydney, Australia. All other data, both paper and electronic, will be stored either centrally in a secure location or in the password-protected database managed by the University of Sydney. All data will be deidentified.

Trial monitoring

The study will be overseen and monitored by the research staff who will examine study procedures, ensure data quality and monitor compliance with the study protocol. All protocol violations will also be recorded. An independent Data Safety Monitoring Board will not be used for this trial, and an interim analysis will not be conducted because the intervention is unlikely to cause harm, and the trial is not sufficiently large enough to warrant stopping it early on the grounds of futility. Ethical approval was obtained on the 17 March 2017 from the Northern Sydney Local Health District HREC, trial number HREC/16HAWKE/431-RESP/16/287.

All serious adverse events (SAEs) from the time of randomisation to the 26-week assessment will be recorded. These will include any events that result in death, disability, hospitalisation or prolongs existing hospitalisation. The trial physiotherapist will record all the relevant information regarding each SAE including the type of event, the start and stop dates, the action taken and the cause of the event.[27] It will be reported to the principal investigator within 24 hours and reported immediately to the ethics committee irrespective of group allocation. It will also be detailed in the annual report.[28] If a SAE has a significant safety issue, a report will be made to the principal investigator within 72 hours, and the trial will be modified to eliminate the safety issue. In contrast, data on other types of non-seious adverse events will be recorded but not immediately reported to the ethics committee. These data will be collected for both groups by asking participants at 6 and 26 weeks to recall any events related to their condition or the intervention.

Provenance

This trial is registered at the Australian and New Zealand Clinical trial registry. It will be conducted in accordance with the National Health and Medical Research Council's National Statement on Ethical Conduct in Human Research[28] and the Note for Good Clinical Practice (CPMP/ICH-135/95).[29 30] This trial was not commissioned and was peer reviewed for ethical and funding approval prior to submission.

Trial status

The first participant was randomised on 19 March 2019, and it is anticipated that the last participant will be recruited at the end of December 2021. Recruitment was

stopped between March 2020 and July 2020, and severely limited until December 2020 due to the global COVID-19 pandemic. The most recent version of the protocol is V.1.2 dated November 2019.

Dissemination plan

The results of this study will be submitted for publication to peer-reviewed journals and be presented at national and international conferences.

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CHAPTER THREE: Protocol for a Process Evaluation: Face-to-face physiotherapy compared to a supported home exercise program for the management of musculoskeletal conditions: the REFORM trial

3.1 Authorship attribution statement.

This statement is to outline the authorship contribution made by **Hannah Withers** to the following manuscript:

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During her PhD candidature Hannah Withers has contributed to:

- the conception and design of this study protocol
- conception and design of this study protocol
- securing funding for the trial
- site management and training of trial personnel
- participant recruitment
- drafting the manuscript
- responding to reviewers' comments

Hannah Withers Date: 17/12/2024

As supervisor for the candidature upon which this thesis is based, I can confirm that the authorship attribution statements above are correct.

Professor Lisa Harvey Date: 17/12/2024

BMJ Open

Protocol for a process evaluation: face-to-face physiotherapy compared with a supported home exercise programme for the management of musculoskeletal conditions: the REFORM trial

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ABSTRACT

Introduction The REFORM (REhabilitation FOR Musculoskeletal conditions) trial is a non-inferiority randomised controlled trial (n=210) designed to determine whether a supported home exercise programme is as good or better than a course of face-to-face physiotherapy for the management of some musculoskeletal conditions. The trial is currently being conducted across Sydney government hospitals in Australia. This process evaluation will run alongside the REFORM trial. It combines qualitative and quantitative data to help explain the trial results and determine the feasibility of rolling out supported home exercise programmes in settings similar to the REFORM trial.

Methods and analysis Two theoretical frameworks underpin our process evaluation methodology: the Realist framework (context, mechanism, outcomes) considers the causal assumptions as to why a supported home exercise programme may be as good or better than face-to-face physiotherapy in terms of the context, mechanisms and outcomes of the trial. The RE-AIM framework describes the Reach, Effectiveness, Adoption, Implementation and Maintenance of the intervention. These two frameworks will be broadly used to guide this process evaluation using a mixed-methods approach. For example, qualitative data will be derived from interviews with patients, healthcare professionals and stakeholders, and quantitative data will be collected to determine the cost and feasibility of providing supported home exercise programmes. These data will be analysed iteratively before the analysis of the trial results and will be triangulated with the results of the primary and secondary outcomes.

Ethics and dissemination This trial will be conducted in accordance with the National Health and Medical Research Council National Statement on Ethical Conduct in Human Research (2018) and the Note for Good Clinical Practice (CPMP/ICH-135/95). Ethical approval was obtained on 17 March 2017 from the Northern Sydney Local Health District Human Research Ethics Committee (trial number: HREC/16HAWKE/431-RESP/16/287) with an amendment for the process evaluation approved on 4 February 2020. The results of the process evaluation will be disseminated through publications in peer-reviewed journals and presentations at scientific conferences.

Trial registration number ACTRN12619000065190.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This process evaluation will be an important aspect of the REFORM (REhabilitation FOR Musculoskeletal conditions) trial as it will explore whether or not the supported home exercise programme and face-to-face physiotherapy were delivered as intended.
⇒ This process evaluation will assess the trial fidelity and provide insights into the potential barriers and facilitators of scaling up supported home exercise programmes for people with musculoskeletal problems.
⇒ The REFORM trial and its process evaluation will be particularly relevant in the current COVID-19 pandemic because we need alternative ways of delivering physiotherapy that do not require ongoing and regular face-to-face contact.
⇒ Unblinded staff involved in the trial will be collecting some of the process evaluation data.
⇒ The results of this trial and its process evaluation may not be applicable to all countries and musculoskeletal conditions, or where physiotherapy is provided by non-government-funded organisations.

INTRODUCTION

Musculoskeletal conditions include conditions such as back pain, hip or knee osteoarthritis, whiplash-associated disorders and ankle sprains. They are the second leading cause of disability and account for 21% of the total years lived

with disability placing a large burden on world health. They are estimated to cost $9.2 billion in health services and $7.4 billion in lost productivity.[1–3] In Australia, 30% of the population and 70% of those aged over 75 years experienced at least one musculoskeletal condition in 2015.[4]

Exercise, support and advice are considered core components of management for most musculoskeletal conditions,[2 5–7] and are typically provided through a course of face-to-face physiotherapy. However, physiotherapy is not always readily available and there can be long waiting lists to access this type of service through publicly funded hospitals[8] resulting in delays accessing care. In addition, a course of face-to-face physiotherapy may foster a sense of dependency on hands-on attention by physiotherapists.[9] Face-to-face physiotherapy is also costly and a potential burden to individuals needing to travel to and from hospitals on a regular basis. There are therefore many potential benefits for patients, physiotherapists and the healthcare system if patients' dependency on regular face-to-face physiotherapy can be reduced.[10] This may be best achieved by moving appropriate patients from face-to face physiotherapy onto supported home exercise programmes. Furthermore, the recent COVID-19 pandemic has impacted traditional models of care where regular face-to-face physiotherapy is not always possible during lockdown periods due to high transmission risk. Alternative non-contact digital modes of service delivery need to be considered to enable ongoing physiotherapy management of people with musculoskeletal conditions.

The REFORM trial is currently being conducted to determine whether a supported home exercise programme that is individualised to the needs of each person and supplemented with ongoing support and advice is as good or better than face-to-face physiotherapy for patients with musculoskeletal conditions. This model of care is based on initial evidence from trials and systematic reviews indicating the benefits of home management for similar health problems.[2 11–20] It is also based on studies that have failed to demonstrate superior outcomes with many supervised physiotherapy sessions compared with few (or no) supervised physiotherapy sessions for some musculoskeletal conditions.[21–27]

The REFORM trial is a single-blind, pragmatic, randomised, controlled, non-inferiority trial. Two hundred and ten participants are being recruited from five public hospitals in areas of Sydney that have culturally and socioeconomically diverse populations. They are eligible for inclusion if they have musculoskeletal conditions that could be appropriately managed with exercise, support and advice (see ref 28 for full inclusion and exclusion criteria details). Only those capable of speaking English will be included even though the target population is culturally diverse because of the logistical problems of sourcing interpreters. Potential participants are given the participant information sheet and once they have read and understood the trial requirements, and given informed consent, they are randomised to either the Supported Home Exercise Group or the Face-to-Face Physiotherapy Group for 6 weeks (see ref 28 for details). Participants allocated to the Supported Home Exercise Group initially receive one face-to-face physiotherapy session in which they are assessed and provided with a personalised home exercise programme. The exercise programme is then sent to participants' mobile phone devices using a freely available App developed by the authors (www.physiotherapyexercises.com; see figure 1). At the same time, the trial physiotherapist downloads the App onto the participants' devices for them, and then shows them how to access the App, use it and record their adherence. The App provides the participants in the Supported Home Exercise Group with advice on how to correctly perform each exercise through written descriptions and images. Participants are instructed to record their exercise adherence on the App, and their adherence is monitored remotely by the trial physiotherapist. This is supplemented with weekly text messages and fortnightly telephone calls to maintain personal contact; provide encouragement, support and advice; and progress the participants' programmes as required (see the REFORM trial protocol[28] where the intervention has been described according to the Template for

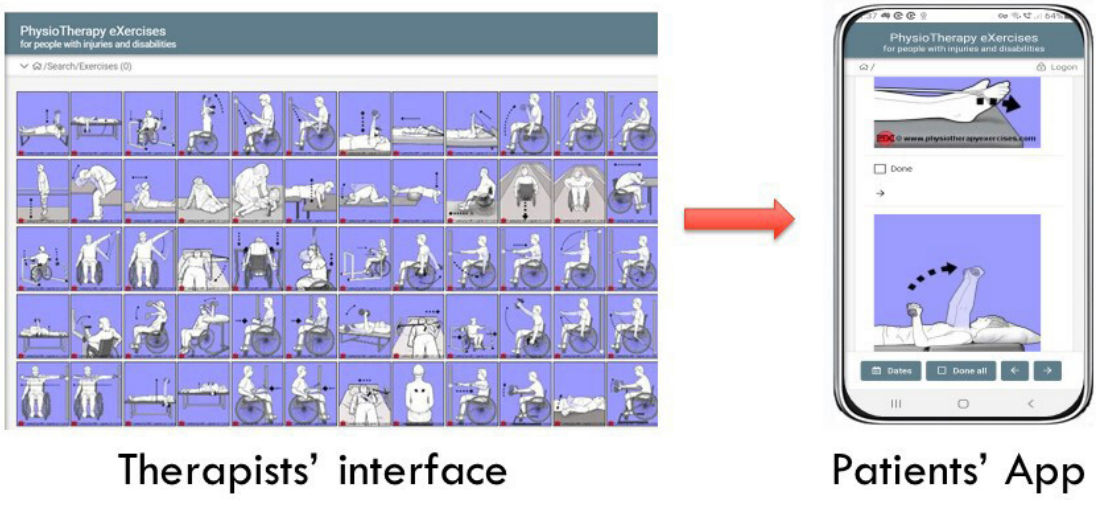

Figure 1 Freely available App developed by the authors (www.physiotherapyexercises.com).

Table 1 Overview of the REFORM trial schedule

	Pre	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 26
Assessments	X						X	X
Process evaluation data collection		X	X	X	X	X	X	X
Economics data collection							X	
Intervention for Face-to-Face Physiotherapy Group								
Regular physiotherapy		X	X	X	X	X	X	
Intervention for Supported Home Exercise Group								
Initial face-to-face assessment and prescription of home exercise programme		X						
Exercises provided on App		X						
Phone calls			X		X			
Text messages		X	X	X	X	X	X	

REFORM, REhabilitation FOR Musculoskeletal conditions.

Intervention Description and Replication checklist). The primary outcome of the REFORM trial is the Patient-Specific Functional Scale (PSFS) at 6 weeks. There will be a number of secondary outcomes measured at 6 and 26 weeks. Separate analyses will be conducted on each outcome and all analyses will be conducted on an intention-to-treat basis. A non-inferiority margin of 1.5 points (out of 10) on the PSFS at 6 weeks has been set to determine whether supported home exercise is as good or better than face-to-face physiotherapy. In addition, a health economics evaluation will be conducted from a health funder plus patient perspective. An overview of the time schedule for the REFORM trial is detailed in table 1.

Recruitment for the REFORM trial began in March 2019 but was temporarily stopped in March 2020 and then again stopped in July 2021 due to the COVID-19 pandemic. Currently, 155 participants have been randomised (n=210). The trial is registered with the Australian New Zealand Clinical Trials Registry (ACTRN12619000065190) and the trial protocol has been published.[28]

The pragmatic nature of the REFORM trial aims to evaluate the effectiveness and cost-effectiveness of the intervention in a real-world setting to readily enable the translation of the results into useable health-related policy and practice.[29] A full-scale implementation/translation study of this intervention will be undertaken if the results of the REFORM trial indicate non-inferiority. The process evaluation, as outlined in this paper, is important because the trial is complex. For example, the intervention has several interacting components that are individualised to the needs of each participant[30]; there are a number of outcomes and the trial targets a diverse group of patients. The process evaluation will help healthcare professionals translate the results of our trial into practice by providing insights into the potential barriers and facilitators. With these insights, healthcare professionals will be better placed to devise strategies that take advantage of the facilitators and overcome the barriers.

Aim

The aims of the process evaluation of the REFORM trial are to:

1. *Explain the trial results and their generalisability*, and specifically to:
   - Understand the context in which this trial was conducted (see the box labelled *Context* in figure 2).
   - Determine whether the trial was implemented as intended (see the box labelled *Implementation* in figure 2).
   - Ascertain whether the causal assumptions as to why a supported home exercise programme may be as good or better than face-to-face physiotherapy for the management of musculoskeletal problems were reasonable (see the boxes labelled *Description of the intervention and its causal assumptions* and *Mechanism of impact* in figure 2). The five causal assumptions are:
     i. Supported home exercise programmes are more convenient and less time consuming than face-to-face physiotherapy. This may be particularly so for those with significant mobility problems or those with limited capacity to travel to and from hospital.
     ii. Supported home exercise programmes will provide more patients with access to physiotherapy services because less overall therapy time is required per patient.
     iii. Supported home exercise programmes are a more cost-effective way of delivering physiotherapy for both the patient and the health system than face-to-face physiotherapy.

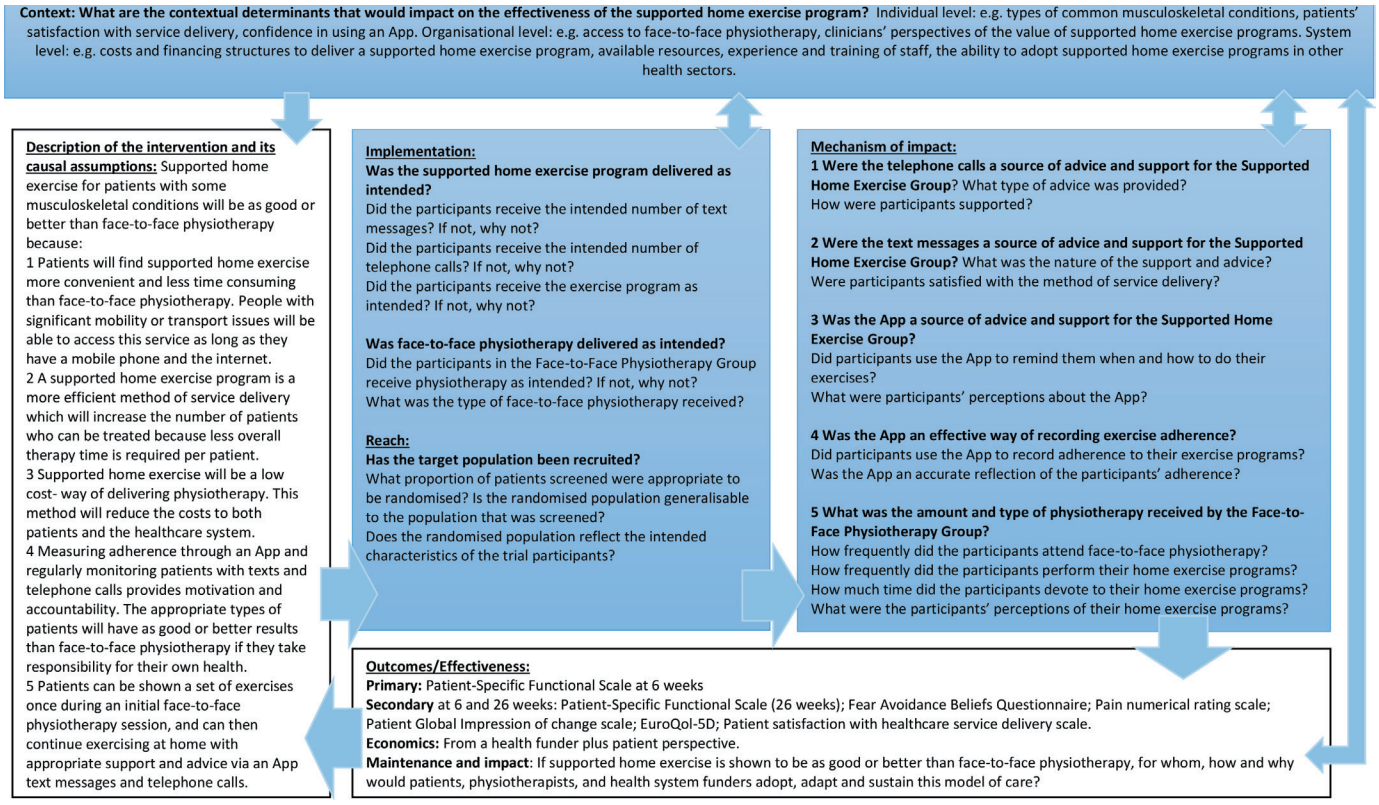

Figure 2 The process evaluation framework for the REFORM trial. The blue boxes (labelled Context, Implementation, and Mechanism of impact) depict the key components of the process evaluation which explore the contextual factors, implementation and ways in which the intervention may work. The white boxes (labelled Description of the intervention and its causal assumptions, and Outcomes) indicate the link between the intervention and the trial outcomes. The key components of the process evaluation are guided by the RE-AIM and Realist frameworks and are based on the assumptions about how the intervention may affect the primary and secondary outcomes. REFORM, REhabilitation FOR Musculoskeletal conditions; RE-AIM, Reach, Effectiveness, Adoption, Implementation and Maintenance.

iv. Supported home exercise programmes with regular support and advice provide motivation and accountability which encourages patients to take responsibility for their health (rather than rely on others to provide treatment). This may improve outcomes.
v. Patients can be shown a set of exercises once during an initial face-to-face physiotherapy session, and can then continue exercising at home with appropriate support and advice via an App, text messages and telephone calls.

2. *Identify barriers and facilitators to the future roll-out of supported home exercise programmes* for the management of musculoskeletal problems (see table 2 for examples of some of the questions addressed through the process evaluation).

METHODS AND ANALYSIS

Theoretical framework

The framework for this process evaluation is outlined in figure 2 and is based on the recommendations by the UK's Medical Research Council's guidelines for process evaluations of complex interventions.[31] This process evaluation is also informed by two theoretical frameworks to inform the methods and to translate the findings into a real-world setting: the Realist framework[32] and the Reach, Effectiveness, Adoption, Implementation and Maintenance (RE-AIM)[29] framework. Both frameworks involve the analysis and interpretation of qualitative and quantitative data collected alongside the trial. The Realist framework will be used to help answer the question once the trial is completed as to why the trial results do (or do not as the case may be) indicate non-inferiority.[32] This requires looking at the veracity of underlying assumptions about the intervention, the particular context in which the trial was conducted and the proposed mechanisms through which the intervention affects the outcomes of the trial. Specifically, this framework will be used to address the first aim of the study, namely explain the trial results and their generalisability. In contrast, the RE-AIM framework will be used to help ensure that the results of the trial have impact and are translated into practice (assuming the results indicate non-inferiority). This will involve looking at different aspects of the trial and considering some of the barriers and facilitators to rolling out supported home exercise programmes to manage musculoskeletal problems such as back pain, hip and knee osteoarthritis, whiplash-associated disorders and ankle

Table 2 Some of the questions addressed through the process evaluation that could explain the barriers and facilitators to the future roll-out of supported home exercise programmes for the management of musculoskeletal problems, based on the Maintenance and Adoption aspects of the RE-AIM framework

Patients	► Are people with common musculoskeletal conditions willing to receive a supported home exercise programme via an App, outside of a trial setting, and why? ► Was the intervention perceived to be more convenient for the Supported Home Exercise Group? Why was that? ► What were the costs associated with receiving treatment to the patients of the Supported Home Exercise Group and Face-to-Face Physiotherapy Group? ► Would patients recommend the intervention to others, and why?
Physiotherapists	► Did physiotherapists feel that the intervention was effective? If not, why not? ► Would physiotherapists recommend this intervention beyond the trial setting, and why or why not? ► What will be the reasons that physiotherapists are willing to adopt the intervention, and use all features of the App (and website) as part of mainstream treatment outside of a trial setting? ► What were the reported problems with providing the intervention?
Stakeholders: health services managers and policy makers	► Do the stakeholders believe this intervention is scalable, and why is that? ► Are stakeholders willing to adopt this model of care as part of their service delivery? ► Are stakeholders willing to invest in scaling up this intervention? ► Would stakeholders advocate for this intervention?
Health systems	► Do public hospitals have the resources to deliver a supported home exercise programme? ► Can this intervention be incorporated into mainstream treatment? ► Are the results generalisable to other patients, public or private hospitals, the private sector or other countries?

RE-AIM, Reach, Effectiveness, Adoption, Implementation and Maintenance.

sprains in a real-world setting.[29] In this way, it primarily addresses the second aim of the study as articulated above. The letters of the RE-AIM acronym summarise the framework. *Reach* refers to the target population, *Effectiveness* describes the impact of the intervention, and is measured by the primary and secondary outcomes of the trial, *Adoption* reflects the population that is willing to adopt the intervention, including clinicians, patients and other stakeholders, *Implementation* explains the fidelity of the protocol, and captures the barriers and facilitators to the future roll-out of the intervention, and *Maintenance* describes the translation of the intervention, or the extent to which the intervention can become part of practice or policy on completion of the trial. These domains of the Realist and RE-AIM frameworks have informed this process evaluation and are highlighted in figure 2 (Reach, Implementation, Effectiveness) and table 2 (Adoption and Maintenance).

Data collection and analyses

A mixed-methods approach will be used to collect both qualitative and quantitative data to address the aims. These data will be analysed iteratively and will be triangulated with the results of the primary trial. All qualitative data will be coded using a coding tree which will enable the relevant themes to be identified and extracted. The themes relevant to the different components of the process evaluation will be identified and explored. The types of data that will be analysed and included in the process evaluation to address the aims are outlined below.

Interviews with trial participants, physiotherapists and other stakeholders

Convenience sampling will be used to select 15 physiotherapists and five stakeholders. The physiotherapists will include physiotherapists and physiotherapy assistants involved in the trial at each site, and physiotherapists from sites that declined to participate in the REFORM trial. The stakeholders will include heads of physiotherapy departments at trial and non-trial hospitals, and representatives from the Australian Physiotherapy Association and government-funded insurance authorities.

Twenty trial participants will be invited to participate once they have completed at least 6 weeks of the REFORM trial. Participants will be selected at random from each of the following strata: site, group allocation and satisfaction with service delivery. This will be done to ensure that the sample is representative of the population of the REFORM trial and that the opinions of people with different experiences are heard. The strata for satisfaction will be based on the results of a question that participants will be asked at 6 weeks. Specifically, they will be asked—'*how satisfied are you with the services you have received?*' They will be asked to rate their satisfaction on an 11-point scale anchored at one end with '*not at all satisfied*' and at the other end with '*extremely satisfied*'. Participants with high and low satisfaction scores will be invited for interview.

A third-party consulting company with over 30 years of experience in qualitative research will be engaged to conduct the interviews. The interviews will follow a guide (see the online supplemental table 1) and will be carried

out on the telephone on a one-on-one basis. Based on our causal assumptions of how the intervention of the REFORM trial works, the interviews will explore (1) fidelity, that is, whether the intervention was delivered as intended, (2) context and mechanisms of the intervention through exploring respondents' perspectives of supported home exercise programmes, and the pros and cons of this model of care compared with face-to-face physiotherapy, and (3) implementation barriers and facilitators to rolling out supported home exercise programmes for the management of musculoskeletal problems in the future. Each interview will last for approximately 30 min, and will be recorded and transcribed verbatim. A coding frame or tree will be developed and the responses coded according to the major themes that emerge. NVivo will be used for data analysis.

Audit of the screening logs

Screening logs will be maintained at each site. These will contain data on the number of people with musculoskeletal problems presenting for face-to-face physiotherapy at each of the participating sites and whether they are suitable for the trial. If they are not suitable then a reason will be recorded. The number of people screened will be compared with the number of people randomised, and the reasons for exclusion will provide some insight in determining if the results are generalisable. For example, if only 2% of all people with musculoskeletal problems presenting for face-to-face physiotherapy are suitable for the trial this will indicate that the intervention may only be applicable to a very small portion of the target population.

Analysis of the characteristics of the participants

Demographic information about participants such as age, gender and type of injury will be collected at baseline. These data will be examined to determine whether or not the participants of the trial reflect the target population. That is, a range of males and females of mixed ages with acute (less than 12 weeks' duration) and chronic (more than 12 weeks' duration) musculoskeletal conditions that are typically managed with exercise, support and advice.

Number and duration of text messages and follow-up telephone calls provided to participants in the Supported Home Exercise Group

Participants allocated to the Supported Home Exercise Group will be sent automated text messages every week and called at weeks 2 and 4 with the option of more telephone calls or personalised text messages if necessary. The weekly automated text messages will be generic so each participant receives the same text for each week. Data will be collected during the 2 and 4-week telephone calls detailing whether or not participants recall receiving the weekly text messages. The duration of all follow-up telephone calls will also be documented. In addition, data will be collected on the number of all answered and unanswered follow-up telephone calls and text messages.

These data will help determine whether the supported home exercise programme was delivered as planned, and in turn help explain the trial results. For example, failure of the text messages and telephone calls to be delivered as intended could help explain a negative trial finding. The overall time physiotherapists spend delivering telephone calls will also be used in the economic analysis to establish the cost of the intervention, and will be important information to provide to funders for the possible future roll-out of the intervention.

Content of the 2 and 4-week telephone calls provided to the participants in the Supported Home Exercise Group

Notes will be taken by the trial physiotherapist during the telephone interactions at the 2 and at 4 weeks' follow-up for those allocated to the Supported Home Exercise Group. The notes will follow the SOAP protocol,[33] where S reflects subjective feedback, O reflects objective measures of progress, A reflects the analysis of the problem and any changes in treatment and P reflects plan for the next few weeks or call. These notes will also detail the advice and support provided and the interactions between the treating physiotherapist and the participant. The notes will be analysed to identify common themes and to better understand the type of support and advice that was given during each interaction. These data will serve two main purposes. First, they will help determine whether the intervention was delivered as intended. Support and advice are key elements of the supported home exercise programme, so it is important to understand how and if they are provided. Second, the data will provide insights into the possible future roll-out of this intervention. For example, an analysis of the data will shed light on the extent of training and expertise required by the physiotherapists and whether this is something that could be reasonably expected of physiotherapists in the real-world setting.

Number and type of physiotherapy sessions provided to the participants in the Face-to-Face Physiotherapy Group

Data will be collected at 6 weeks through self-report to determine the type and frequency of physiotherapy received by participants in the Face-to-Face Physiotherapy Group. In addition, participants in this group will be asked if they were provided a home exercise programme and, if so, how many times and for how long each day they spent exercising. These data will give an insight into trial fidelity and protocol adherence in relation to what happened on the ground, and help determine if the face-to-face physiotherapy was delivered as intended. This in turn will help explain the trial results.

The adherence of participants in the Supported Home Exercise Group to their home exercise programmes as recorded through the App (www.physiotherapyexercises.com)

The exercise App provided to participants includes a feature which enables them to record whether they have done their exercises each day. These data are automatically

relayed back to the trial physiotherapist through the App and will be collated to assess adherence. However, it is acknowledged that participants may not accurately record their exercise adherence on the App because they may forget or have internet or other technical difficulties. In an effort to quantify the accuracy of the reporting via the App, participants in the Supported Home Exercise Group will be asked during their 2 and 4-week follow-up telephone calls if the App is an accurate reflection of what they did and, if not, whether they did more or less than recorded through the App.

An underlying causal assumption as to why a supported home exercise programme may be as good or better than face-to-face physiotherapy for the management of musculoskeletal problems is that exercise programmes can be done at home with appropriate support,[12] and that exercise is a core component of the management for most musculoskeletal conditions.[2] Participants will receive support and encouragement to adhere to their exercise programmes via the App, text messages and telephone calls. Therefore, data on adherence will help determine whether the trial was implemented as intended and help explain the trial results. For example, if the trial proves non-inferiority with good adherence, this will suggest that the causal assumptions were correct, and vice versa. Interestingly, if the trial results indicate that the supported home exercise programme is as good or better than face-to-face physiotherapy in the face of poor adherence, this will suggest that the home exercises per se were less important than other aspects of the programme such as the support and advice. The adherence data will also help guide any possible future roll-out of the supported home exercise programme. If adherence is poor, this will suggest that more attention will need to be paid to this aspect of the programme. Strategies to increase adherence may need to be developed. In the same way, the adherence data will provide insights into the usefulness of the App for recording adherence. If the App proves to be successful for this purpose, then the future roll-out of the supported home exercise programme will need to focus on ensuring physiotherapists and their patients are comfortable and confident in using the App.

Participants' self-reported satisfaction with service delivery

Participants from both groups will be asked to self-report their satisfaction with service delivery at 6 weeks. This will be recorded on an 11-point scale ranging from 0 to 10, where 0 indicates '*not at all satisfied*' and 10 indicates '*extremely satisfied*'. These data will be presented descriptively.

Participants' levels of satisfaction will give insights into whether the assumptions underlying the proposed model of care are reasonable. For example, one assumption is that participants allocated to the Supported Home Exercise Group would find the model of care more convenient than face-to-face physiotherapy. Another assumption is that participants' physical symptoms can be effectively managed through home exercise, support and advice. If these assumptions are not correct then those allocated to the Supported Home Exercise Group are less likely to be satisfied with service delivery than those allocated to the Face-to-Face Physiotherapy Group. Such a finding could help explain a negative trial finding or visa versa. These data will also flag possible barriers and facilitators to the future roll-out of supported home exercise programmes if this model of care is found to be as good or better than face-to-face physiotherapy. If participants are highly satisfied then this finding can be used to advocate for supported home exercise programmes to stakeholders, funders or future patients who may have uncertainties about its acceptability (see table 2).

The costs associated with the two interventions from the health funder plus patient perspective

An economic evaluation will compare the supported home exercise programme with face-to-face physiotherapy and will be conducted from a health funder plus patient perspective (as patients will contribute time and money to the treatments). All costs will be collected during the trial period and valued in 2021 Australian dollars. Health funder costs will include physiotherapists' time to deliver all aspects of the face-to-face physiotherapy and the supported home exercise programme to both groups. This includes time devoted to organisation and scheduling of telephone calls. Other healthcare utilisation (eg, visits to doctors, exercise physiologists, masseurs) will be determined by participant self-report at 6 weeks. Participant costs will vary across the two groups and include the costs associated with the time to attend the face-to-face physiotherapy (including travel time) for those allocated to the Face-to-Face Physiotherapy Group, and the time to receive telephone calls and to complete the prescribed home exercise programme for those allocated to the Supported Home Exercise Group. The cost of any equipment purchased will also be included.

These findings will be primarily reported in a paper specifically devoted to the cost-effectiveness and cost-utility of supported home exercise compared with face-to-face physiotherapy. However, we will also use these data in conjunction with other data collected as part of the process evaluation to help provide insights into the possible barriers and facilitators to rolling this intervention out on completion of the trial. For example, the results of the health economics analysis will be used to interpret any comments made in the interviews with managers about the cost of the intervention.

DISCUSSION

The REFORM trial aims to demonstrate whether a supported home exercise programme is as good or better than face-to-face physiotherapy for patients with a musculoskeletal condition seeking care in a public hospital outpatient setting. The process evaluation will help explain the trial results and their generalisability. It will also help identify barriers and facilitators to the future

roll-out of the supported home exercise programme. Importantly, it will help clinicians and stakeholders identify how, why and for whom this intervention could have an impact.

If the results of this non-inferiority trial show that a supported home exercise programme is as good as or better than face-to-face physiotherapy then it will be important to determine the implementability of this health intervention in a real-world setting.[34] The cost-effectiveness of the intervention as well as the attitudes of the patients, clinicians and stakeholders towards the intervention will have an impact on the scalability of this method of service delivery. Interviews will explore the perceived barriers and facilitators to rolling out this intervention and this information will be combined with health economics data to make recommendations for the implementation of this intervention.

PATIENT AND PUBLIC INVOLVEMENT

Patients and the public were involved in the development of the exercise App (www.physiotherapyexercises.com) which is a key component of the supported home exercise programme. In addition, patients and the public are being involved in the REFORM trial through this process evaluation. We are capturing their perspectives through the interviews. These will shape the interpretation of the trial results and the future roll-out of the intervention if it is found to be as good or better than face-to-face physiotherapy as typically provided in a public hospital setting.

ETHICS AND DISSEMINATION

This trial is registered at the Australian New Zealand Clinical Trials Registry. It will be conducted in accordance with the National Health and Medical Research Council National Statement on Ethical Conduct in Human Research[35] and the Note for Good Clinical Practice (CPMP/ICH-135/95).[36] Ethical approval was obtained on 17 March 2017 from the Northern Sydney Local Health District Human Research Ethics Committee (trial number: HREC/16HAWKE/431-RESP/16/287) with an amendment for the process evaluation approved on 4 February 2020. It is anticipated that one publication will be devoted to some of the findings from the interviews. In particular, it will focus on consumers and stakeholders' perceptions of the intervention. This may be published prior to the completion of the trial. A second paper will be written that addresses the key purposes of the process evaluation and will be published after the completion of the trial once the results are known. It will include the results of all data sources. This second paper will draw on some of the findings from the first paper but will also include additional data gained from the interviews. The two papers are deemed appropriate to ensure all data are fully reported.

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Contributors LAH, JVG, HGW, JC, CGM, CS, MDJ, MLF and AJH were responsible for the design of the intervention and the trial. HL, LAH, JVG and HGW were responsible for the design of the process evaluation. LAH, HGW, MLF, BRL, AJH, DAT, IJS and MDJ secured funding. AJH is responsible for the economics analysis. JRZ is responsible for the post-trial translation of the intervention. TEL, JC, HGW, AB, JJC, KD and BAP are responsible for collecting data. LS, JJC, IJS, BAP, DW, KD, AB, MJT, MDJ and HGW are responsible for the sites. All authors have read and approved the final manuscript.

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CHAPTER FOUR: Patients', physiotherapists' and other stakeholders' experiences and perceptions about supported home physiotherapy for people with musculoskeletal conditions: A qualitative study.

4.1 Authorship attribution statement.

This statement is to outline the authorship contribution made by **Hannah Withers** to the following manuscript:

"**Withers HG**, Hueiming L, Glinsky JV, Chu J, Jennings M, Hayes AJ, Starkey I, Palmer B, Szymanek L, Cruwys J, Wong D, Duong K, Barnett A, Tindall M, Lucas B, Lambert TE, Sherrington C, Maher CG, Ferreira M, Taylor D, Zadro J, Hart K, Hodge W, Harvey LA. Patients', physiotherapists' and other stakeholders' experiences and perceptions about remotely delivered home physiotherapy for people with musculoskeletal conditions: A qualitative study. *Physiotherapy* 124 (2024) 143-153. doi.org/10.1016/j.physio.2024.01.006"

During her PhD candidature Hannah Withers has contributed to:

- conception and design of this qualitative study
- participant recruitment
- collection of data, transcribing interviews and developing the coding tree for theme extraction
- Interpreting the data and extracting themes
- drafting the manuscript
- responding to reviewers' comments

Hannah Withers Date: 17/12/2024

As supervisor for the candidature upon which this thesis is based, I can confirm that the authorship attribution statements above are correct.

Professor Lisa Harvey Date: 17/12/2024

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Patients', physiotherapists' and other stakeholders' experiences and perceptions about supported home physiotherapy for people with musculoskeletal conditions: a qualitative study

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Abstract

Objectives Exercise, support and advice are the key treatment strategies of musculoskeletal problems. The aims of this study were to determine patients', physiotherapists', and other stakeholders' perspectives about supported home physiotherapy for the management of musculoskeletal problems and to identify the barriers and facilitators to rolling out this model of physiotherapy service delivery.

Methods This study was conducted as part of a process evaluation run alongside a large trial designed to determine whether supported home physiotherapy is as good or better than a course of in-person physiotherapy. Forty interviews were conducted with 20 trial

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participants, 15 physiotherapists, and 5 other stakeholders. The interviews were semi-structured and based on interview guides. Each interview was transcribed and a three-tiered coding tree was developed.

Results Six key themes were identified. Supported home physiotherapy (i) is convenient for some patients, (ii) does not always align with patients' and therapists' expectations about treatment (iii) is suitable for some but not all, (iv) can reduce personal connection and accountability, (v) has implications for physiotherapists' workloads, and (vi) has barriers and facilitators to future implementation.

Conclusions Findings suggest that patients are far more accepting of supported home physiotherapy than physiotherapists assume. This model of service delivery could be rolled out to improve access to physiotherapy and to provide a convenient and effective way of delivering physiotherapy to some patients with musculoskeletal conditions if our trial results indicate that supported home physiotherapy is as good or better than in-person physiotherapy.

Clinical trial registry number ACTRN12619000065190

Contributions of this Paper

- The findings from this study suggest that supported home physiotherapy is likely to be an acceptable model of service delivery for some musculoskeletal conditions.
- The most notable and perhaps hardest barriers to overcome will be patients' beliefs about the importance of hands-on therapy, and physiotherapists' beliefs that patients will accept nothing less.
- Time will tell whether the recent COVID-19 experience will have a lasting impact on the widespread acceptance of supported home physiotherapy.

Keywords: Physical therapists; Physical therapy modalities; Musculoskeletal diseases; Covid-19

Introduction

Many musculoskeletal conditions are best managed through exercise, support and advice [1–4]. This is typically provided through a course of in-person physiotherapy. In Australia, many patients seek this type of physiotherapy through publicly funded hospitals because it is provided free of charge. However, there are long waiting lists for physiotherapy appointments in some public hospitals. A possible solution to this problem is to reduce the need for in-person physiotherapy by moving the appropriate patients (those who primarily require exercise, support and advice) onto supported home physiotherapy supplemented with just one initial in-person physiotherapy session. This could potentially enable physiotherapists to focus their attention on those who require regular in-person physiotherapy thereby reducing waiting lists and increasing accessibility to physiotherapy. In addition, supported home physiotherapy may reduce patients' dependence on passive treatments, improve outcomes [5], and offer a way of providing ongoing physiotherapy for patients unable to regularly attend in-person physiotherapy.

Prior to COVID-19, we set up a randomised controlled, non-inferiority trial (called the REFORM trial) involving 210 participants to determine whether supported home physiotherapy resulted in outcomes that were as good or better than in-person physiotherapy for the management of patients with musculoskeletal conditions in which exercise, support and advice are the key treatment strategies (see ref [6] for full details of the trial protocol and for the trial process evaluation protocol [7]). Participants randomised to the control group received usual in-person physiotherapy at the hospitals' outpatient clinics for 6 weeks. This could include manual therapy, exercise and electrotherapy along with support and advice. Participants randomised to the intervention group received supported home physiotherapy for 6 weeks. This consisted of one initial in-person physiotherapy session at which time participants were assessed, prescribed an individualised exercise program and provided with support and advice. The exercise program was loaded onto the participant's mobile device using a freely available smartphone/tablet application (App) developed by the authors (www.physiotherapyexercises.com; see Fig. 1). The App provided an image of the exercises and simple written instructions. Participants were then encouraged to continue their exercise programs at home and to use the App to record adherence. Adherence was remotely monitored through the App by their treating physiotherapist. Participants were then provided with ongoing support and advice over the telephone by the treating physiotherapist, and with weekly text messages [6]. Outcomes were assessed at 6 weeks and 6 months. This model of care is based on initial evidence from trials and systematic reviews to support remote management of similar musculoskeletal problems [1,8–17]. It is also based on studies that have failed to demonstrate superior outcomes when the number of in-person physiotherapy sessions are increased [18–24]. The last participant was randomised in November 2022.

The trial provided an opportunity (as part of the process evaluation) to interview participants, physiotherapists and other stakeholders to capture their perspectives (pros and cons) about supported home physiotherapy for the

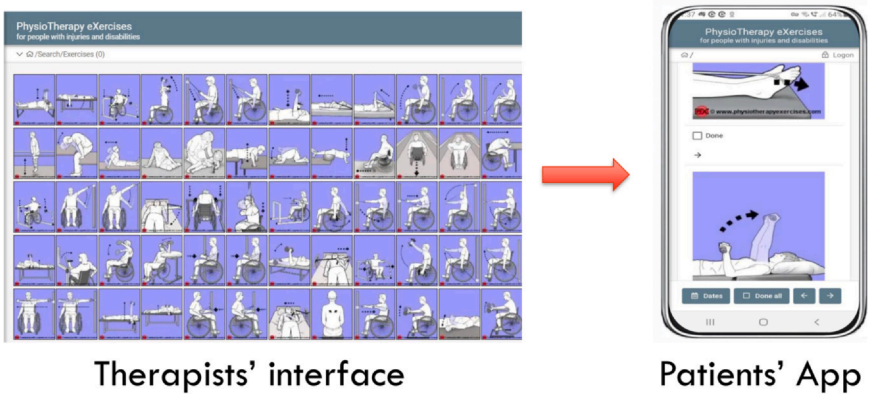

Fig. 1. The interface used by the physiotherapists to generate individualised exercise programs that were sent to patients' mobile devices as an App. These were generated through freely available exercise prescribing software at www.physiotherapyexercises.com (images copied with permission from www.physiotherapyexercises.com).

management of musculoskeletal conditions. The participants were interviewed at the time of the first COVID-19 lockdown in Sydney, Australia, however, all participants had received treatment as part of the trial prior to the onset of COVID-19, and were asked to reflect on their experiences at this time. Nonetheless, the patients' perspectives and those of the physiotherapists and other stakeholders need to be interpreted in the context of COVID-19 [25,26]. Their experiences and perspectives may change but an understanding of the pros and cons of supported home physiotherapy at any time still has relevance to decisions about how best to provide physiotherapy services in the future.

The two aims therefore of this study were to:

1. Determine patients', physiotherapists', and other stakeholders' perspectives about supported home physiotherapy for the management of musculoskeletal problems (in which exercise, support and advice are the key treatment strategies), and
2. To identify the barriers and facilitators to rolling out this model of care post COVID-19 if the results of our randomised controlled trial indicate that supported home physiotherapy leads to outcomes that are as good or better than a course of in-person physiotherapy for the target population.

Methods

Design

Qualitative methodology was used to address our aims. Specifically, patients', physiotherapists', and other stakeholders' were interviewed to capture their perspectives. Themes were then identified using a hybrid inductive/deductive approach.

Setting

The REFORM trial was conducted at five public hospitals across Greater Metropolitan Sydney in areas that have culturally and linguistically diverse populations. The interviews were conducted between August 2020 and November 2020 during a lock-down period when recruitment for the trial was temporarily ceased. The interviews were part of the process evaluation for this trial (the protocol for the process evaluation can be found here [7]). Consequently, only some of the components of the interviews were relevant to the aims of this study. Other components were included to address other aims of the process evaluation and will be reported later alongside the main trial results. An independent consultancy company (ARTD) was engaged to work with the authors on all stages of the study reported in this paper including data collection and analysis. They were used because of their expertise in qualitative research, and to minimise bias.

Data collection

A total of 40 interviews were conducted with 20 trial participants (nine from the control group and 11 from the intervention group), 15 physiotherapists, and five other stakeholders. The stakeholders included three Physiotherapy Managers and two key representatives from non-hospital-based organisations, including the State Insurance Regulatory Authority (see Table 1 for the characteristics of the interviewees). The interviews were conducted on a one-to-one basis over the telephone and each lasted between 20 and 45 minutes. Two people from the independent consultancy company conducted all the interviews (KH and PS). They had extensive experience in evaluating health programs and conducting semi-structured interviews, and had expertise in qualitative research methods. Importantly, they were likely impartial about methods of physiotherapy delivery. All interviews were recorded after obtaining consent from each interviewee.

The 20 trial participants were selected from the 101 participants who had completed the 6-week assessment at the time of the interviews (approximately 700 patients were screened to recruit these 101 participants). Of these, only 62

Table 1
Demographics.

	Patients (n = 20 of 101)	Physiotherapists (n = 15)	Stakeholders (n = 5)
Gender, n			
Male	2 (of 29)[†]	5	4
Female	18 (of 72)[†]	10	1
Age, median (IQR)	54 (42 to 66)	-	-
Hospital/site, n			-
Campbelltown	7 (of 36)[b]	3	-
Liverpool	3 (of 14)[b]	3	-
Bankstown	2 (of 8)[b]	3	-
Blacktown/Mt Druitt	8 (of 43)[b]	3	-
Other	0	3	
Group allocation		-	-
Intervention Group	11	-	-
Control Group	9		
Focus of treatment, n		-	-
Knee (*ACL rehabilitation, OA knee and Anterior knee pain*)	4	-	-
Back *(chronic LBP)*	7	-	-
Shoulder (*impingement, bursitis, tendinitis*)	6	-	-
Neck	1	-	-
Hip (*Glut. tendonitis, Hip OA and pubis symphysis)*	2		
Satisfaction with Service Delivery, n		-	-
Low satisfaction (0 to 3/10 points)	1 (of 7)[a]		
High satisfaction (7-10/10 points)	19 (of 62)[a]	-	-
Professional experience, n	-		-
Hospital based	-	13	-
Non-hospital based	-	2	
Hospital based Managers	-	-	3
Non-hospital-based Managers	-	-	2
Years in current position, median (IQR)	-	14 (3 to 17 years)	-
Years since graduation, median (IQR)	-	14 (7 to 21 years)	-

Abbreviations: IQR: interquartile range, LBP: Low Back Pain, Glut: Gluteal, OA: osteoarthritis, ACL: anterior cruciate ligament, N: numbers
[a] number included in the process evaluation out of the total number recruited.
[b] number out of the total number recruited at each site.

consented to be contacted about the possibility of being interviewed. We selected the 20 participants using purposive, maximum variation sampling to capture the widest range of perspectives possible [27,28]. We planned to sample based on variables that were likely to have an impact on the participants' opinions and perceptions about supported home physiotherapy. We planned to do this in an effort to ensure that participants from both groups within the study and four of the five sites of the trial were included. We also planned to sample in a way that reflected varying levels of satisfaction with both forms of physiotherapy service delivery. Satisfaction with service delivery was based on the results of an outcome measure collected at 6 weeks in which participants were asked to rate their satisfaction with the physiotherapy they had received as part of the trial on a scale of 0–10 where 0 indicated "*not at all satisfied*" and 10 indicated "*extremely satisfied*". Only participants with either very low (0–3) or very high (7–10) ratings were invited to be interviewed. However, there were only seven people from the total sample that had very low satisfaction with the physiotherapy service they had received of which only one agreed to be interviewed. Ultimately 35 participants were invited by telephone, 20 accepted and 15 declined.

The physiotherapists and stakeholders were selected using convenience sampling [27]. All physiotherapists involved with the trial were from outpatient settings and were invited and agreed to be interviewed. In addition, two physiotherapists from one hospital that declined to be a site for the REFORM trial were also interviewed. Stakeholders were selected to bring an organisational and policy-focussed perspective of the intervention.

The interviews were semi-structured and based on interview guides; one each for the five different types of interviewees (participants from the control group, participants from the intervention group, physiotherapists, stakeholders in and external to the hospital setting; see Appendix 1 for the Interview Guides). The Interview Guides were designed by the research team to address the two main aims, namely (i) perspectives about supported home physiotherapy, and (ii) the barriers and facilitators to rolling out this model of care in the future. They sought to capture interviewees' perceptions, beliefs and attitudes irrespective of their prior experience with supported home physiotherapy. For example, the control participants were asked about this model of service delivery even though they had not experienced it. In addition, the Interview Guides were also designed to address additional aims of the process evaluation (not reported in this paper).

Data management and theme analysis

Data were managed and analysed using NVivo software after each interview was transcribed ad verbatim. A three-tiered coding tree was then developed by HGW, LAH and two qualitative researchers from the independent consultancy company, using a hybrid inductive/deductive approach to coding and theme identification [28,29]. Specifically, data relevant to the questions proposed in the protocol of the process evaluation for the REFORM Trial were identified (see the protocol for the process evaluation of the REFORM trial [7]). The first tier of the coding tree had eight categories, and the second and third tiers had up to six categories each. For example, the first of the Tier One categories of the coding tree captured comments about the pros and cons of supported home physiotherapy. These comments were then divided into three Tier Two categories irrespective of who made the comment namely (i) pros and cons for the patient, (ii) pros and cons for the physiotherapist, and (iii) pros and cons for the other stakeholders. Each Tier Two comment was further coded inductively from the data and deductively into categories that captured the different types of pros and cons, for example time, cost and in/convenience. Another Tier One category of the coding tree captured comments about the future possible rollout of supported home physiotherapy. All these comments were coded at the Tier Two level according to whether they were comments about (i) feasibility or (ii) acceptability. Then each Tier Two comment was further coded according to (i) barriers (ii) facilitators (iii) feasible/acceptable and (iv) not feasible/acceptable.

Three people coded the data: two researchers from the consultancy company (KH and WH) and one of the authors (HGW). Between them, these three people had qualifications in physiotherapy, health and science and they were all trained in qualitative research methods. Initially, each person coded an initial interview and then came together to discuss and resolve differences in coding decisions. Thereafter the three people independently coded the remaining interviews but came together if required to further discuss any ambiguities.

Once all the text had been coded, two people analysed the data using a thematic approach (KH, PS). They compared responses by site and the characteristics of the respondent, and then compared responses across respondent groups. At this stage a third senior person from the consultancy company (WH) refined and shaped the theme analysis using further NVivo queries to explore the data. The theme analysis was then again reviewed by those involved in the coding and two other authors (JVG and LAH).

Results

Six key themes that related to the aims of this study were extracted. They are summarised below.

Theme 1: Supported home physiotherapy is convenient for some patients.

Trial participants who received supported home physiotherapy appreciated the convenience of doing therapy at a time that suited them. It was most appreciated by participants who, for a variety of reasons, found it difficult or inconvenient to attend appointments at the hospital for in-person physiotherapy. These participants embraced supported home physiotherapy as it gave them the flexibility to do their therapy when and where it suited them and reduced the need for them to spend time travelling.

"The fact that you can… do it anytime at home. You're not locked into a time like an appointment at 1 o'clock, you know. You can do it whenever you want." (Participant 004 from the intervention group)

For some participants, physically getting to appointments was difficult or stressful because they did not or could not drive, could not easily find hospital parking, found the cost of parking or travel a financial burden, or found using public transport time consuming. Four participants who received supported home physiotherapy embraced the remote method of service delivery because they found the social interactions associated with in-person physiotherapy challenging. Other participants talked about having work commitments or caring responsibilities that limited their abilities to attend appointments.

"That was actually good… because my wife had her own ill [ness] issues, it was actually easier for me to do my exercises at home while making sure that my wife, that her issues were being taken care of as well." (Participant 028 from the intervention group)

Theme 2: Supported home physiotherapy is suitable for some but not all.

Participants who were familiar with or educated about exercise believed that they were well suited to supported home physiotherapy because they needed less guidance. They were content to be shown the exercises once and to rely on the App to remind them how to perform the exercises with any tips and advice from their physiotherapist over the telephone.

Interviewees believed that individuals who were motivated by a strong desire to improve their health and who were self-motivated were well suited to supported home physiotherapy. Some examples of internal motivators described by participants were wanting to get back to favourite hobbies or sports, or to improve their day-to-day lives and mobility. Those participants who expressed a strong desire to improve their health tended to continue with their exercise programs even after their involvement with the trial had finished. Whilst physiotherapists believed that patients should take responsibility for managing their own health and hence develop their own motivators, they

also acknowledged the physiotherapist's role as motivator and the necessity for providing encouragement and monitoring adherence.

Many physiotherapists expressed concerns about the suitability of supported home physiotherapy for those not familiar with using mobile devices and Apps, and the ability or willingness of some patients to learn how to use the technology. The physiotherapists typically observed that older people were more likely to be in this group than younger people. In line with this observation, a few older participants expressed a preference for in-person appointments even though they mastered the App.

"I didn't even know what an App was, because I certainly used my phone for phone calls and my pictures in that sense. But she downloaded it and she went through it with me on the App itself, and also on the computer, so I could see what she sees… Very simple to use, once she showed me how." (Participant 010 from the intervention group)

Some physiotherapists also believed that patients with limited English language proficiency may be less suited for supported home physiotherapy. They suggested videos of the exercises within the App to help these patients even though the App is available in most languages with text to describe the exercises.

Physiotherapists believed that supported home physiotherapy is more suited to patients with chronic, rather than acute injuries, and less suited to post-surgery patients or those who require manual therapy. For example, they suggested patients with anterior cruciate ligament or rotator cuff and other shoulder injuries often require more frequent in-person physiotherapy appointments at the beginning of their rehabilitation and greater guidance through their exercises. Physiotherapists agreed that although these conditions require more hands-on therapy at the beginning of treatment, these patients could then potentially be moved to supported home physiotherapy in the later stages of treatment. This is because by that stage, treatments are largely focused around ensuring patients understand the exercises, use correct techniques, and adhere to treatment programs. A few physiotherapists believed that supported home physiotherapy may not be appropriate for patients with long-term chronic pain, such as back pain persisting for decades, as these patients may require regular reviews of their condition and progress, and may require ongoing physical examinations from the physiotherapist to continue to learn more about their condition and tailor treatment accordingly. Several participants believed that if they experienced pain or their pain got worse, they would need hands-on treatment and the supported home physiotherapy would not be sufficient. In contrast, physiotherapists commonly reported that they would be comfortable providing supported home physiotherapy for patients with lower levels of pain, good gait and good limb movement. They also felt comfortable transferring patients who can self-manage their rehabilitation onto this form of service delivery. Some participants with arthritis reported coping well with this method of service delivery.

Theme 3: Need for personal connection and accountability.

Participants wanted some personal connection with their treating physiotherapists so their needs could be understood. This was also felt to be important by the physiotherapists who often cited this as an advantage of in-person physiotherapy. However, participants who had received the supported home physiotherapy felt that the initial in-person assessment and telephone calls created sufficient personal connection to meet their needs. Participants who received supported home physiotherapy also commonly talked about having a sense of accountability to their physiotherapist because the participants knew their exercise adherence was being monitored through the App and the physiotherapist would telephone them. Others stated that they adhered to their exercise programs right up until the end of the trial because they felt supported by the telephone calls and text messages.

"Pokes me a little bit, and maybe because I was slacking off a little. In a nicest way of course, but that's important too. Because I think in my age group, it can be sort of monotonous. You know, just a little poke here and there, like she's saying, 'I know what you're doing, I can see it'; yeah, okay, alright." (Participant 027 from the intervention group)

However, some physiotherapists without direct experience of providing supported home physiotherapy believed that it may be more difficult to keep some patients accountable when supporting them remotely.

A few participants reported deferring or not doing their home exercises. They did not feel accountable to the physiotherapist regardless of the text messages, App and telephone calls. These participants felt removed from and 'out of sight' of the physiotherapist. They commonly pointed out that the success of supported home physiotherapy relies on physiotherapists trusting patients "to be honest" about indicating that they had performed their exercises, and that it would be very easy to "cheat". Further, these participants believed they would feel more motivated by meeting their physiotherapist in person.

Most trial participants who were interviewed found the App easy to use and said that they accurately recorded what they did. However, some reported deliberately overreporting exercise adherence in an effort to please their physiotherapist. One other stakeholder noted that the App enables physiotherapists to readily monitor and review participants' adherence to their therapy.

"…because you go see a physio on Monday and they say, "Here's your exercises", and then you come back next

Monday and it's really hard to see whether they've been doing them [the exercises], whereas [with the App] you've got real-time monitoring." (Other stakeholder, SH01).

The telephone calls were deemed important because they provided an opportunity for the patient to ask questions and get tailored advice as required. Most felt sufficiently supported by the telephone calls with the physiotherapist and the App, to be confident about doing their exercises correctly. However, some participants felt the telephone calls were not sufficient to ensure that they were doing the prescribed exercises correctly and worried that they may be doing them incorrectly. Some physiotherapists expressed concerns about not being able to pick up on 'red flags' indicative of other problems in need of attention merely through periodic telephone calls and felt that it was safer if the patients were seen regularly.

Theme 4: Supported home physiotherapy does not always align with patients' and therapists' traditional expectations about usual in-person physiotherapy.

Some participants persistently expressed a belief in the superior value of in-person treatment. It was apparent that some believed that therapy should be primarily provided through regular in-person consultations. Several older participants who received supported home physiotherapy also expressed the belief that therapy should include in-person treatment. They felt that having a personal connection through in-person appointments meant their condition would be better understood by their physiotherapist, they could access hands-on treatment, and the therapy would be more tailored to their needs.

"I think also because we have a very diverse patient group, their expectations of healthcare are very diverse. For some cultures there is an expectation of hands-on therapy because that's what physios do and that's why we're here and why aren't you giving me a massage? Often an aspect of Anglo-Saxon culture as well, that perception of what is physio and what do we do, that plays into that expectation." (Physiotherapist, PT15)

Physiotherapists commonly believed that supported home physiotherapy should always be supplemented with periodic in-person appointments, rather than as a standalone model of care. Those in the trial received an initial in-person appointment to enable the physiotherapist to assess the patient, select an appropriate home exercise program and teach them how to do their exercises. However, a few of the interviewed physiotherapists suggested a second in-person appointment midway through the treatment plan so they could assess the efficacy of the exercises and update the participants' exercise programs.

Theme 5: Implications for physiotherapists' workloads and ability to provide physiotherapy for more patients.

All physiotherapy services in the participating trial hospitals had a waitlist that varied depending on the patients' urgency for treatment. Physiotherapists from three of the trial hospitals stated that the trial enabled them to reduce their waiting times for physiotherapy.

"I think personally to me, equity in healthcare is very important, and so having this program, which reduces the waiting list and people are seen in a timelier manner, that definitely appeals to me. For this program to come in and reduce our waiting times, that's a definite huge bonus." (Physiotherapist 08, trial site).

Outside the context of the trial, physiotherapists believed that if supported home physiotherapy was to become part of their service model, this would enable them to treat more patients and reduce waiting lists. They indicated that the initial appointment may take longer than a normal initial appointment because of the extra time required to upload the App on the patient's device and make sure the patient can use it effectively as well as troubleshoot any potential technology-related issues. They also believed that they would need to invest time upfront into mastering each brand of mobile device and would need training if they were expected to be able to support patients' use of the App. The physiotherapists acknowledged that once a patient was set up on an exercise program and App, the subsequent follow up telephone calls would require less time than regular in-person appointments.

Some physiotherapists expressed uncertainty over the impact of introducing supported home physiotherapy on their workloads. They were concerned that they might be expected to continue to provide the same number of in-person appointments as well as manage additional patients on supported home physiotherapy. Some also expressed concerns that patients may be less likely to keep a telephone appointment than a face-to-face appointment and they may waste time chasing patients up on the telephone which could offset the time saved from fewer one-to-one appointments.

Theme 6: Barriers and facilitators to the future rollout of supported home physiotherapy, and the implications COVID-19 had on participants' perspectives.

The interviews coincided with the COVID-19 pandemic although all trial participants were reflecting on the physiotherapy care that they received prior to COVID-19 as part of the trial. Many physiotherapists said that COVID-19 had accelerated their own, and service managers' awareness of and acceptance of supported home physiotherapy as a viable option of care for some patients. Some patients in the intervention group also acknowledged that their acceptance of supported home physiotherapy was accelerated during the COVID-19 pandemic.

"… to tell you the truth, current situation and circumstances it's… it's what's keeping me moving more. It's what's keeping the strength up in my legs because of the spinal surgery." (Participant 044 from the intervention group)

As a result, stakeholders believed that physiotherapists are likely to be confident to continue to use supported home

physiotherapy as an option into the future; and better understand the types of patients and conditions for which it is appropriate.

Stakeholders were largely positive about the potential to integrate supported home physiotherapy into the service model of hospitals. Stakeholders and physiotherapists commonly agreed that supported home physiotherapy would be an acceptable method of providing care, with the proviso that physiotherapists offered it in combination with periodic in-person care.

"… being able to track a patient and what they're doing away from therapy, so it's exercises, if they have any problems. if they're recording themselves and showing technique, we can eyeball that and correct that." (Physiotherapist, PT06)

Stakeholders commonly noted that the successful introduction of supported home physiotherapy must be supported by hospital management and be properly resourced. They highlighted the need for infrastructure and training along with the development of guidelines for physiotherapists. This was deemed particularly important for new graduates who may have less clinical knowledge and experience and therefore may find it harder to assess a patient's condition and progress his/her exercise programs without regular in-person appointments.

Several stakeholders also identified a barrier involving potential privacy breaches and security issues with data storage if the use of information technology is adopted more broadly in the future. For example, participants' first names and mobile phone numbers are required to send them their exercises and to text them. The systems used to text and send exercises to patients need to be trustworthy and scrutinised to ensure confidence in their data security systems. The level of management support for and resourcing of supported home physiotherapy appeared to vary across the hospitals involved in the trial. This influenced physiotherapists' attitudes towards the feasibility of readily integrating supported home physiotherapy into practice models. For example, some physiotherapists said they do not currently have the capacity to integrate supported home physiotherapy alongside in-person appointments because of the perceived length of time it would take to set up the service model. Some physiotherapists had previously encountered challenges using other types of supported home physiotherapy, noting that setting up patients to use technology and ensuring the technology is working properly could be very time consuming.

Some factors that would facilitate the roll out of this intervention also became evident. The most direct facilitating factor was the COVID-19 pandemic. COVID-19 restrictions and the need to isolate appeared to change patients' attitudes towards an acceptance of the supported home physiotherapy, and to a lesser extent, the attitudes of physiotherapists and other stakeholders.

An accelerated acceptance of supported home physiotherapy has also facilitated a change in the structure of health services. This has resulted in some patients and physiotherapists expressing a willingness to acquire new technology-based skills for assessing and prescribing treatment, providing feedback and advice, and recording adherence. These attitudes have highlighted the need for change in education, training and support in physiotherapy outpatient departments. Patients also reported that supported home physiotherapy has increased access to physiotherapy and is convenient, cost effective and less time consuming; factors that will facilitate the rollout of the intervention in the future.

Discussion

The results of this study provide important insights into patients', physiotherapists' and stakeholders' perceptions of supported home physiotherapy, and identify some of the likely barriers and facilitators to the possible rollout of this model of care in the future. These insights will help direct the implementation phase of the REFORM Trial if the results of the trial indicate that this model of service delivery leads to outcomes that are as good or better than a course of in-person physiotherapy.

One of the main findings from this study is that patients are more accepting of supported home physiotherapy than physiotherapists often assume. Some physiotherapists believe that patients want in-person physiotherapy for hands-on treatments and the personal contact, and that they are unlikely to accept anything less [30]. Whereas in fact, many patients were very satisfied and accepting of supported home physiotherapy. These patients tended to place a lot of importance on the exercises per se, and had confidence in their own abilities to be able to do the exercises at home without direct one-to-one supervision. They were prepared to sacrifice any perceived benefits of regular in-person physiotherapy for the convenience of supported home physiotherapy. Nonetheless, there were some patients who clearly missed the close and regular contact with a physiotherapist. They did not feel that their needs were being adequately met or understood when left to do their own home exercise program irrespective of the feedback and advice provided over the telephone. Others felt that they lacked the discipline to do a home exercise program without direct and regular supervision. Additionally, some merely lacked confidence and wanted someone to check that they were doing the exercises correctly.

All stakeholder groups indicated that supported home physiotherapy is unlikely to be accepted without good quality evidence to support its effectiveness and efficiency. Other barriers to the future rollout included access to mobile devices or limited ability to use them despite up to 86% of Australian households having access to the internet and 87% reporting having at least one device that has the ability

to connect to the internet [31]. Whilst the patients who had experience with the trial App generally found it easy to use, some physiotherapists were concerned about their abilities to set patients up on the App and support them in its use. They were also concerned about how long this would take. Interestingly however, those expressing these concerns had limited experience with the App so were merely expressing the problems they anticipated. Nonetheless, training and support for physiotherapists in the use of the App will clearly be an important aspect of any future rollout of this model of care.

Many interviewees, particularly physiotherapists, expressed concerns about the suitability of supported home physiotherapy for all. We were aware of these concerns before undertaking the interviews and prior to commencing the trial. It was for this reason that the REFORM trial only included people with musculoskeletal conditions that were deemed best managed with exercise, support and advice [10,12,14,16]. Some conditions require more care than this, including manual therapy, regular review and update of exercises, and careful monitoring for signs of deterioration. People with conditions requiring this more extensive level of care will continue to require regular in-person physiotherapy. Alternatively, they could be managed with a hybrid model which combines in-person physiotherapy with supported home physiotherapy. And of course, there is the option of adding videoconferencing which has become increasingly acceptable to all as a method of service delivery [32]. Importantly, decisions about the appropriate model of care for a patient needs to be made in collaboration with the patient. This encourages the active participation of patients and ensures that care is patient-centred [33].

COVID-19 increased the uptake of telehealth options. However, its future and ongoing use requires education and training, workforce planning and hospital design [34]. Work has commenced in this area with the development of a capability framework that identifies the skills that physiotherapists require to effectively deliver telephone-based physiotherapy. This is a first step to ensuring the workforce is adequately trained and skilled: a possible barrier to the widespread rollout of the intervention [30]. Another challenge to the future rollout of any form of supported home physiotherapy will be appropriate triage of those who are and are not suitable for this service. This should include a process of shared decision making with patients to ensure their preferences are taken into consideration.

Supported home physiotherapy could improve access to physiotherapy and provide a convenient and effective way of delivering physiotherapy to patients with musculoskeletal conditions. For example, this could enable people who live in rural and isolated parts of Australia to gain access to physiotherapy services that they may not otherwise receive. Similarly, it may enable those who are disabled or disadvantaged in some way to better access physiotherapy services by removing the need for frequent travel to hospital. Being able to access physiotherapy at any time at home or work, also increases convenience and results in less absenteeism from work [31]. In addition, by offering the appropriate patients the option of home supported physiotherapy, this may reduce the waiting times for physiotherapy at public hospitals [35,36]. The economic implications of home supported physiotherapy versus in-patient physiotherapy will be explored in a full health economics analysis once the trial is completed. However, reducing the number of visits to hospital will invariably reduce the time and costs associated with travel for patients.

A key strength of our study was the inclusion of a mix of physiotherapists and stakeholders with differing opinions about the pros and cons of supported home physiotherapy. In addition, we included participants from the REFORM Trial: some of whom had experienced our model of care as part of the trial. Despite our best attempts, only one person who was dissatisfied with supported home physiotherapy received as part of the trial accepted our invitation for an interview (as evident by a score of less than 3/10 points on the final satisfaction scale). Whilst this could be a source of bias, it reflected the low proportion of participants (ie., 7%) who were dissatisfied with the way physiotherapy was provided (that is, only seven of the 101 participants who had completed the 6-week assessment scored less than 3 points on the satisfaction scale).

Our findings may not be generalisable beyond the sort of person who was willing to participate in the REFORM Trial and beyond public hospitals in Sydney. For example, perhaps those very opposed to the possibility of missing out on in-person physiotherapy declined to be involved. Consequently, our sample may be reflective of a certain sort of person. In addition, COVID-19 has likely impacted patients' and physiotherapists' expectations about different models of service delivery and has possibly improved acceptance of supported home physiotherapy. If this study was conducted prior to the COVID-19 pandemic or after it had finished, the findings may have been different. For example, at least one study from Australia concluded that COVID-19 increased physiotherapists' confidence and feelings of success treating patients via telehealth. It found that physiotherapists felt better able to identify appropriate patients, make decisions and overcome challenges associated with managing patients remotely as the COVID-19 pandemic progressed [37]. Nonetheless, the perceptions of the intervention participants' and some of the physiotherapists reflect their experiences with either delivering or receiving home supported physiotherapy. Their experiences are just as relevant now that COVID-19 has largely passed as when they were interviewed.

In conclusion, the findings from this study suggest that supported home physiotherapy is likely to be an acceptable model of service delivery that could be rolled out if the trial results indicate patient outcomes are as good or better than in-person physiotherapy. However, there will be barriers to its future rollout. The most notable and perhaps hardest barriers to overcome will be patients' beliefs about the

importance of hands-on therapy, and physiotherapists' beliefs that patients will accept nothing less. Time will tell whether the recent COVID-19 experience will have a lasting impact on the widespread acceptance of supported home physiotherapy as the need for social isolation wanes.

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Ethical approval: This trial is registered at the Australian and New Zealand Clinical trial registry (ACTRN12619000065190) and was conducted in accordance with the NHMRC National Statement on Ethical Conduct in Human Research (2018) and the Note for Good Clinical Practice (CPMP/ICH-135/ 95). Ethical approval was obtained on the 17 March 2017 from the Northern Sydney Local Health District HREC, trial number HREC/16HAWKE/431-RESP/16/287 with an amendment for the Process Evaluation approved on 04/02/ 2020.

Conflict of Interest

None declared.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.physio.2024.01.006.

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CHAPTER FIVE: Remotely delivered physiotherapy compared to face-to-face physiotherapy for the management of musculoskeletal conditions (REFORM): A randomised controlled, non-inferiority trial.

5.1 Authorship attribution statement.

This statement is to outline the authorship contribution made by Hannah Withers to the following manuscript:

"**Withers HG**, Glinsky JV, Chu J, Jennings M, Hayes AJ, Starkey I, Parmeter R, Boulos M, Cruwys JJ, Duong K, Jordan I, Wong D, Trang S, Duong M, Hueiming L, Hayes AJ, Lambert TE, Zadro J, Sherrington C, Maher CG, Lucas BR, Taylor D, Ferreira ML, Harvey LA. Remotely delivered physiotherapy is as effective as face-to-face physiotherapy for musculoskeletal conditions (REFORM): a randomised trial. *Journal of Physiotherapy.* 70(2024) 124-133 doi.org/10.1016/j.jphys.2024.02.016"

During her PhD candidature Hannah Withers has contributed to:

- conception and design of the research
- collection of the data
- interpretation of the findings
- drafting the manuscript
- responding to reviewers' comments

Hannah Withers Date: 17/12/2024

As supervisor for the candidature upon which this thesis is based, I can confirm that the authorship attribution statements above are correct.

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Research

Remotely delivered physiotherapy is as effective as face-to-face physiotherapy for musculoskeletal conditions (REFORM): a randomised trial

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KEY WORDS

Telehealth
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ABSTRACT

Question: Is remotely delivered physiotherapy as good or better than face-to-face physiotherapy for the management of musculoskeletal conditions? **Design**: Randomised controlled, non-inferiority trial with concealed allocation, blinded assessors and intention-to-treat analysis. **Participants**: A total of 210 adult participants with a musculoskeletal condition who presented for outpatient physiotherapy at five public hospitals in Sydney. **Intervention**: One group received a remotely delivered physiotherapy program for 6 weeks that consisted of one face-to-face physiotherapy session in conjunction with weekly text messages, phone calls at 2 and 4 weeks, and an individualised home exercise program delivered through an app. The other group received usual face-to-face physiotherapy care in an outpatient setting. **Outcome measures**: The primary outcome was the Patient Specific Functional Scale at 6 weeks with a pre-specified non-inferiority margin of −15 out of 100 points. Secondary outcomes included: the Patient Specific Functional Scale at 26 weeks; kinesiophobia, pain, function/disability, global impression of change and quality of life at 6 and 26 weeks; and satisfaction with service delivery at 6 weeks. **Results**: The mean between-group difference (95% CI) for the Patient Specific Functional Scale at 6 weeks was 2.7 out of 100 points (−3.5 to 8.8), where a positive score favoured remotely delivered physiotherapy. The lower end of the 95% CI was greater than the non-inferiority margin. Whilst non-inferiority margins were not set for the secondary outcomes, the 95% CI of the mean between-group difference ruled out clinically meaningful differences. **Conclusion**: Remotely delivered physiotherapy with support via phone, text and an app is as good as face-to-face physiotherapy for the management of musculoskeletal conditions. **Trial registration**: ACTRN12619000065190. **[Withers HG, Glinsky JV, Chu J, Jennings MD, Starkey I, Parmeter R, Boulos M, Cruwys JJ, Duong K, Jordan I, Wong D, Trang S, Duong M, Liu H, Hayes AJ, Lambert TE, Zadro JR, Sherrington C, Maher C, Lucas BR, Taylor D, Ferreira ML, Harvey LA (2024) Remotely delivered physiotherapy is as effective as face-to-face physiotherapy for musculoskeletal conditions (REFORM): a randomised trial. *Journal of Physiotherapy* 70:124–133]**

Introduction

Physiotherapy is important for the management of musculoskeletal (MSK) conditions[1,2] and is typically provided through regular face-to-face sessions with a physiotherapist.[3] In Sydney, Australia, many patients access face-to-face physiotherapy through government-funded hospitals where the service is provided free of charge; however, there can be long waiting times for this service. This is partly due to the high demand for physiotherapy that comes with an ageing population, the increased prevalence of chronic diseases,[4,5] the increased awareness of the benefits of physiotherapy and the current financial stress on households limiting people's abilities to pay for physiotherapy services provided outside the public health system. Long waiting times for physiotherapy could be managed by

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moving some people with MSK conditions away from a heavy reliance on regular face-to-face physiotherapy, provided that this does not compromise outcomes.[6,7] This could increase access to physiotherapy[8] and reduce the burden on the healthcare system.[1] Less reliance on face-to-face physiotherapy would also benefit those who have difficulty regularly travelling to and from physiotherapy appointments. This is particularly the case in remote parts of Australia and for people with limited mobility or with other carer or work responsibilities.[1]

There are a number of possible models of care to reduce reliance on regular face-to-face physiotherapy, many of which have been evaluated in clinical trials and systematic reviews, and some of which have been necessary due to COVID-19. These include videoconferencing, telephone-based support, text messages, exercise apps and self-help websites. For example, studies have examined the benefits of telephone calls instead of face-to-face physiotherapy.[9] Other studies have compared the effectiveness of telephone calls with no intervention.[10] Others have compared web-based educational programs with or in addition to face-to-face physiotherapy.[11,12] Work in this area is particularly advanced for the management of osteoarthritis[13–15] and back pain;[16] however, the intervention for these two conditions often includes many different aspects of overall management including diet, activity levels, pain management and medication. In addition, the focus is rarely on a model of care suitable for people with the range of MSK conditions that typically present to Sydney public hospitals for physiotherapy.

We were specifically interested in a model of care that included an initial face-to-face session with a physiotherapist, at which time the physiotherapist assessed the patient, provided them with support and advice and gave them a home exercise program. The physiotherapist then monitored them remotely through an exercise app and provided two short follow-up telephone calls. In addition, patients received weekly automated text messages to encourage adherence with their home exercise program. The text messages were incorporated because of the evidence pointing to the motivating effects of regular text messages for changing people's behaviour (eg, ceasing smoking, losing weight or increasing physical activity).[17–20] The home exercise program was provided through an app because it has recently been shown that this leads to greater exercise adherence than providing home exercises on paper handouts, particularly when the therapist can review when patients have exercised.[21,22] We hypothesised that this model of care (henceforth called remotely delivered physiotherapy) may be appropriate for the management of some MSK conditions in which the key aspects of physiotherapy management are exercise, support and advice,[23] including conditions such as back pain and other soft tissue injuries.

There are no studies that have specifically examined this proposed model of care for patients with a variety of MSK conditions. The most comparable studies have either looked at different components of this model of care in isolation, or looked at a similar model of care in the African context.[24,25] For example, studies have examined the benefits of telephone calls provided in addition to physiotherapy[24,26] or in combination with face-to-face physiotherapy or group sessions.[27–29] A notable trial (PhysioDirect) from the UK examined the effectiveness of a supported home exercise program; however, the participants in the control group were not provided with physiotherapy at the same time and instead were placed on a waiting list for face-to-face physiotherapy.[26] In addition, the initial assessment and advice was provided by telephone (although some participants were seen by a physiotherapist if required). It is therefore unknown whether our proposed model of care (ie, remotely delivered physiotherapy) can provide outcomes as good as or better than those achieved with usual face-to-face care, as delivered in an outpatient hospital setting, for patients with MSK conditions.

Therefore, the research question for this randomised trial was:

Is remotely delivered physiotherapy as good as or better than usual face-to-face physiotherapy for MSK conditions?

Methods

Design

The REFORM trial was a randomised, controlled non-inferiority trial in which participants were randomised to either remotely delivered physiotherapy or usual care (Figure 1). The assessor and statisticians were blinded. The protocol was published[30] and the trial was prospectively registered. Participants were recruited from five public hospitals in Sydney, Australia, between March 2019 and November 2022. Recruitment was stopped for two periods during this time due to the COVID-19 pandemic. Participants were assessed at baseline, and then at 6 and 26 weeks after randomisation.

A computer-generated randomisation schedule was stratified by site and produced by an independent researcher. It was imported into a Research Electronic Data Capture (REDCap[a]) system and not disclosed to anyone. Once a participant completed the baseline assessment, the trial physiotherapist (HW) logged onto REDCap and retrieved the participant's group allocation. The participant was deemed to have entered the trial at this point.

Participants, therapists and centres

A physiotherapist screened patients from the outpatient waiting lists of each hospital. Potentially eligible patients were telephoned, at which time the trial was explained to them (using a script) and they were invited to participate. At one site, an administrative staff member rang every patient on the waiting list and followed a written script designed to screen patients and invite them to participate. Patients who declined to participate remained on the waiting list for a standard appointment. Those who expressed an interest in participating were invited to attend a face-to-face appointment with the trial physiotherapist. At this time the trial was fully explained, and patients were given a patient information sheet and an opportunity to ask questions. However, patients were not told that face-to-face was considered the 'gold standard' or that the study was attempting to determine whether remotely delivered physiotherapy was as good as or better than face-to-face physiotherapy. Instead, they were only told that the study was comparing two ways of delivering physiotherapy. All participants signed a consent form and were again checked for eligibility. Baseline assessments were then conducted before participants were randomised to one of the two groups: usual care or remotely delivered physiotherapy.

The trial was pragmatic with broad inclusion criteria. Patients were eligible for inclusion if they presented for outpatient physiotherapy and had any MSK condition that was best managed with exercise, support and advice. This was determined by the physiotherapists who screened participants for suitability. Patients were only included if they could read, speak and write in English; had access to a smart device and internet; were available for 6 weeks; and were able to complete the 6-week and 26-week assessments. Patients were excluded if they were pregnant, had a mental illness that could affect compliance, were deemed at risk without face-to-face treatment (eg, risk of falling with unsupervised exercise or had a wound that required dressings), or had a postoperative physiotherapy protocol prescribed by a surgeon.

All participants in the remotely delivered physiotherapy group were treated by the trial physiotherapist. She was trained in using the website and app and had $>$ 15 years of experience as a MSK physiotherapist. The participants in the usual care group were treated by an outpatient physiotherapist at the site.

Intervention

Participants allocated to the usual care group received usual care, as prescribed by the treating physiotherapist in the outpatient department. The number of sessions and duration of sessions that were provided were at the discretion of the treating physiotherapist, and the physiotherapists were free to provide participants with a

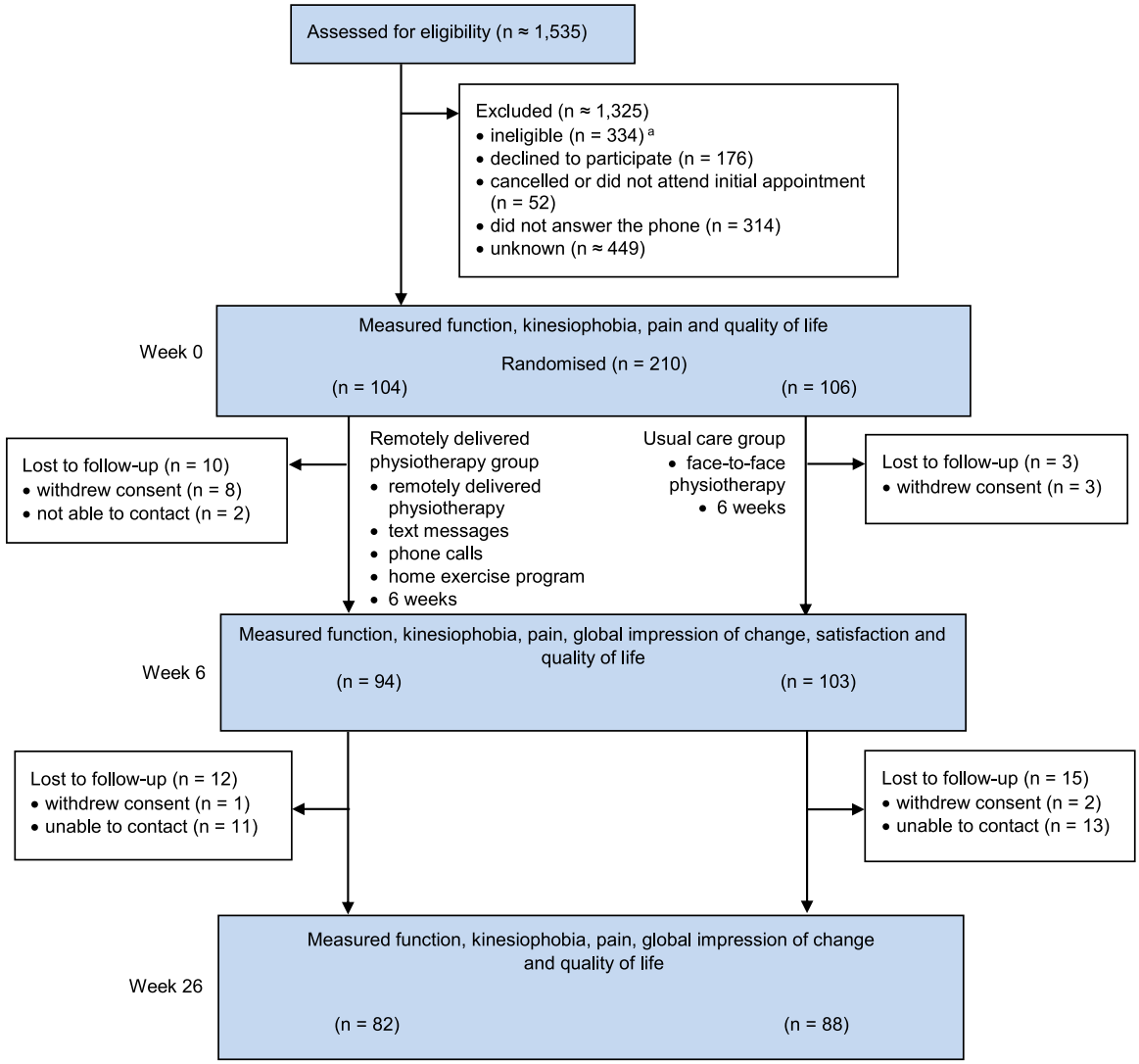

Figure 1. Flow of participants through the trial.
[a] No smart device (n = 44), needed interpreter (n = 170), patient had postoperative protocol (n = 66), aged < 18 (n = 13), pregnant (n = 6), at risk of harm without face-to-face physiotherapy (n = 34), passed away (n = 1). Due to COVID lockdowns and staff transitions it was not possible to maintain accurate screening logs at all the sites. Numbers for the 6 week and 26 week assessments reflect those who completed the Patient Specific Functional Scale. Some participants completed it but not the other outcomes at 6 and 26 weeks (see numbers indicated in Tables 4 and 5 for details).

home exercise program if deemed appropriate and they were free to provide this in any format. This was done to mimic current practice.

Participants allocated to the remotely delivered physiotherapy group received an initial face-to-face assessment with the trial physiotherapist. Following this, they were prescribed an individualised home exercise program, based on the exercises available on www.physiotherapyexercises.com (a freely available exercise-prescribing software with > 1,500 exercises, created by the authors). The selected exercises were put on participants' mobile devices as a web-based app (some participants required help with this). The app provided an image and brief description of each exercise; it also enabled participants to tick each exercise each day they practised an exercise. The participants were taught how to use the app.

Each participants' exercises were selected by the trial physiotherapist to address the participants' key problems (identified during the initial face-to-face assessment) and goals (identified during the baseline assessment). The exercises were adapted, if necessary, so that participants could use objects around their homes to substitute for gym equipment. A typical exercise program consisted of six to ten exercises that participants were asked to practise at least once per day. Participants were given guidance on how many repetitions of each exercise to perform, but this varied from participant to participant. Some participants were taught at the initial face-to-face assessment how to progress their exercises over the 6 weeks. For example, they were told how and when to increase the number of repetitions, or they were provided with copies of more difficult exercises on their app to progress onto with time. The trial physiotherapist telephoned the participants at 2 and 4 weeks. During this call, the participants' exercises were reviewed and instructions were given about whether and how to progress each exercise. The trial physiotherapist also encouraged the participants to continue practising their exercises and provided feedback, support and advice. However, the telephone calls were not intended to be a substitute for a face-to-face physiotherapy session, and were typically 5 to 10 minutes in duration.

The participants were also sent weekly automated text messages generated from a prepaid website. The text messages encouraged adherence to their home exercise programs but were not individualised, and participants could not respond to them. A detailed description of the intervention is outlined in Table 1 on the eAddenda according to the Template for Intervention Description and Replication (TIDieR) checklist.

After the 6-week intervention period, participants were told that they were free to pursue whatever treatment they wished for their MSK conditions, but this was not encouraged or facilitated. Some participants from both groups may have received face-to-face physiotherapy after the 6-week assessment, but these data were not collected.

Outcome measures

The primary outcome was the Patient Specific Functional Scale (PSFS) at 6 weeks. Secondary outcomes included the PSFS (at 26 weeks) and measures that captured pain, quality of life, impression of therapeutic benefit, satisfaction with service delivery as well as the TAMPA Scale for Kinesiophobia (TSK), and the Late Life Function and Disability Index (LLFDI). All secondary outcomes (except satisfaction and service delivery) were measured at 6 and 26 weeks. Outcomes were collected by the trial physiotherapist at baseline during a face-to-face session and prior to randomisation, and then by an assessor over the telephone at 6 and 26 weeks after randomisation (the participants responded to questions on REDCap[a] with the support of the assessor who was blinded to the group allocation of each participant). A brief summary of each outcome is as follows.

Primary outcome

The primary outcome was the PSFS at 6 weeks.[31] It required participants at baseline to identify up to five functional activities that were most important to them and which they found difficult to perform. Participants were then asked to rate their ability to perform each activity on an 11-point scale (where 0 indicated an inability to perform the activity and 10 indicated an ability to perform the activity at pre-injury level). Scores for each activity were summed and expressed in proportion to the total possible score (determined by the number of identified activities multiplied by 10 points), where a score of 100 points indicated that the participant could perform all activities as they did prior to injury. This outcome was sensitive to changes that were important to the participants and could be used across a wide range of MSK conditions including those involving the neck, knee and back.[32]

Secondary outcomes

The TSK quantifies fear of movement and reinjury. Participants scored 17 items on a scale of 1 (strongly disagree) to 4 (strongly agree).[33,34] The scores were summed to derive a total possible score of 17 to 68 points; the lowest score indicated no kinesiophobia.

Pain was measured on a numeric rating scale from 0 (no pain) to 10 (worst pain imaginable).[35] Participants were asked to score their average pain over the past 24 hours.

Impression of therapeutic benefit was measured using the patient global impression of change scale,[36] which is a 15-point scale ranging from −7 (very much worse) to +7 (very much better) and anchored in the middle at 0 (no change).

Patient satisfaction with healthcare service delivery was measured on a scale from 0 (complete dissatisfaction) to 10 (complete satisfaction). This was only collected at 6 weeks.

Health-related quality of life was measured using the EuroQoL 5-Dimension Quality-of-Life Questionnaire (EQ-5D-5L).[37] A health state index score was then calculated from individual health profiles using an Australian valuation.[38] The EQ-5D-5L has been validated with a wide range of MSK conditions;[39] scores range from below 0 to 1, where 0 indicates death and 1 indicates full health.

The LLFDI has three components. The functional performance component measures 32 standardised items capturing participants' perceptions about their abilities to perform discrete actions or tasks; this is rated on a scale from 0 (no difficulty) to 5 (cannot do).[40] The frequency of performing life tasks measured with the disability component captures 16 standardised items measuring participants' perceptions about the frequency they perform socially defined life tasks, using the options: *very often, often, once in a while, almost never* and *never*. Limitations in capability of performing life tasks measured with the disability component measures 16 standardised items capturing participants' perceptions about their limitations in performing socially defined tasks from the options: *completely, a lot, somewhat, a little* or *not at all*. Scores are transformed into a score from 1 to 100, where a higher score indicates a higher level of functioning.[41] Although the LLFDI was originally designed for an aged population, it has been widely used in MSK populations.[42]

Data on adherence to home exercise programs were collected in different ways for the two groups. Participants in the usual care group were asked at 6 weeks whether they had been provided with a home exercise program. Those who had been provided with a home exercise program were asked how many times per week they had practised their exercises over the preceding 6 weeks. Participants in the remotely delivered physiotherapy group were just asked how many times per week they had practised their exercises, but they were asked this question at 2, 4 and 6 weeks (each time reflecting on the preceding 2 weeks). The data from the three time points were averaged to reflect the number of times they had exercised per week. Data on adherence to the home exercise programs for the remotely delivered physiotherapy group were also collected through the exercise app; this relied on participants ticking off exercises as they practised them each day.

Data analysis

A sample size of 210 was based on 80% power for a non-inferiority margin of −15 points on the primary outcome measure (the PSFS). That is, remotely delivered physiotherapy was to be deemed as good as usual care if the lower limit of the 95% CI associated with the mean between-group difference on the PSFS at 6 weeks was greater than −15 points (where a positive value favoured remotely delivered physiotherapy), and it was deemed better if the lower limit of the 95% CI associated with the mean between-group difference on the PSFS at 6 weeks was greater than 0 points. This calculation assumed a standard deviation of 2[32] and 15% drop out rate.

An intention-to-treat statistical analysis was conducted according to the trial protocol. Separate linear regression analyses were used for each outcome at 6 and 26 weeks, with baseline data, site and duration since onset of injury ($<$ 12 weeks and $>$ 12 weeks) entered as covariates. Each regression analysis was conducted twice: once with and once without multiple imputation for missing data.

Results

Compliance with the study protocol

The trial was conducted largely according to the protocol, with two exceptions. First, while the protocol stated that randomisation would be blocked and stratified by both site and onset of injury ($<$ 12 weeks versus $>$ 12 weeks since onset), the randomisation was only blocked and stratified by site. Second, while the protocol stated that usual care would consist of face-to-face physiotherapy, five of 106 patients from the usual care group received some or all of their physiotherapy treatments via telehealth due to COVID-19 restrictions.

Baseline characteristics

Tables 2 and 3 show the characteristics of the participants at baseline: 65% were female and the median age was 53 years (IQR 41 to 66). The most common presenting symptom was pain or injury to the knee (23%) and back (30%); 84% of participants had sustained their injury (or had onset of symptoms) $>$ 12 weeks earlier and 16% of participants reported that their symptoms and/or flare up were due to osteoarthritis.

Flow of participants through the study

Figure 1 shows the flow of participants through the trial. Approximately 1,535 participants were screened for inclusion (this number is an estimate only because COVID-19 and other factors prevented accurate recording). A total of 210 participants were randomised from the five sites, with 104 randomly assigned to the remotely delivered physiotherapy group and 106 to the usual care group. Then, 197 and 181 participants were assessed for the primary outcome (the PSFS) and secondary outcomes, respectively, at 6 weeks; 170 and 156 participants were assessed for the PSFS and other

Table 2
Baseline demographic characteristics of the study participants.

Characteristic	Remotely delivered physiotherapy (n = 104)	Usual care (n = 106)
Age *(yr)*, median (IQR)	52 (40 to 64)	56 (41 to 68)
Gender, n (%)		
male	40 (38)	32 (30)
female	63 (61)	74 (70)
non-binary	1 (1)	0 (0)
Work status, n (%)		
unemployed	58 (56)	61 (58)
employed	40 (38)	41 (39)
student	5 (5)	3 (3)
unpaid carer	1 (1)	1 (1)
Site of recruitment, n (%)		
hospital 1	8 (8)	9 (8)
hospital 2	29 (28)	30 (28)
hospital 3	12 (12)	13 (12)
hospital 4	36 (35)	35 (33)
hospital 5	19 (18)	19 (18)

Some percentages do not sum to 100 due to the effects of rounding.

secondary outcomes at 26 weeks, respectively. Some participants completed the PSFS but not the other outcomes at 6 and 26 weeks (see numbers indicated in Tables 4 and 5 for details).

Adherence

Participants in the remotely delivered physiotherapy group received the intervention largely as per the protocol (see Table 6 for details). The text and follow-up phone calls were delivered as per the protocol and all participants were given an individualised exercise program delivered to their mobile devices via the app. Adherence to their home exercise program according to data collected via the app was poor, with only 50% of participants practising two or more exercises on 3 days in week 1. This figure dropped to 1 day by week 2 (Figure 2). However, participants reported practising their home exercises on a median (IQR) of 4 days/week (3 to 7) when asked at 2, 4 and 6 weeks.

Participants in the usual care group received a median of three (IQR 2 to 4) face-to-face sessions with a physiotherapist over the 6 weeks. Usual care sessions consisted mainly of one-on-one treatments including manual therapy and exercises. Eighty-eight participants reported receiving a home exercise program in addition to their face-to-face treatment (see Table 6 for details); these were largely provided in paper format. Participants reported practising their home exercises on a median of 7 days/week (IQR 4 to 7) when asked at 6 weeks.

Table 3
Baseline clinical characteristics of the study participants.

Characteristic	Remotely delivered physiotherapy (n = 104)	Usual care (n = 106)
Duration since onset of injury, n (%)		
< 12 weeks	19 (18)	14 (13)
> 12 weeks	85 (82)	92 (87)
Location of injury, n (%)		
foot	3 (3)	1 (1)
lower leg	6 (6)	8 (8)
knee	23 (22)	25 (24)
thigh	3 (3)	1 (1)
hip	8 (8)	6 (6)
hand	1 (1)	2 (2)
forearm	2 (2)	2 (2)
elbow	1 (1)	0 (0)
shoulder	22 (21)	21 (20)
back	29 (28)	34 (32)
abdomen	1 (1)	1 (1)
neck	5 (5)	5 (5)
Diagnosis, n (%)		
osteoarthritis	16 (15)	18 (17)
neck pain	5 (5)	6 (6)
back or leg pain (± post-surgery)	29 (28)	37 (35)
fracture wrist, fibula, humerus, scaphoid, ankle or femur	11 (11)	6 (6)
frozen shoulder, shoulder capsulitis, impingement or muscle tear	17 (16)	16 (15)
hip bursitis or tendinopathy or pain or weakness	7 (7)	4 (4)
ACL or meniscal injury ± repair; PF or knee joint pain; hamstring injury	12 (12)	8 (8)
ankle pain, tendonitis or sprain	6 (6)	3 (3)
miscellaneous	1 (1)	8 (8)
Taken pain killers in the last 6 weeks, n (%)	78 (75)	72 (68)

Some percentages do not sum to 100 due to the effects of rounding.
ACL = anterior cruciate ligament, PF = patellofemoral.

Outcomes

The mean between-group difference (95% CI) for the PSFS at 6 weeks was 2.7 points (–3.5 to 8.8) favouring remotely delivered physiotherapy (see Table 4). These results indicate that remotely delivered physiotherapy is as good as face-to-face physiotherapy because the lower end of the 95% CI is greater than the non-inferiority margin of –15 points. The results at 26 weeks were similar with a mean between-group difference (95% CI) of –1.8 points (–9.3 to 5.6). There was minimal difference between results with and without imputation of missing data (see Tables 4 and 5 for results without imputation of missing data; and see Table 7 on the eAddenda for results with imputation of missing data).

Whilst non-inferiority margins were not set for any of the secondary outcomes (Tables 4 and 5), the 95% CI of the mean between-group difference ruled out clinically meaningful differences. Individual participant data are presented in Table 8 (see Table 8 on the eAddenda).

Discussion

The results of this trial show that remotely delivered physiotherapy for people with MSK conditions is as good as face-to-face physiotherapy that is typically provided in outpatient settings at public hospitals in Sydney, Australia. These results are consistent with the findings of two similar studies conducted in Africa.[9,25] They also align with the findings from a large UK trial (PhysioDirect), although the intervention and comparison in this study were different to the current study. The results of the current study are important because remotely delivered physiotherapy may be more convenient than face-to-face physiotherapy for some patients and may help to reduce outpatient waiting times in public hospitals. Remotely delivered physiotherapy may also be less costly than face-to-face physiotherapy, although this is yet to be clarified through an economic analysis.

The interpretation of our results is dependent on a nominated non-inferiority margin, which was set at –15 points (where a negative value favoured usual care) on the primary outcome measure (the PSFS measured at 6 weeks) prior to commencing the trial and after careful consideration. We reasoned that the potential benefits of remotely delivered physiotherapy to both patients and service providers would justify the potential sacrifice for people with MSK doing worse by 15 points on the PSFS (than they would otherwise do with usual care). However, it was found that participants did not have worse outcomes with remotely delivered physiotherapy. The mean (95% CI) between-group difference in PSFS was 2.7 points (–3.5 to 8.8) favouring remotely delivered physiotherapy. The lower end of the 95% CI indicates that the potential sacrifice on the PSFS with remotely delivered physiotherapy was not greater than 3.5 points. The secondary outcome measures at both 6 and 26 weeks supported these findings. Whilst non-inferiority margins were not set for these outcomes, the 95% CI of the mean between-group differences ruled out clinically meaningful differences.

There are several caveats to the interpretation of these results. The most important caveat is that the findings may only be applicable to the types of patients who present at the five included hospitals with similar MSK conditions as those in this study. These five hospitals service areas of Sydney that are culturally and socioeconomically diverse, with a high percentage of people from non-English speaking

Table 4
Mean (SD) outcomes for each group, mean (SD) within-group difference and mean between-group difference (95% CI) for outcomes measured at all timepoints. Higher values indicate better results and a positive between-group difference favours the remotely delivered physiotherapy group, except where stated. The number of participants contributing data for each outcome is indicated in the top row, except for the number of participants contributing data for the Patient Specific Functional Scale at 6 and 26 weeks. These numbers are greater and indicated in the PSFS cells. The between-group differences reflect the results from the analyses with no imputation of missing data.

Outcome	Groups						Within-group difference				Between-group difference	
	Baseline		Week 6		Week 26		Week 6 minus baseline		Week 26 minus baseline		Week 6 minus baseline	Week 26 minus baseline
	Remotely delivered physiotherapy	Usual care	Remotely delivered physiotherapy	Usual care	Remotely delivered physiotherapy	Usual care	Remotely delivered physiotherapy	Usual care	Remotely delivered physiotherapy	Usual care	Remotely delivered physiotherapy minus usual care	Remotely delivered physiotherapy minus usual care
	(n = 104)	(n = 106)	(n = 90)	(n = 91)	(n = 74)	(n = 82)	(n = 90)	(n = 91)	(n = 74)	(n = 82)	(n = 181)	(n = 156)
PSFS *(0 to 100)*	35.8 (16.4)	33.8 (17.3)	57.3 (24.9) (n = 94)	52.2 (25.9) (n = 103)	58.4 (28.8) (n = 82)	57.7 (28.4) (n = 88)	21.6 (22.2) (n = 94)	18.5 (25.7) (n = 103)	21.5 (24.1) (n = 82)	22.8 (27.7) (n = 88)	2.7 (−3.5 to 8.8) (n = 197)	−1.8 (−9.3 to 5.6) (n = 170)
TSK *(17 to 68)* [a]	42.2 (6.0)	41.5 (7.1)	40.7 (6.7)	40.4 (7.9)	41.2 (7.4)	39.2 (7.8)	−1.2 (5.6)	−0.9 (5.4)	−0.5 (7.4)	−1.6 (6.2)	0.1 (−1.3 to 1.6)	1.7 (−0.2 to 3.6)
Pain VAS *(0 to 10)* [a]	4.6 (2.5)	4.6 (2.8)	4.2 (2.8)	4.2 (2.7)	4.2 (2.8)	3.8 (2.9)	−0.4 (2.5)	−0.4 (2.3)	−0.2 (2.5)	−0.7 (2.5)	0.1 (−0.5 to 0.8)	0.6 (−0.2 to 1.3)
EQ-5D-5L utility score *(−0.59 to 1)*	0.687 (0.259)	0.652 (0.285)	0.770 (0.230)	0.747 (0.248)	0.754 (0.284)	0.743 (0.291)	0.075 (0.251)	0.106 (0.203)	0.051 (0.253)	0.082 (0.224)	−0.009 (−0.064 to 0.047)	−0.022 (−0.092 to 0.048)
LLFDI-Function *(1 to 100)*	53.6 (11.7)	53.7 (11.3)	58.2 (13.8)	57.3 (13.2)	60.2 (17.4)	58.3 (14.5)	4.2 (7.6)	3.6 (7.5)	4.8 (11.2)	4.9 (9.4)	0.2 (−1.9 to 2.3)	−0.6 (−3.7 to 2.5)
LLFDI- Disability *(1 to 100)*	49.5 (6.4)	50.1 (6.7)	49.7 (6.5)	49.3 (7.3)	49.5 (6.1)	49.8 (7.1)	−0.1 (6.6)	−0.7 (5.1)	−0.7 (6.3)	0.2 (4.6)	0.5 (−1.1 to 2.1)	−0.7 (−2.3 to 1.0)
LLFDI-Limitation *(1 to 100)*	62.1 (12.7)	62.5 (13.7)	65.5 (14.7)	62.7 (14.6)	65.4 (14.9)	62.6 (15.0)	2.9 (14.4)	−0.2 (11.0)	2.7 (14.5)	0.1 (15.5)	2.8 (−0.8 to 6.3)	2.6 (−1.5 to 6.8)

EQ-5D-5L = EuroQoL 5-Dimension Quality-of-Life Questionnaire, LLFDI = Late-Life Function & Disability Instrument, PSFS = Patient Specific Functional Scale, TSK = Tampa Scale for Kinesiophobia, VAS = visual analogue scale. Shaded cell = primary outcome.

[a] Lower values indicate better results and a negative between-group difference favours the remotely delivered physiotherapy group.

Table 5
Mean (SD) outcomes for each group and mean between-group difference (95% CI) for global impression of change and satisfaction. Higher values indicate better results and a positive between-group difference favours the remotely delivered physiotherapy group. The between-group differences reflect the results from the analyses with no imputation of missing data.

Outcome	Groups				Between-group difference	
	Week 6		Week 26		Week 6	Week 26
	Remotely delivered physiotherapy	Usual care	Remotely delivered physiotherapy	Usual care	Remotely delivered physiotherapy minus usual care	Remotely delivered physiotherapy minus usual care
	(n = 90)	(n = 91)	(n = 73)	(n = 82)		
Global impression of change *(−7 to 7)*	9.5 (2.7)	9.8 (2.6)	8.7 (3.7)	9.0 (4.2)	−0.4 (−1.1 to 0.3)	−0.5 (−1.8 to 0.7)
Satisfaction *(0 to 10)*	7.3 (2.8)	7.8 (2.7)	–	–	−0.6 (−1.4 to 0.2)	–

backgrounds (those with insufficient English were excluded). It would be interesting to now repeat this study with broader inclusion criteria; for example, including people with all types of MSK conditions, people on post-operative therapy protocols, people from rural or remote areas, people unable to speak English, children, and people presenting to physiotherapy at public and private facilities from a range of countries. The results of this study should help future trialists counteract concerns about reducing or removing face-to-face physiotherapy for these groups of patients within a carefully conducted and monitored clinical trial.

Another important caveat to the interpretation of these results is that the findings may only be valid in situations where usual care consists of a small number of face-to-face physiotherapy sessions similar to that provided in this study. The median number of face-to-face physiotherapy sessions was three (IQR 2 to 4). The results may have been different if participants received more face-to-face physiotherapy sessions as part of usual care. The study did not standardise usual care, mandate a minimum number of sessions, or place any restrictions around the type or amount of physiotherapy participants received before or after the 6-week intervention period. This study wanted to mimic what typically happens in Sydney public hospitals. It is possible that the participants received fewer treatments than would be offered elsewhere because of long waiting lists at the included public hospitals. The pressures on public hospitals make these results all the more pertinent. Any strategy to reduce waiting times for patients needs to be considered, and these results indicate the potential to treat an average of three patients through the model of remotely delivered physiotherapy for every one patient treated through face-to-face physiotherapy (this does not account for the small amount of time required to make two follow-up phone calls for each patient). Increasing the number of patients that can be treated would invariably reduce waiting times, enabling more patients to receive and benefit from physiotherapy.

Remotely delivered physiotherapy consisted of a package of different treatments including a home exercise program, text messages and phone calls; the relative importance of each component is unknown and it is possible that some components may be redundant. Notably, 88 of 104 participants in the usual care group received a home exercise program, although the provision of home exercise programs for participants in this group was left to the physiotherapists' discretion. Adherence to the home exercise program was greater in the usual care group (participants reported practising their exercises a median of 7 days/week) than in the remotely delivered physiotherapy group (participants reported practising their exercises a median of 4 days/week). There is no obvious explanation for this discrepancy, although it is possible that participants in the remotely delivered physiotherapy group provided a more accurate self-assessment of their adherence because they knew that their adherence data were collected via the app. Alternatively, those in the usual care group may have better adhered to their home exercise program because they felt more accountable with the additional face-to-face sessions. Regardless, the results indicate that 25% of participants from both groups reported practising their exercises fewer than three to four times per week. This aligns with the results of other studies, some of which report non-adherence rates as high as 65%.[43]

Table 6
Components of the interventions for the two groups.

Component	Groups	
	Remotely delivered physiotherapy	Usual care
Face-to-face sessions *(n)*, median (IQR)	1 (1 to 1)	3 (2 to 4)
Text messages sent *(n)*, median (IQR)	6 (6 to 6)	–
Phone calls received *(n)*, median (IQR)	2 (2 to 2)	–
Participants provided with a home exercise program *(n)*	104	88
Participants self-reported practising their home exercises *(sessions/wk)*, median (IQR)	4 (3 to 7)	7 (4 to 7)

Advice and support were another component of the remotely delivered physiotherapy. This can influence what patients believe to be true about their condition[2,44] and can foster strong values of self-management and feelings of empowerment.[43] Nonetheless, it is unknown whether the advice and support were critical to the results of the study. Interestingly, participants in the remotely delivered physiotherapy group had an average of eight points of contact with a physiotherapist over the 6 weeks, whilst those in usual care only had three. However, six of the eight points of contact for those in the remotely delivered physiotherapy group merely comprised an automated text message and two were relatively short phone calls (5 to 10 minutes). This is in contrast with the three points of contact for participants in the usual care group during the face-to-face physiotherapy sessions; each lasting between 30 and 45 minutes. So the overall time with a physiotherapist was greater for participants in the usual care group than the remotely delivered physiotherapy group. There are many issues like this that will be further explored in a process evaluation that was conducted alongside the trial and is currently being finalised.[4]

Some people with MSK conditions and physiotherapists may continue to prefer face-to-face physiotherapy regardless of the results of this study. However, there will be others who embrace the option of a remotely delivered physiotherapy model of care and will be reassured in the knowledge that outcomes will be similar, irrespective of the model of care. Of course, some may opt for a combination of the two models of care;[45,46] for example, they may opt for two face-to-face physiotherapy sessions over 6 weeks combined with two phone calls, the app and text messages. The results of the qualitative work performed in parallel with this study indicated that many people with MSK conditions welcomed fewer visits to their physiotherapists. [47] This can be for many different reasons, including less travel, less lost time and more flexibility to exercise at a convenient time. Importantly, there was no difference in participants' satisfaction with the two models of care provided in this study (see Table 5). One option moving forward in the light of the results of this study is to empower patients as far as possible to decide on the model of care they prefer once they have been fully informed about the pros and cons of each.[48] This would ensure that care is patient-centred and the service provided to patients meets their needs and expectations.[49] This may only be possible in certain settings and may require minor system changes to ensure that text messages can be automated and phone calls can be timetabled.

There were two important limitations to this study. First, there was a 26% loss to follow-up for secondary outcomes at 26 weeks.

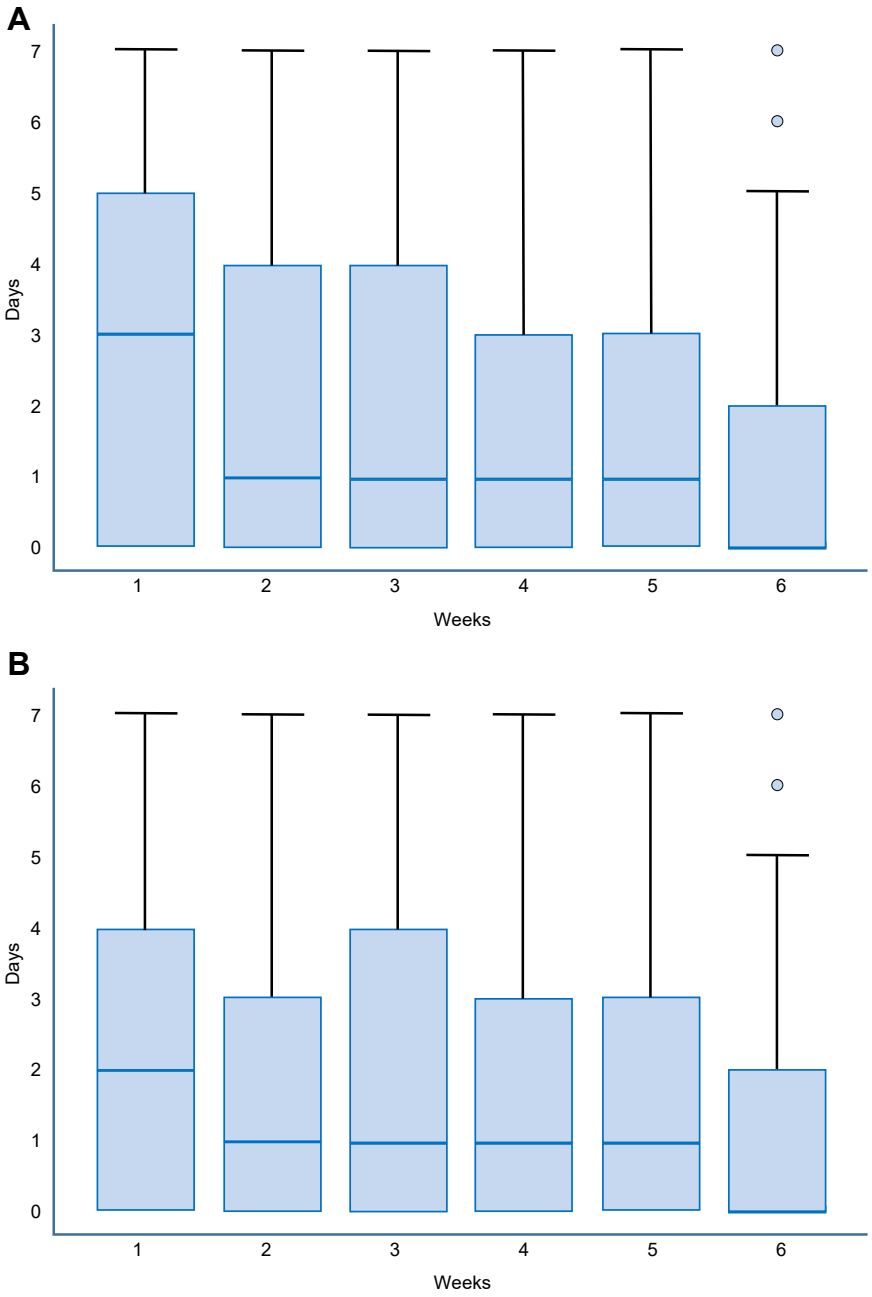

Figure 2. Record of exercise adherence collected via the app in the remotely delivered physiotherapy group. A. Median number of days on which participants did at least two exercises per day. B. Median number of days on which participants did at least six exercises per day.

There is no indication that those lost to follow-up were in any way systematically different to those not lost, but we cannot be sure. The loss to follow up at 26 weeks was primarily because participants were unwilling to perform the assessment (not because they were unable to be contacted or found). Nonetheless, there was very little loss to follow-up (only 6%) for the primary outcome at 6 weeks (the PSFS). Therefore, despite the high loss to follow up at 26 weeks, the primary findings are robust. The second limitation was the use of self-reported outcomes in non-blinded participants. We tried to minimise this potential problem by keeping participants naïve to the real purpose of the study. They were only told that two ways of providing physiotherapy were being compared. They were not led to believe that one way may be superior to another, and were not told that the purpose of the study was to determine whether one way of providing physiotherapy was as good as another. Interestingly, any potential bias would probably work in the opposite direction to the results, namely favouring usual care, because physiotherapists and participants tend to believe that face-to-face physiotherapy is superior to remotely delivered physiotherapy.[46]

Overall, the results of this trial support the use of remotely delivered physiotherapy for the treatment of some MSK conditions. These findings are important for giving researchers confidence to go on and further test this and similar models for different patients and in different clinical settings. Models of care that reduce patients' dependence on regular face-to-face physiotherapy may reduce waiting times for physiotherapy in places of high demand, thereby increasing access to physiotherapy for all people with MSK conditions.

What was already known on this topic: Many patients access face-to-face physiotherapy through government-funded hospitals, but there can be long waiting lists for this service.
What this study adds: Remotely delivered physiotherapy with support via phone, text and an app is as good as face-to-face physiotherapy for the management of musculoskeletal conditions. This could increase access to physiotherapy, reduce the burden on the healthcare system and benefit those who have difficulty regularly travelling to physiotherapy appointments.

***Footnotes*:** [a] REDCap, REDCap Consortium, Nashville, USA.

***eAddenda*:** Tables 1, 7 and 8 can be viewed online at https://doi.org/10.1016/j.jphys.2024.02.016.

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CHAPTER SIX: Health Economics analysis

6.1 Authorship attribution statement.

This statement is to outline the authorship contribution made by **Hannah Withers** to the following manuscript:

"Hayes AJ, **Withers HG,** Glinsky JV, Chu J, Jennings M, Hayes AJ, Starkey I, Parmeter R, Boulos M, Cruwys JJ, Duong K, Jordan I, Wong D, Trang S, Duong M, Hueiming L, Lambert TE, Zadro J, Sherrington C, Maher CG, Lucas BR, Taylor D, Ferreira ML, Harvey LA. Remotely delivered physiotherapy for musculoskeletal conditions: economic evaluation of the REFORM randomised trial."

During her PhD candidature Hannah Withers has contributed to:

- conception and design of the trial
- collection of the data
- analysis and interpretation of the findings
- drafting the manuscript

Hannah Withers Date: 17/12/2024

As supervisor for the candidature upon which this thesis is based, I can confirm that the authorship attribution statements above are correct.

Professor Lisa Harvey Date: 17/12/2024

6.2 Paper under peer-review

Title: Remotely delivered physiotherapy for musculoskeletal conditions is cost saving for the health system and patients: economic evaluation of the REFORM randomised trial.

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ABSTRACT

Question: Is remotely delivered physiotherapy cost-saving and cost-effective when compared with usual face-to-face outpatient physiotherapy as typically provided in Australian public hospitals?

Design: Economic evaluation embedded within a randomised controlled, non-inferiority trial and using a health system plus patient perspective.

Participants: Patients with musculoskeletal (MSK) conditions presenting to Sydney public hospitals for physiotherapy treatment.

Intervention: The REFORM trial was a randomised controlled trial comparing remotely delivered physiotherapy to usual care provided in an outpatient department setting. The remotely delivered physiotherapy involved one face-to-face physiotherapy session in conjunction with text messages, phone calls and an individualised exercise program delivered through an 'App'.

Outcome measures: The economic evaluation included the Patient Specific Functional Scale (PSFS) at 6 weeks in the cost-minimisation and cost-effectiveness analyses, and quality adjusted life years (QALYs) at 26 weeks in the cost-utility analysis. Health system and patient resource use were derived from patient self-report.

Results: Costs per participant over 6 weeks were $742 for remotely delivered physiotherapy and $910 for face-to-face physiotherapy with a mean cost difference of -$168 (95%CI, -$339 to $1). There was a 97.5% probability of remotely delivered physiotherapy being cost saving within the non-inferiority margin of the PSFS, and an 87.5% probability of being dominant to face-to-face physiotherapy (less costly and more effective). There was a 51.1% probability of being cost-effective at a nominal $50,000/QALY threshold.

Conclusion: Remotely delivered physiotherapy costs less than face-to-face physiotherapy and it is similarly effective and moderately cost effective.

INTRODUCTION

One in 3 people are affected by musculoskeletal (MSK) conditions such as back pain, osteoarthritis, shoulder injuries or ankle sprains [1]. They account for the 4th highest burden of disease globally [2]. In 2019 in Australia, MSK conditions were estimated to be the leading cause of years lived with disability [2] and accounted for 25% of the non-fatal disease burden [3]. This burden is expected to increase as the population ages [4]. In addition, MSK conditions cause the most time lost from work, and early retirement due to disability [5,6]. There are significant costs associated with the inability to attend work (absenteeism), and even greater costs related to attending work while underperforming due to pain or discomfort (presenteeism) [6]. The scale and implications of MSK conditions make it important to find effective and cost-effective ways of treating them.

Physiotherapy is a key treatment provided to people with MSK conditions. In Australia most physiotherapy for MSK conditions is provided through the private sector where patients pay for the service. This is reflected in the Australian workforce data indicating that 72% of physiotherapists work in the private sector [7]. Patients can also access physiotherapy at no cost through public hospitals but there are often long waiting times [7-9]. Consequently, those unable to pay for private physiotherapy have less access to timely care than those able to self-fund [10]. Similarly those who are geographically isolated or who have difficulty travelling to and from face-to-face physiotherapy appointments may be less likely to receive physiotherapy irrespective of whether accessing private or publicly funded care. All these factors that limit access to timely physiotherapy can compromise outcomes and result in increased pain, lower quality of life and greater use of health services [5].

We developed a model of remotely delivered physiotherapy to increase access to timely physiotherapy. The model involved one face-to-face physiotherapy appointment followed by text messages, phone calls and an individualised exercise program delivered through an 'App'.

We reasoned that this may increase the efficiency of delivering physiotherapy and thereby decrease waiting times, and it may be more convenient for some patients. Our model was based on prior studies that have used similar models of care [11-13]. It was also based on studies that have shown that the main factors that contribute to cost efficiency of remotely delivered physiotherapy are the need for fewer face-to face visits [14-17] and reduced travel costs [18,19].

We went on to conduct a randomised controlled non-inferiority trial comparing our model of remotely delivered physiotherapy with usual face-to-face physiotherapy typically delivered in public hospital outpatient departments in Sydney [11]. While remotely delivered physiotherapy proved to be as good as face-to-face physiotherapy for Patient Specific Functional Scale (PSFS) at 6 weeks, it was important to determine whether it saved money for the health systems and for patients. This information is critical to inform decisions about implementing remotely delivered physiotherapy in publicly funded hospital outpatient settings. Therefore the research question for this economic analysis was: Is a remotely delivered physiotherapy cheaper than face-to-face physiotherapy as delivered in a public hospital outpatient setting, and is it cost-effective? This economic question was investigated from a health system plus patient perspective and involved a cost-minimisation analysis and cost-effectiveness analysis at 6 weeks and cost-utility analysis at 26 weeks.

METHODS

Outcome Measures

Design

We conducted an economic evaluation alongside the REFORM trial. The aim of the economic evaluation was to compare the costs and benefits of remotely delivered physiotherapy with face-to-face physiotherapy, delivered in an outpatient hospital setting. A health system plus

patient perspective was chosen for the base case analysis, as physiotherapy was primarily provided in the public system and because patients also incurred out-of-pocket costs for health care, travel and time contributions to treatments. A health funder only perspective was investigated in a sensitivity analysis.

Participants

Participants from REFORM were included in the economic sub-study if they completed the resource use questions at 6 weeks and the EQ-5D-5L quality of life questionnaire at baseline, and either 6 weeks or 6 months.

Intervention

The REFORM trial was a randomised controlled (RCT), non-inferiority trial comparing remotely delivered physiotherapy to face-to-face physiotherapy provided in an hospital outpatient setting [11]. Briefly, patients who presented to a participating hospital with an MSK condition were screened for eligibility, recruited and randomly allocated to one of the two groups: remotely delivered physiotherapy or face-to-face physiotherapy. The remotely delivered physiotherapy group received one initial face-to-face physiotherapy session, which lasted for 1 hour. Participants were assessed by the physiotherapist and received an exercise program generated through www.physiotherapyexercises.com. The www.physiotherapyexercises.com website is freely available and enables physiotherapists to generate individualised exercise programs for their patients that can be sent to their mobile devices as an 'App'. Pre-programmed, supportive text messages were sent weekly to each participant and follow up phone calls were made at week 2 and week 4 by the physiotherapist.

The face-to-face physiotherapy group received standard face-to-face physiotherapy in an outpatient setting, as typically provided by outpatient physiotherapists. Face-to-face physiotherapy consisted of manual therapy, exercise prescription and education, as determined

by the treating physiotherapist. Initial sessions lasted for 45 -60 minutes with follow up sessions lasting for 30 minutes. Most patients received a total of 3 (2 to 4) sessions over the 6-week period [11].

The primary outcome for the trial was the Patient Specific Functional Scale (PSFS) measured at 6 weeks and the secondary outcome was QALYs. The full trial results have been published elsewhere [11].

Health Economic Analysis

Measurement of Costs

The costs of delivering remotely delivered physiotherapy and face-to-face physiotherapy were derived from trial records using a standard micro-costing approach. Health funder costs for remotely delivered physiotherapy included training, physiotherapists' time, the cost of clinical space, administrative costs, text messaging, phone calls and web hosting. For face-to-face physiotherapy, health funder costs included the cost of physiotherapy, clinical space, and administrative costs. Other healthcare use, such as general practitioner (GP) and specialist appointments, (not part of the trial) were self-reported by patients, and valued using standard Medical Benefits Schedule (MBS) scheduled fees.

Patient costs were self-reported by participants and completed via a telephone call at 6 weeks. This included costs associated with time taken to attend physiotherapy and other health care appointments, travel time, transport costs, parking, and costs of any health equipment such as exercise equipment or walking aids. Patient out-of-pocket costs for GP and specialists' visits were estimated from the gap amount that is charged in addition to what is covered by Medicare. Patient time contributions to treatments, including doing exercises at home and travelling to appointments was valued using a human capital approach and using average hourly wage rates.

All costs were valued in 2022 Australian Dollars (AUD) and no discounting was applied due to the short 6-month duration of the trial and follow-up.

Cost-minimisation and cost-effectiveness

A cost-minimisation analysis was conducted because the results of the primary trial showed that remotely delivered physiotherapy was non-inferior to face-to-face physiotherapy for the primary outcome: the Patient Specific Functional Scale (PSFS) at 6 weeks. A cost-minimisation analysis assesses only the difference in costs between the two groups, however, in order to examine uncertainty, non-parametric bootstrapping of 1000 cost and outcome pairs was generated to determine uncertainty intervals for incremental costs and outcomes. From the bootstrapped incremental costs, we determined the probability of remotely delivered physiotherapy being cost saving, within the non-inferiority margin of the PSFS. We also constructed a cost-effectiveness scatter plot which illustrates heterogeneity and from which we could determine the probability of the intervention being dominant to face-to-face physiotherapy (i.e. both cost-saving and more effective).

Cost-utility analysis

A cost-utility analysis was conducted over the period covering the active intervention and follow-up, using quality adjusted life-years (QALYs) gained at 26 weeks. Participants completed the EQ-5D-5L [20] quality of life questions at baseline, 6 weeks and 26 weeks via telephone with a blinded assessor. Utility values at each time-point were derived using the Australian valuation of EQ-5D-5L [21] and these were used to calculate the QALYs using the area under the curve approach. For two participants who did not have EQ-5D-5L data at 6 weeks, QALYs were determined from baseline and 26 weeks; for 27 participants who did not have EQ-5D-5L data at 26 weeks, utility scores at 6 weeks were carried forward to 26 weeks for calculation of QALYs. For each bootstrapped sample, incremental QALYs were adjusted for baseline differences in utility scores (**Appendix Table 5**) using regression methods [22]. The utility values for the

Australian valuation have a range of -0.301 (worse than death) to 1 (perfect health). As cost data were only collected during the active part of the trial (0-6 weeks), the calculation of incremental costs in this analysis assumes healthcare utilisation to be similar in both arms of the trial between 6 and 26 weeks.

Statistical Analysis/ Economic Analysis

All analyses were conducted in STATA v17. Code is available on request.

Uncertainty/Sensitivity analysis

Joint uncertainty in incremental costs and incremental outcomes was assessed by non-parametric bootstrapping of 1000 samples with replacement. Uncertainty intervals in costs and outcomes were derived from bootstrapped replicates, using the percentile method and replicates were plotted on a cost-effectiveness plane. We also carried out a sensitivity analysis in which we considered costs from the perspective of the health system only, as any future implementation may depend on decisions by health care providers.

This health economic evaluation was reported according to the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) [23] and the checklist may be found in Supplementary material.

RESULTS

There was a total of 210 participants at baseline in the REFORM trial, and a total of 177 (84.3%) participants were included in the economic evaluation sub-study (remotely delivered physiotherapy =88; face-to-face physiotherapy =89). Retention rates between baseline and 6 weeks were very similar in the remotely delivered physiotherapy group (84.6%) and in the face-to-face group (83.9%). Demographic and clinical characteristics of REFORM study participants at baseline and participants of the economic evaluation sub-study are shown in **Table 1**. Participants in the economic evaluation sub-study were very similar to those in the main

REORM trial in terms of mean age, work status, and duration since onset of injury. MSK conditions were predominantly back, knee and shoulder conditions and were similar in the economic evaluation to the primary study at baseline. At baseline, there were more female than male participants (61% in face-to-face physiotherapy, 70% in remotely delivered physiotherapy) and this was similar for the economic evaluation study (71% in face-to-face physiotherapy, 58% in remotely delivered physiotherapy).

Costs

A summary of the mean per patient costs and outcomes, and differences for remotely monitored physiotherapy and face-to-face physiotherapy is shown in **Table 2**. The overall mean (95%CI) cost difference for remotely delivered physiotherapy versus face-to-face physiotherapy in the base case perspective was -$168 (-$339 to $1); a $30 saving for the health funder and $138 saving for the patient.

Details of resource use for remotely delivered physiotherapy and face-to-face physiotherapy, by the health funder and patients, including all volumes and unit prices, are provided in **Appendices 1-4**. Sources of unit costs are shown in **Appendix 6**. Per participant health funder costs for remotely delivered physiotherapy over 6 weeks were $144 per participant, and for face-to-face physiotherapy were $174 per participant, a saving of $30 per patient (**Table 2**). Similarly, patient mean costs were lower in the remotely delivered physiotherapy group ($598) (**Table 2**) than the face-to-face physiotherapy group ($736), primarily due to travel time and other costs related to receiving treatment (**Appendix 3**). Other health care costs over the 6 weeks active intervention period were similar in both groups (**Appendices 2 &4**).

Cost-minimisation and cost-effectiveness

From a health funder plus patient perspective, the mean per patient cost of remotely delivered physiotherapy was $742 and for face-to-face physiotherapy was $910. The between group

difference in costs was -$168 at 6 weeks (favouring the remotely delivered physiotherapy group **Table 2**). The cost-effectiveness plane for the primary outcome indicates that the majority of the bootstrapped costs and outcomes lie below the horizontal axes representing a 97.5% probability of remotely delivered physiotherapy being cost-saving and non-inferior (**Figure 1**). When considering uncertainty in both costs and outcomes, remotely delivered physiotherapy was dominant to usual care with 87.5% of bootstrapped replicates indicating greater effectiveness and lower costs for the PSFS outcome. As most of the1000 bootstrapped replicates were in the south-east quadrant of the scatterplot (or the less costly and more effective quadrant) indicating that the intervention was dominant, incremental cost-effectiveness ratios were not calculated.

Cost Utility Analysis

The mean between group difference in QALYs at 26 weeks, after adjusting for baseline utility was -0.003 (**Table 2**). Bootstrapped replicates of incremental costs and incremental QALYs, fell mainly in the south-west and south-east quadrants, with 41% of bootstrapped replicates indicating that remotely delivered physiotherapy was less costly and more effective than face-to-face physiotherapy **(Figure 2).** The probability of remotely delivered physiotherapy being cost effective compared to face-to-face physiotherapy at a nominal $50,000 per QALY threshold was 51%.

Sensitivity Analysis

The sensitivity analysis indicated that when using a health system only perspective remotely delivered physiotherapy was still cost saving. There were mean (95% CI) savings of $30 (-$62 to $1) per participant, to the health funder and an 87.5% probability of remotely delivered physiotherapy being cost-saving compared to face-to-face physiotherapy. For the health funder perspective, the probability of the remotely delivered physiotherapy being cost-effective at a $50,000/QALY threshold was 41%. This scenario of changing the perspective made very little

difference to the probability of remotely delivered physiotherapy being cost-saving or cost-effective at the commonly used threshold of $50,000/QALY.

DISCUSSION

Implications and Limitations

In addition to being as good as face-to-face physiotherapy, this economic evaluation has shown that remotely delivered physiotherapy for patients with MSK conditions is also cheaper than face-to-face physiotherapy provided in an outpatient hospital setting. Regardless of the perspective taken (health funder plus patient or health funder only) there was a 97.5% probability of remotely delivered physiotherapy being cost-saving and non-inferior to face-to-face physiotherapy for the PSFS outcome at 6 weeks. Importantly, there were savings for patients as well as for the health care provider. In the cost-effectiveness analysis, the probability of REFORM being both less costly and more effective based on the PSFS outcome was high (88%). The probability of being cost-effective based on QALYs over a 6-month period was 51%. This finding of only moderate cost-effectiveness for the QALY outcome at 26 weeks, but highly effective and cost-saving for the clinical outcome of PSFS, suggests that health-related quality of life measured with the EQ-5D-5L is not picking up on subtle differences in patient function.

Strengths of the economic evaluation, include the prospective publication of the protocol, and its conduct alongside the rigorous randomised controlled non-inferiority REFORM trial. Individual patient data were collected during the trial, and uncertainty analyses completed which take account of patient heterogeneity. The primary perspective accounted for the time and costs of patient contributions to the management of their MSK condition, which was appropriate given the anticipated benefits of remotely delivered physiotherapy to productivity [17,24]. Additionally, a detailed micro-costing was undertaken, and reporting of the economic evaluation adhered to CHEERs best practice guidelines [23]. The detailed reporting of the health

system costs to deliver remotely delivered physiotherapy will help hospitals understand the financial implications of this model of care which will be important for future implementation.

This is one of only a handful of economic evaluations of remotely delivered physiotherapy for MSK conditions in Australia. A recent systematic review of the economic impact of telerehabilitation for MSK conditions, found 11 studies, of which only 2 were from Australia and they were not full cost-effectiveness studies [7]. Only three of the included studies measured patient costs [14,16,19]. Our inclusion of the patient perspective, and the finding of savings for patients adds to the literature in this area and may contribute to acceptability by patients of a blended model of care.

The high probability of remotely delivered physiotherapy being effective and cost saving aligns with two recent systematic reviews [7,17] which found that remotely delivered treatments for MSK conditions can achieve similar outcomes and are cheaper when traditional physiotherapy in a hospital outpatient setting is replaced or enhanced with remote methods of delivery.

One limitation of this study is the time horizon for the economic evaluation. Follow-up was limited to 6 months (the maximum duration of follow-up) and it is possible that the benefits of remotely delivered physiotherapy may extend beyond this time period. Additionally, the economic evaluation did not consider workplace productivity loss (absenteeism or presenteeism) due to the short-term nature of the trial. This might be expected to be substantial [1] and might impact on the results in this study if substantially different in each group. Longer term economic impacts and impacts on workplace productivity would be interesting to examine in future research. Additionally, resource use was self-reported by patients and may have been subject to bias.

The results of the trial and economic evaluation are limited to the provision of physiotherapy services in a public hospital outpatient setting, despite recruiting patients from multiple culturally and linguistically diverse sites in Sydney. Furthermore, the vast majority of

physiotherapists treating MSK conditions in Australia work in a private care setting [7]. Consequently, we cannot over generalise the results of the economic impact of this intervention outside the public hospital system, as the economic implications of remotely delivered physiotherapy may not be applicable in a private health setting. Future research could consider whether the same patient outcomes and economic benefits can be found in settings other than publicly funded hospital outpatient departments.

In conclusion, there is likely to be an economic benefit to both the health system and the patient, by moving some people with MSK conditions to a remote model of care without compromising on patient outcomes. This may reduce wait times for physiotherapy resulting in greater efficiency, increased access and more equitable provision of physiotherapy care.

Ethics approval*:* Ethical Approval was obtained on the 17 March 2017 from the Northern Sydney Local Health District HREC, trial number HREC/16HAWKE/431-RESP/16/287. An extension of ethical approval was obtained on 16 March 2022. Recruitment commenced in March 2019 and was completed in November 2022 with the last follow-up assessment completed in May 2023.

Provenance: Not invited. Peer reviewed.

Ethical Approval: Ethical Approval was obtained on the 17 March 2017 from the Northern Sydney Local Health District HREC, trial number HREC/16HAWKE/431-RESP/16/287. An extension of ethical approval was obtained on 16 March 2022. Recruitment commenced in March 2019 and was completed in November 2022 with the last follow-up assessment completed in May 2023.

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Figures and Tables

Table 1: Demographic and clinical characteristics of REFORM study participants at baseline and participants included in the Economic Evaluation sub study.

	REFORM Trial Baseline		Economic Evaluation Baseline	
Characteristic	Remotely delivered physiotherapy (n = 104)	Face-to-face physiotherapy (n = 106)	Remotely delivered physiotherapy (n=88)	Face-to-face physiotherapy (n=89)
Age *(yr)*, median (IQR)	52 (40 to 64)	56 (41 to 68)	52 (39 to 64)	57 (41 to 67)
Gender, n (%)				
Male	40 (38)	32 (30)	36 (41)	26 (29)
Female	63 (61)	74 (70)	51 (58)	63 (71)
Non-binary	1 (1)	0 (0)	1(0)	0(0)
Work status, n (%)				
Unemployed	58 (56)	61 (58)	50 (57)	53 (60)
Employed	40 (38)	41 (39)	34 (39)	34 (38)
Student	5 (5)	3 (3)	4 (5)	2 (2)
Unpaid carer	1 (1)	1 (1)	0(0)	0(0)
Duration since onset of injury, n (%)				
< 12 weeks	19 (18)	14 (13)	16 (18)	12 (13)
> 12 weeks	85 (82)	92 (87)	72 (82)	77 (87)
Type of MSK injury, n (%)				
Foot	3 (3)	1 (1)	1 (1)	3 (3)

Lower leg	6 (6)	8 (8)	7 (7)	4 (4)
Knee	23 (22)	25 (24)	23 (24)	21 (23)
Thigh	3 (3)	1 (1)	1 (1)	2 (2)
Hip	8 (8)	6 (6)	6 (6)	6 (7)
Hand	1 (1)	2 (2)	2 (2)	1 (1)
Forearm	2 (2)	2 (2)	2 (2)	2 (2)
Elbow	1 (1)	0 (0)	0 (0)	1 (1)
Shoulder	22 (21)	21 (20)	19 (20)	20 (22)
Back	29 (28)	34 (32)	30 (32)	26 (29)
Abdomen	1 (1)	1 (1)	1 (1)	1 (1)
Neck	5 (5)	5 (5)	4 (4)	3 (3)

Some percentages do not sum to 100 due to the effects of rounding.

Table 2: Mean (SD) costs (2022 AUD) and outcomes for remotely delivered physiotherapy and usual care and mean (95% CI) difference between the two groups.

	Remotely delivered physiotherapy (intervention) N=88	**Face-to-face usual care (control) N=89**	**Difference Intervention – control (Bootstrapped 95% CI)**
Health funder plus patient costs	742 (568)	910 (540)	-168 (-339 to 1)
Patient costs	598 (524)	736 (473)	-138 (-292 to 13)
Health funder total costs	144 (102)	174 (113)	-30 (-62 to 1)
PSFS at 6 weeks (points/100)	58.7 (24.0)	53.2 (25.6)	4.5 (-2.5 to 11.8)
QALYs over 26 weeks	0.377 (0.100)	0.368 (0.123)	-0.003 (-0.233 to 0.0191) [a]

[a] Incremental QALYs adjusted for baseline differences in utility scores

Figure 1: Incremental cost effectiveness plane for primary outcome (PSFS%) gained.

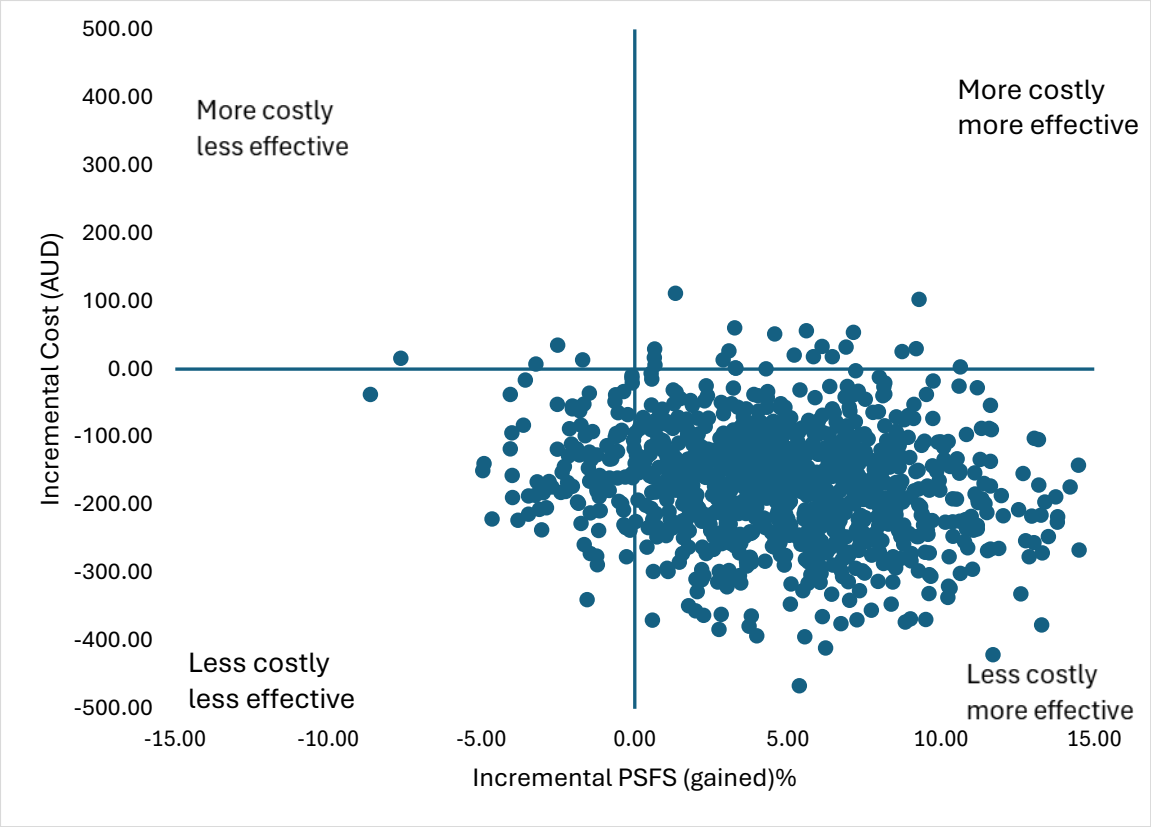
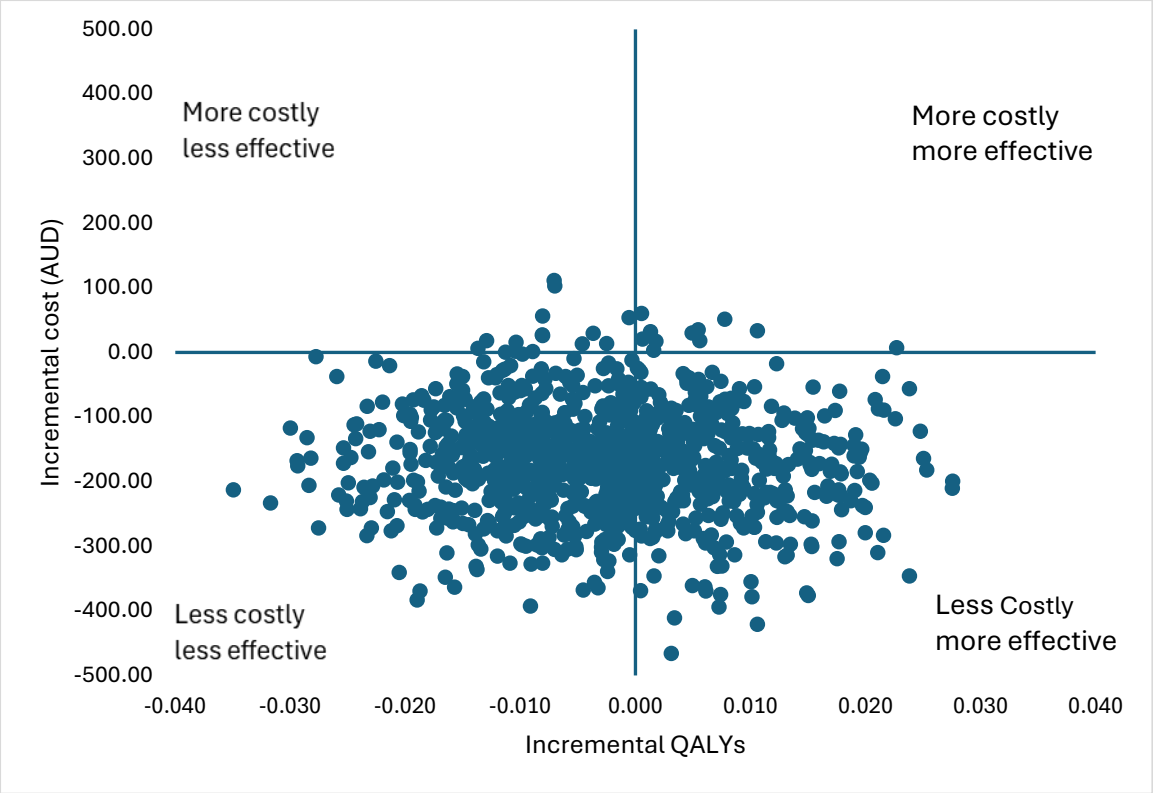


Figure 2: Incremental Cost Effectiveness Plane per QALY gained.



CHAPTER SEVEN: Discussion

7.1 Key Findings

The overarching aim of this thesis was to investigate whether remotely delivered physiotherapy could achieve outcomes that were as good or better than usual care physiotherapy for people with MSK conditions that can be treated with exercise, support and advice.

This thesis presents research consisting of 2 protocols and 3 studies that were designed to (i) identify the attitudes and perceptions of patients', physiotherapists' and stakeholders' about remotely delivered physiotherapy (ii) investigate whether remotely delivered physiotherapy was as good or better than usual care physiotherapy and (iii) determine the cost effectiveness of remotely delivered physiotherapy.

The key findings were:

1. Patients are more accepting of the idea of remotely delivered physiotherapy than physiotherapists think, and patients reported high satisfaction with service delivery.
2. Remotely delivered physiotherapy is as good as usual face-to-face physiotherapy as typically provided in a public hospital outpatient department.
3. Remotely delivered physiotherapy is a cost saving and cost-effective way of providing physiotherapy to some patients with MSK conditions.

7.2 Overview

Patients are more accepting of the idea of remotely delivered physiotherapy than physiotherapists think, and patients reported high satisfaction with service delivery.

Chapter 4 presented a qualitative study examining whether or not remotely delivered physiotherapy was likely to be accepted by patients and physiotherapists [92]. Forty semi-structured interviews were conducted, asking questions about the attitudes and beliefs that

patients, physiotherapists and stakeholders held about remotely delivered physiotherapy. Six main themes were extracted. Firstly, remotely delivered physiotherapy is more convenient for some patients. Secondly, some patients' expectations for physiotherapy will not be met with remotely delivered physiotherapy. Thirdly, remotely delivered physiotherapy is not suitable for every patient with a MSK condition. Fourthly, remotely delivered physiotherapy may reduce personal connections and patients' accountability for adhering to home exercise programs. Fifthly, remotely delivered physiotherapy can affect physiotherapists' workloads and finally, there are barriers and facilitators to rolling out this intervention.

The likely barriers and facilitators to rolling out this intervention included whether or not a physiotherapist was confident in identifying the types of patients and conditions that were appropriate for remote treatment. Additionally, for remotely delivered physiotherapy to be successfully introduced into outpatient departments, there must be support from management and it must be properly resourced. Physiotherapists must also be willing to acquire new skills to be able to effectively deliver treatment remotely for MSK conditions.

A surprising theme that emerged from this study was the idea that patients are more receptive to the idea of remotely delivered physiotherapy than physiotherapists believe. Patients reported high satisfaction with service delivery in addition to a willingness to forgo any potential benefit of face-to-face physiotherapy for the convenience of remotely provided treatment. Most patients, physiotherapists and stakeholders also reported that remotely delivered physiotherapy was only suitable to some patients.

Remotely delivered physiotherapy is as good as usual face-to-face physiotherapy as typically provided in a public hospital outpatient department.

Chapter 5 presents the findings from the randomised, controlled, non-inferiority trial which compared remotely delivered physiotherapy with usual face-to-face physiotherapy that was typically provided in a public hospital outpatients department. The primary aim was to

determine whether or not remotely monitored physiotherapy for MSK conditions was as good (or better) than face-to-face physiotherapy. The REFORM trial found that an initial face-to-face session, an individualised exercise program delivered through an app and supported with weekly text messages and 2 follow up phone calls is as good as a 6-week program of face-to-face physiotherapy as typically provided in a public hospital outpatient setting. The point estimate of the between group difference (95% CI) on the Patient Specific Functional Scale (PSFS) was 3% (-3% to 9%). The lower end of the 95% CI indicated that the potential sacrifice on the (PSFS) with remotely delivered physiotherapy was not greater than 3%. The mean and upper end of the 95% CI suggested that patients may even do better with this approach by 9%. There were no significant differences between the groups for the secondary outcomes which supported the findings from the primary outcome.

An interesting finding was that despite the use of text messages for motivation and an App, patients' adherence to their exercise programs was low. Data from the App indicated that participants only performed 2 or more exercises on a median (IQR) of 3 (0 to 5) days per week during the first week. This decreased to 1 (0 to 4) day per week by the second week and to 0 (0 to 2) days per week by week 6. This aligns with the results of other studies, some of which report non-adherence rates as high as 65% [93]. Interestingly, the self-reported data obtained during each phone call at week 2, 4 and 6 indicated a much higher rate of adherence. This contrast underscores the need for a more detailed understanding of the factors that influence patient adherence, and the importance of using multiple strategies to encourage adherence and improve accuracy when measuring adherence outcomes.

Remotely delivered physiotherapy is a cost saving and cost-effective way of providing physiotherapy to some patients with MSK conditions.

Chapter 6 presents the results of the health economics analysis which was embedded within the REFORM trial. A cost-minimisation analysis assesses only the difference in costs between

the two groups and was conducted because the results of the REFORM trial showed that remotely delivered physiotherapy was non-inferior to face-to-face physiotherapy. In addition to being as good as face-to-face care, remotely delivered physiotherapy was also found to be cost saving. When taking uncertainty into account, the probability of remotely delivered physiotherapy being cost saving and effective for the PSFS outcome was 97.5% and there was an 87.5% probability the REFORM intervention was dominant to usual care (less costly and more effective quadrant on the scatterplot). The probability of the intervention being cost-effective at a $50,000/QALY threshold was 51% for the QALY outcome, indicating that the intervention was moderately cost-effective.

7.3 Implications for practice

The studies in this thesis add to the growing body of evidence on models of care that empower people and reduce their reliance on regular face-to-face physiotherapy [94]. The findings are important because they can be used to inform patient care and improve the treatment strategies for some patients with MSK conditions. Remotely delivered physiotherapy is a practical and feasible treatment option that can be applied in a real-world setting.

Remote interventions have the potential to increase access to health services without compromising on patient outcomes. The REFORM qualitative study revealed that some hospital stakeholders believe that a remote method of service delivery can decrease wait times for treatment and can improve efficiency in outpatient departments because patients can access the service at a convenient time, and do not have to travel for appointments.

The findings from the PhysioDirect trial support the viability of remote care pathways in managing MSK conditions, emphasising the importance of accessibility and patient convenience [45]. By offering remotely delivered services such as the REFORM intervention, physiotherapists can potentially reach more patients, particularly those who may have difficulty attending in-person appointments due to distance, mobility issues, or time constraints. This can

help address disparities in access to care, especially for patients in rural areas or lower socioeconomic groups [95]. However, it is also important to consider that in order for remotely delivered physiotherapy to achieve good patient outcomes, and be accessible, patients must have a level of digital literacy and access to the required technology.

A central element of the REFORM intervention was facilitating exercise adherence. Despite the existing literature indicating that the use of text messages and Apps can potentially increase exercise adherence [58], reported adherence to the home exercise program was low. The REFORM trial deliberately included the use of an App to optimise patient adherence, however the results suggest that the App did not increase adherence. Additionally, patients' adherence decreased over the 6-week intervention period, indicating that the use of an App may not be sufficient on its own to ensure patients remain engaged and adhere to home exercise programs. Ongoing, more dynamic strategies may be necessary to help maintain long term adherence and maintain motivation over time such as real-time feedback, or continuous encouragement.

In contrast, the PEAK trial demonstrated a higher level of adherence in a digitally supported physiotherapy program. Participants in the digital intervention group actively engaged with the program, with 82% completing the majority of their prescribed exercises and adhering to the educational components [44]. As demonstrated by the REFORM trial, this level of adherence is not crucial for ensuring patient outcomes that are as good as face-to-face physiotherapy. The differences in adherence between the two trials suggest that the face-to-face videoconferencing component, likely contributes to optimising long-term patient adherence to remotely delivered exercise programs.

Themes that emerged from the qualitative study in **Chapter 4** are supported by existing literature which shows that advice and support can influence what patients believe to be true about their condition [15,96] and can foster strong values of self-management and feelings of empowerment in patients [93]. Clinically, this suggests that remote interventions must include

components of advice and support, as this may be as important, if not more so, than exercise adherence for successful treatment outcomes in MSK conditions. The results of the REFORM trial showed that remotely delivered physiotherapy was as good as usual care and the study findings indicate that some importance should be placed on including support and advice as a component of the treatment for MSK conditions.

In addition to demonstrating non inferiority for patient outcomes, remotely delivered physiotherapy was cost-saving from both a health provider and patient perspective. There were less out of pocket costs and travel for the patient, and the remote delivery of physiotherapy was less expensive. The intervention was deliberately designed to be accessible for most patients, requiring only a smart device and an internet connection. The App was free, user-friendly and easy to navigate, which minimised the need for extensive training, and patients could be taught how to use the App during their initial face-to-face physiotherapy session. Other economic implications could include improved resource allocation for publicly funded physiotherapy providers, leading to more patients being able to access treatment and greater health system efficiency. These features make remotely delivered physiotherapy a potentially simple and effective option for the treatment of some MSK conditions.

However, as highlighted in the qualitative study in **Chapter 4**, one important implication of remotely delivered physiotherapy is that physiotherapists must have experience in treating MSK conditions and be confident in providing appropriate advice and support over the telephone. Clinically, this emphasises the need for physiotherapists delivering remote care to be well-trained and proficient in offering effective guidance, ensuring that patients receive the necessary support in the absence of face-to-face treatment.

7.4 The Current Evidence Base:

Since the conception of the REFORM trial, there have been many studies which have demonstrated that remotely delivered physiotherapy can be as good as face-to-face

physiotherapy for certain MSK conditions, provided that the programs are thoughtfully designed and implemented. Challenges such as digital literacy, access to technology, and the need for ongoing motivation strategies remain areas for further research and development. Several recent studies have contributed to the body of evidence that supports the use of videoconferencing to deliver physiotherapy [44,95]. Additionally, a recent Delphi review developed a framework which aims to inform physiotherapy curricula, guide professional development in telehealth, and assist physiotherapists in delivering quality telephone-based care [97].

One pilot study evaluated the feasibility of a hybrid face-to-face and remote approach to treatment for patients with rheumatoid arthritis and spondyloarthritis. The study involved using a mobile phone App to collect electronic patient-reported outcomes over a 3-month period [98]. While this study concluded that integrating digital health solutions into clinical practice is feasible for chronic inflammatory conditions, there is a lack of evidence investigating a hybrid approach to the treatment of MSK conditions.

Hybrid models of care that combine in-person and digital physiotherapy interventions, provide a versatile and effective approach to managing musculoskeletal conditions. By enhancing accessibility, patient engagement, and clinical outcomes, these models represent a valuable evolution in physiotherapy care delivery. The REFORM trial has aimed to enhance the limited evidence that is currently available in this area.

In all, the findings from this body of work support the use of remotely delivered physiotherapy for the treatment of some MSK conditions. Understanding the clinical implications of remotely delivered physiotherapy can help physiotherapists and healthcare administrators ensure that the intervention is delivered correctly, that patients are adequately supported, and that resources are used effectively to achieve the best possible outcomes.

7.5 Suggestions for future research

The findings from the REFORM trial are important for giving researchers the confidence to go on and further test this and similar models of care for different patients and in different clinical settings. A Process Evaluation conducted alongside the REFORM trial is currently being finalised. It will expand on the qualitative study presented in this thesis in **Chapter 4** and will explore questions about the fidelity of the intervention. It will also attempt to identify the facilitators and barriers to rolling out this intervention. **Chapter 3** of this thesis presents the Process Evaluation protocol which describes the study [99].

Given that the REFORM intervention has been shown to be as good as usual care and cost-saving, the next step would be to design a study focused on developing an implementation strategy to roll out this intervention across a wider range of hospitals in Australia [14]. Such a study would help facilitate the adoption and delivery of remotely delivered physiotherapy, ensuring its integration into routine practice. It could also address barriers to implementation, such as changes needed in physiotherapist behaviour and practice.

Specifically, this research could increase physiotherapists' willingness and confidence in providing remote physiotherapy for MSK patients, ultimately reducing the dependency on face-to-face treatment while maintaining high-quality care. In addition, the detailed micro-costing of the REFORM intervention helps to understand the financial implications of rolling out this intervention more broadly. An implementation study would provide crucial insights into how remotely delivered physiotherapy can be effectively adopted and sustained within real-world healthcare settings. It would help healthcare providers, policymakers, and researchers understand the practical challenges and opportunities for integrating this intervention into routine care, potentially improving access to physiotherapy services with more people able to access the care they need [100].

Another recommendation for future research is to design a study that can include different populations. Due to time constraints and budget, only patients who could speak and read English were able to be included in the REFORM trial. Including people from non-English speaking backgrounds, Aboriginal and Torres Strait Islander communities, younger people, or private patients will allow greater generalisations to be made about the effectiveness and cost effectiveness of remotely delivered physiotherapy. Another consideration would be to test if remotely delivered physiotherapy remains as effective as usual care in public hospitals that routinely provide more than 3 face-to-face sessions as a comparison. Patients from a private physiotherapy setting may also benefit from an option for remotely delivered physiotherapy now that there have been changes made to payment structures for the billing of physiotherapy.

A final recommendation for future research is looking at alternate ways of providing remotely delivered physiotherapy. In addition to the aforementioned examples, it might be worthwhile to evaluate the effectiveness of group sessions using remotely delivered physiotherapy. One scoping review by Wallace et al, (2021) found that there was only a very small number of studies (n=2) available looking at effectiveness and cost effectiveness of providing group treatments remotely [65]. The included studies did not specify if the population only had MSK conditions, although a common theme that emerged was that patients found a benefit in the shared experience, pain validation and peer support. These findings indicate that a randomised controlled trial investigating remotely delivered physiotherapy to groups with a qualitative component embedded, could potentially identify benefits in addition to functional outcomes, such as increasing accessibility, increasing exercise adherence and decreasing wait times.

These suggested research avenues could help refine and optimise remotely delivered physiotherapy, ensuring it becomes an even more accepted and accessible option for patients while addressing challenges related to adherence, cost-effectiveness, and patient engagement.

7.6 Conclusion

The key findings of this thesis show that remotely delivered physiotherapy for people with some MSK conditions is as good as face-to-face physiotherapy as typically provided in outpatient settings at public hospitals in Sydney. These findings are important because remotely delivered physiotherapy may be more convenient for patients, may increase access to services and is less expensive, compared to face-to-face physiotherapy.

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APPENDICES

Appendix 1: Text messages sent each week to the Supported Home exercise Group. All participants randomised to the Supported Home Exercise Group will receive the following text messages each week of their 6-week exercise program (Chapter 2)

Appendix 2: Description of the intervention based on the TIDieR checklist (Chapter 2 and Chapter 5)

Appendix 3: Visit schedule for Study (Chapters 2 and 5)

Appendix 4: Interview questions (Chapters 3 and 4)

Appendix 5: Coding Tree (Chapter 4)

Appendix 6: Table 6 and 7 The results for the analyses repeated with multiple imputation (Chapter 5)

Appendix 7: CHEERS checklist for Health economic evaluation reporting (Chapter 6)

Appendix 8: Tables 1-4 Resource use for intervention delivery for remotely delivered physiotherapy and face-to-face physiotherapy. (Chapter 6)

Appendix 9: Table 5 Mean (SD) utility scores measured with the EQ-5D-5L for patients in remotely delivered physiotherapy and face-to-face physiotherapy, measured at baseline, 6 and 26 weeks.

Appendix 10: Table 6 Costs and sources (Chapter 6)

Appendix 1

Table 2: Text messages sent each week to the Supported Home exercise Group. All participants randomised to the Supported Home Exercise Group will receive the following text messages each week of their 6-week exercise program.

Week One	"You've got the hang of all your exercises, keep it up."
Week Two	"You're doing well. Remember to complete your exercises each day."
Week Three	"All of your effort will pay off in the long run. Keep exercising!"
Week Four	"You're already half way through. Keep up the hard work."
Week Five	"Almost there. One week to go. Keep going with recording your exercises"
Week Six	"Well done! You have completed 6 weeks of home exercises!"
Week Six Reminder	"Your 6-week phone call is coming up!"
Week 26 Reminder	"Reminder! Your 26-week call is coming in the next few days."

Appendix 2: A detailed description of the intervention is outlined according to the Template for Intervention Description and Replication (TIDieR) checklist.

Checklist Item	Remotely delivered physiotherapy	Usual care
	Setting: Home	*Setting*: Outpatients
Brief Name:	Supported Home Exercises Group	Face-to-Face Group.
Why:	Exercise, support and advice are considered core components of management for most MSK conditions. Exercise can be provided remotely as part of a home exercise program while support and advice can be provided over the telephone.	Pragmatic trial design
What:		
Materials for Therapists	A detailed protocol outlining the trial procedures. Knowledge on accessing and devising and exercise programme using www.physiotherapyexercises.com and creating an App to monitor adherence. Programming test messages using a website. Study phone for follow up phone calls.	A detailed protocol. Provision of physiotherapy in a public hospital outpatient setting.
Materials for Participants	Device such as a smart phone or tablet. Access to the internet. Participants were provided with an exercises programme and an App to monitor adherence.	Participants were provided with outpatient usual care.
Who provided	Trial physiotherapist who is a PhD candidate at University of Sydney.	Physiotherapists employed at the study site hospitals.
How	Initial face-to-face session for assessment and exercise prescription.	Face-to-face physiotherapy consisting of usual care.
Where	Initially on site in a study hospital in the outpatient department, then in the participants' home environment.	Onsite at a study hospital in the outpatient department.
When and How much?	One initial session lasting Approximately one hour Participants were asked to exercise on their own each day. The trial physiotherapist called at week 2 and week 4 to monitor adherence and give support and advice.	One initial session lasting Approximately one hour. Regular face-to-face physiotherapy sessions of up to one hour per session. The frequency was determined by the treating physiotherapist.

Tailoring:	Each participant prescribed an individualised exercise programme following an initial assessment by the trial physiotherapist.	Determined by the outpatient physiotherapist.
Modifications:	No modifications have been made.	Some modifications were made to usual care due to COVID-19 restrictions. Telehealth was the only treatment option for a small number of participants (5/106) while restrictions were in place.
Trial Fidelity:	Regular communication between the investigators and the sites, double data entry, team meetings and reviews of the protocol ensured trial fidelity.	Data detailing the type of treatments and number of sessions was be used to assess usual care.

Appendix 3 Table 4: Visit schedule for study

	Enrolment	**B/L Assessment**	**Allocation**							**Week 6 Assessment**	**HEQs**	**Week 26 Assessment**
	Day -7 to 0	Day 0	Day 0	Week1	Week2	Week3	Week4	Week5	Week6	Week 6	Week 6	Week 26
Visit Activity		Clinic								Ph	Ph	Ph
Eligibility	✓											
Informed Consent	✓											
Randomisation allocation			✓									
Face-to-face Physiotherapy				✓	✓	✓	✓	✓	✓		✓	
Supported Home Exercise				✓ (Text)	✓ (Text/ph)	✓ (Text)	✓ (Text/ph)	✓ (Text)	✓ (Text)		✓	
ASSESSMENTS												
PSFS		✓								✓		✓
TSK		✓								✓		✓
Pain		✓								✓		✓
PGIC		✓								✓		✓
PSHCSD		✓								✓		✓
EuroQol-5D		✓								✓		✓
LLFDI – function		✓								✓		✓

	Enrolment	**B/L Assessment**	**Allocation**							**Week 6 Assessment**	**HEQs**	**Week 26 Assessment**
LLFDI – disability (freq)		✓								✓		✓
LLFDI – disability (capability)		✓								✓		✓
AEs										✓		✓
Abbreviations: *PSFS: Patient specific functional scale. TSK: Tampa Scale for Kinesiophobia. PGIC: Patient Global impression of Change. PSHCSD: Patient Satisfaction with Health Care Service Delivery. LLFDI: Late Life Function and Disability Instrument. AEs: Adverse Events. PH: Phone. B/L: Baseline. HEQs: Health Economics Questions.*												

Appendix 4 Interview Guides:

The REFORM Trial

Version 5: Interview guides

Date: 10 June 2020

Revisions made by ARTD

Interview guide for participants

(Questions do not have to be asked in this order, and not all questions have to be covered.)

Hi, my name is [name] from ARTD Consultants. Thank you for taking part in this interview. ARTD has been commissioned by the Kolling Institute—who are comparing two different methods of delivering physiotherapy (face-to-face; and remotely monitored)—and they want to find out if the remotely monitored intervention was helpful compared to face-to-face physiotherapy.

We would like to ask you questions about your physiotherapy treatment. 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? I will keep the file in a secure location until we finish writing the report and then it will be destroyed. Our interview will be transcribed by one of our associates, and she has signed a confidentiality agreement to ensure your privacy and confidentiality. Would you like to suggest a pseudonym for us to use for the purposes of transcribing this 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.

(Interviewer please tick)

Face-to-Face Group (F2FG)? ☐ Supported Home Exercise Group (SHEG) ☐

Questions for the supported home exercise group (APP GROUP)

I am interested in exploring if the text messages and phone calls you received from the physio were helpful. The next questions will explore the care you received in greater detail. Please feel free to be honest about what it was like for you.

Treatment received

1. **Please tell me about your experiences overall of using the App for physiotherapy.**

   Prompts:

- What aspects of the experience do you like most, and why?
- What do you like least, and why?

2. **How convenient was your treatment?**

   Prompts:

- How convenient was it for you to attend the outpatient department for your initial assessment?
- How do you feel about not having to attend the hospital for ongoing treatment?

In this next part of the interview, I am going to explore what you thought of the three different ways the physio supported your rehabilitation in this trial.

3. **Firstly, I'd like to ask you about the text messages you received.**

   Prompts:

- Were they helpful?
- Did they motivate you to keep doing the exercises set by the physio? Why, or why not?

4. **Next I'd like to get your views about the follow-up phone calls (2-4 week call from Trial coordinator)**

   Prompts:

- What kinds of things did you talk about with the physio?
- How did you find the calls? What was helpful? What wasn't?

- Do you feel as though you got any benefit from the phone calls?

5. **Lastly, I want to discuss the Physiotherapy Exercises App.**

   Prompts:

   - 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?
   - How long did you use the App?
   - How long did you do the rehabilitation exercises? Why or why not?

Outcomes

6. **Having been in the trial what are the pros and cons of face-to-face treatment versus technology (App, texts, phone calls) for physiotherapy?**
7. **Would you recommend this method of delivering physiotherapy for others? What kinds of people would this approach suit? Who wouldn't it suit?**
8. **What else would you liked to have received as part of your physiotherapy treatment during the trial?**

   Prompts:

   - Do you have enough access to the physio?
   - How well was your physiotherapy individualised to your needs?
   - Were you able to discuss different treatment options with your physio?

Thank you so much for your time.

Questions for Patients in the face-to-face physiotherapy group.

1. **Please tell me about your experiences of physiotherapy treatment during the trial.**

   Prompts:

   - What aspects of the experience do you like most, and why?
   - What do you like least, and why?

2. **Now I'd like to ask you about how the treatment was managed.**

   Prompts:

   - Can you tell me about the process of scheduling appointments? What was the availability of your physiotherapist?
   - Did you always have the same person?
   - How convenient was it for you to travel to and attend physiotherapy sessions at the hospital?

- Can you comment on the frequency of your appointments?

3. **How did your physio make sure that the physiotherapy met your needs?**

   Prompts:

   - Were you able to readily discuss different treatment options with your physiotherapist?
   - What is it about seeing a physiotherapist in person that you like or don't like?

4. **How often did you have physiotherapy?**

   Prompt:

   - Is that what you expected? Why or why not?

Outcomes

5. **Would you recommend physiotherapy to others with a similar condition to yours? Why/ why not?**
6. **What else would you like to have received as part of your physiotherapy treatment?**

   Prompt:

   - Do you have enough access to the physio?

- How well was your physiotherapy individualised to your needs?

Thank you so much for your time.

Interview guide for healthcare professionals

(Questions do not have to be asked in this order, and not all questions have to be covered.)

Hi, my name is [name] and I'm from ARTD Consultants. Thank you for taking part in this interview. The Kolling Institute has asked us to talk with relevant stakeholders about how they can better care for people with some MSK conditions. 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 for agreeing to take part. We are interviewing physiotherapists who treat people with MSK conditions in an outpatient setting. We will use your feedback and the feedback of others to write a summary of what people have told us. There will be no identification of any real names or identification of where you live or which hospitals you work in or of the patients you see. We ask that you do not name any patients in our interview when discussing the kinds of treatment you provide.

Are you happy for me to record the interview? I will keep the file in a secure location until we finish writing the report and then it will be destroyed. Our interview will be transcribed by one of our associates, and she has signed a confidentiality agreement to ensure your privacy and confidentiality. Would you like to suggest a pseudonym for us to use for the purposes of transcribing this 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

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 REFORM trial.**

   Prompts:

   - What pleased you about the trial?
   - What surprised you?

- What were your concerns?
- What would you do differently?

3. **How did the physios 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 rollout

5. **On the basis of your experience in the trial, how easy do you think it will be to introduce delivering physiotherapy through an App in a hospital setting?**
6. **Given the COVID-19 crisis, which has forced a move to telehealth, are there any lessons from the trial that have informed physios' response to the current public health crisis? Has the COVID-19 crisis changed your or your colleagues' attitudes towards delivering rehabilitation remotely?**
7. **Looking back on the approach used to deliver physiotherapy remotely in the trial – are there any aspects of the intervention that could have been delivered differently?**
8. **What is the potential for remote physiotherapy service delivery 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 remote physiotherapy as part of a suite of service options, from patients' perspectives?**

Prompts:

- What are the main advantages for patients in having physio rehab delivered through an App compared to usual practice?
- How acceptable is remote physiotherapy likely to be to those accessing physiotherapy in a public hospital? Why or why not?
- How much responsibility do you think should be on the individual for managing their own rehabilitation?

- What kinds of patients could be adequately monitored through text messages and phone calls?

10. **What are the pros and cons from a clinician's perspective?**

    Prompts:

    - How compatible/ acceptable will delivering physiotherapy through an App be to hospital physios?
    - What are the main advantages for physios in delivering physiotherapy rehabilitation through an App, compared to usual practice? What are the main disadvantages?

11. **What has to be in place for remote physiotherapy to be viable to deliver in the hospital setting?**

    Prompts:

    - What are some things that will make this hard/ easy?
    - Could remote physio 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 remote physiotherapy would have for patients; physiotherapists; for hospitals? (Ask about health, service access, cost savings for the hospital).**
13. **If the trial was found to be beneficial, 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 Heads of Department

(Questions do not have to be asked in this order, and not all questions have to be covered).

Hi, my name is [name] and I'm from ARTD Consultants. Thank you for taking part in this interview. The Kolling Institute has asked us to talk with relevant stakeholders about how their organisation can better care for people with some MSK conditions. 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 for agreeing to take part. We are interviewing stakeholders who work in various health care settings. We will use your feedback and the feedback of others to write a summary of what people have told us. There will be no identification of any real names or identification of where you live or which hospitals you work in or of the patients you see. We ask that you do not name any individuals in our interview when discussing the kinds of treatment or services you provide.

Are you happy for me to record the interview? I will keep the file in a secure location until we finish writing the report and then it will be destroyed. Our interview will be transcribed by one of our associates, and she has signed a confidentiality agreement to ensure your privacy and confidentiality. Would you like to suggest a pseudonym for us to use for the purposes of transcribing this interview?

Do you have any questions before we start?

Context: To understand the extent to which telerehabilitation will play a role in the service delivery of physiotherapy

Impact of COVID-19

The trial has coincided with the COVID-19 crisis. COVID-19 created a situation where tele-rehabilitation was the only option available to some clinicians and patients to continue treatment.

1. **How did you manage the move away from face-to-face treatment?**

   Prompts:

- Did you have the tools to manage this change in service delivery? Please describe.
- What were the pros and cons of delivering a service through these channels?

2. **How have clinicians reacted to delivering physiotherapy without face-to-face contact?**

- What worked well?
- What did clinicians find challenging?

3. **Now I'd like to get your views on managing the trial. How easy was it to coordinate and run this trial in the outpatient department?**

   Prompts:

   - What were the logistics of recruitment?
   - What were your concerns?
   - Did the demographics of the patients affect recruitment?
   - How long is the typical waiting list for face-to-face services?

4. **Given your hospital's experience with the trial and COVID-19, what lessons have you learnt about delivering physiotherapy remotely?**

   Prompts:

   - What place could the App have in a suite of services for outpatients needing physiotherapy?
   - What organisational changes would be needed for the App to become part of business-as-usual service delivery?
   - How likely are hospital executives to support the introduction of the App as a mode of service delivery?
   - How acceptable is remote physiotherapy likely to be to people accessing physiotherapy in a public hospital? Why or why not?
   - How much responsibility should be on the individual for managing their own rehabilitation?
   - What kinds of patients could be adequately monitored through text messages and phone calls?

5. **What is the potential for remote physiotherapy services to provide more patients with treatment sooner? How important is it to cut down waiting lists?**

6. **Is gaining timely access to health services and physiotherapy services in particular an issue for your patients and the wider community?**

   Prompts:

   - Are there any particular groups this affects more than others?

- Is remote service delivery a reasonable way to increase access to rehabilitation services? Why/ why not?

7. **What are the types of services that telerehabilitation might impact?**

   Prompts:

- What impact would telehealth have on Inpatients, and on outpatients? And what impact would telehealth have on impatient area of hospital vs outpatient areas of hospitals, e.g. less people coming to outpatients, etc What impact would telehealth have on home-based physiotherapy? On group-based physiotherapy? On physiotherapy delivered through classes?

8. **Does telerehabilitation have a role in service delivery post COVID-19?**

9. **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 stakeholders not in a hospital setting

Note - These stakeholders will not be familiar with the REFORM project.

(Questions do not have to be asked in this order, and not all questions have to be covered).

Hi, my name is [name] and I'm from ARTD Consultants. Thank you for taking part in this interview. ARTD has been commissioned by the Kolling Institute—who are comparing two different methods of delivering physiotherapy (face-to-face; and remotely monitored)—to talk with a range of stakeholders to explore their views on remotely monitored interventions and how they compare with face-to-face physiotherapy. 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 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 no identification of any real names or identification of where you live or which hospitals you work in or of the patients you see. We ask that you do not name any individuals in our interview when discussing the kinds of treatment or services you provide.

Are you happy for me to record the interview? I will keep the file in a secure location until we finish writing the report and then it will be destroyed. Our interview will be transcribed by one of our associates, and she has signed a confidentiality agreement to ensure your privacy and confidentiality. Would you like to suggest a pseudonym for us to use for the purposes of transcribing this interview?

Do you have any questions before we start?

Telehealth

1. **How does telehealth in its various forms fit with the strategic/ business plans for your organisation?**

   Prompts:

   - Do you have any funding models/ fee for service in place for the provision of telerehabilitation? How do these fees compare to standard face-to-face treatment, e.g. costs more/ costs less?
   - Is telerehabilitation a treatment option for Workers' compensation/ SIRA /Third party insurance claims?

If yes:

What kinds of telehealth are covered by these claims/ what types of treatment would they fund? e.g. videoconference consult? Fitbit with remote monitoring? What about mixed models, e.g. for an ACL an option might be to have face-to-face for testing and remote monitoring of exercises?

- (Only ask if the organisation is **not** currently using telehealth) What research evidence would you need to see before implementing any forms of telehealth? E.g. evidence that it works

2. What are the types of services that telehealth might impact?

Prompts:

- What impact would telehealth have on Inpatients, and on outpatients? And what impact would telehealth have on impatient area of hospital vs outpatient areas of hospitals, e.g. less people coming to outpatients, etc What impact would telehealth have on home-based physiotherapy? On group-based physiotherapy? On physiotherapy delivered through classes?

3. How easy do you think it will be to introduce delivering physiotherapy through an App – in a public health setting; in a private health setting?

Prompts:

- How acceptable is remote physiotherapy likely to be to those accessing physiotherapy in a public hospital? Why or why not?
- How acceptable is remote physiotherapy likely to be to those accessing physiotherapy in a private health setting? Why or why not?
- How beneficial do you think this intervention would be? If found to be beneficial, would you want to provide this intervention in the future?
- How does the App fit in with benchmarks for Allied Health and physiotherapy outcomes?
- How much responsibility do you think should be on the individual for managing their own health?
- What kinds of patients could be adequately monitored through text messages and phone calls?

4. **What is the potential for remote physiotherapy service to provide more patients with treatment sooner?**

   Prompts:

   - How important is it to cut down waiting lists?
   - How important is it cut down the length of time between the date of the injury and the onset of treatment?

5. **Have you observed any inequities in access to health services in your community, particularly access to physiotherapy services? Is accessing services difficult for any particular groups? If yes, how important is it that LHDs respond to such inequities? Why/ why not?**

Impact of COVID-19

I now want to talk about the impact of COVID-19. COVID-19 created a situation where telerehabilitation was the only option available to some clinicians and patients to continue treatment.

6. **What are your thoughts on a move away from face-to-face treatment?**

   Prompts:

   - What do you think the general opinion among clinicians is regarding using telerehabilitation to deliver physiotherapy?
   - What do you think patients think about using telerehabilitation to deliver physiotherapy?

7. **Do you think COVID-19 has had/ will have a long term/ permanent effect on how health providers look at service delivery?**
8. **Have there been any other changes to your service model due to the increased use of telerehabilitation because of COVID-19 restrictions?**

Context: To understand the perceived barriers/ facilitators for telerehabilitation

9. **What are some of the barriers or facilitators for health professionals in rolling out telerehabilitation?**

   Prompts:

   - What are some things that will make this hard/ easy?

- Can you foresee any loopholes that would need to be closed/ sorted out before rolling out the App?
- Would there be any safety or risk management concerns on an individual level, service level and/or organisational level?
- Can you foresee any data security or privacy issues, including the use of platforms for video conferencing, and where data is stored – could they be easily hacked, etc
- Can you foresee any issues re insurance/ indemnity arrangements?

10. **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.

Appendix 5: REFORM Trial - coding tree

Stakeholder type	Physiotherapist Patient – Supported home exercise program Patient – Usual care Heads of Department
Hospital	Campbelltown Blacktown and Mt Druitt Bankstown Liverpool Royal North Shore (not in the REFORM Trial)

Level 1	Level 2	Level 3
A. Describe the hospital's normal operation	A.1 Conditions seen A.2 Waitlist A.3 Processes for prioritising patients	
B. Suitability of remotely delivered physiotherapy (includes supported home exercise program)	B.1 For patients	B.1.1 Which patients would be/ were more willing to embrace it B.1.2 Which patients would not be/ were not willing to embrace it B.1.3 Health conditions/ type of patient for which it is appropriate B.1.4 Health conditions/ type of patient for which it is not appropriate B.1.5 Benefits for patients B.1.6 Disadvantages for patients
	B.2 For clinicians	B.2.1 Worked well/ facilitators to take up B.2.2 Barriers B.2.3 Advantages for clinicians B.2.4 Disadvantages for clinicians B.2.5 Relevance to practice B.2.6 Acceptability
	B.3 For hospitals	B.3.1 Facilitators B.3.2 Barriers B.3.3 Advantages B.3.4 Do not support or neutral about telehealth for rehab B.3.5 Support telehealth for rehab
C. Recruitment for the Trial	C.1 Enablers	
	C.2 Difficulties	
D. Trial coordination	D.1 About the Trial coordinator's role	D.1.1 Positive D.1.2 Negative D.1.3 Not satisfied D.1.4 Do differently
	D.2 Role of Trial coordinators within the hospital	D.2.1 Positive D.2.2 Negative D.2.3 Do differently

E. The Trial	E.1 Initial assessment	E.1.1 Helpful/ Positive E.1.2 Not helpful/ Negative E.1.3 Other information needed E.1.4 Found surprising
	E.2 Text messages	E.2.1 Helpful/ Positive E.2.2 Not helpful/ Negative E.2.3 Other information needed
	E.3 Phone calls	E.3.1 Helpful/ Positive E.3.2 Not helpful/ Negative E.3.3 Other information needed
	E.4 Final contact with Hannah/ physio	E.4.1 Helpful/ Positive E.4.2 Not helpful/ Negative E.4.3 Other information needed
	E.5 Seeing physios at the hospital (usual care group)	E.5.1 Helpful/ Positive E.5.2 Not helpful/ Negative E.5.3 Other information needed
	E.6 Experiences overall	E.6.1 Satisfied E.6.2 Not satisfied E.6.3 Other information needed/ other support needed/ anything that could have been delivered differently
F. Future of the Trial re implementation or not	F.1 Feasibility	F.1.1 Barriers F.1.2 Facilitators F.1.3 Feasible F.1.4 Not feasible
	F.2 Acceptability	F.2.1 Barriers F.2.2 Facilitators F.2.3 Acceptable approach F.2.4 Not acceptable
G. Impact of COVID	G.1 On clinicians' attitudes to delivering telehealth	G.1.1 Positive impact G.1.2 Negative impact G.1.3 Neutral impact

	G.2 On hospital	G.2.1 Positive impact G.2.2 Negative impact G.2.3 Neutral impact
H. Good quotes		

Appendix 6: Table 7 The results for the analyses repeated with multiple imputation

Outcome	Between-group difference	
	Week 6 minus baseline	Week 26 minus baseline
	Remotely delivered physiotherapy minus Usual care	Remotely delivered physiotherapy minus Usual care
PSFS *(0 to 100)*	2.6 (-3.8 to 8.9)	-1.6 (-9.2 to 6.0)
TSK *(17 to 68)* [a]	0.1 (-1.4 to 1.6)	1.9 (-0.1 to 3.8)
Pain VAS *(0 to 10)* [a]	0.1 (-0.5 to 0.8)	0.6 (-0.1 to 1.3)
EQ-5D-5L utility score *(–0.59 to 1)*	-0.008 (-0.063 to 0.047)	-0.019 (-0.089 to 0.051)
LLFDI-Function *(1 to 100)*	0.3 (-1.8 to 2.4)	-0.5 (-3.6 to 2.6)
LLFDI- Disability *(1 to 100)*	0.5 (-1.0 to 2.1)	-0.7 (-2.3 to 0.9)
LLFDI-Limitation *(1 to 100)*	2.9 (-0.6 to 6.4)	2.5 (-1.6 to 6.7)
Global impression of change (–7 to 7)	-0.3 (-1.1 to 0.4)	-0.5 (-1.7 to 0.7)
Satisfaction (0 to 10)	-0.5 (-1.3 to 0.3)	-

EQ-5D-5L – EuroQoL 5-Dimension Quality-of-Life Questionnaire, LLFDI = Late-Life Function & Disability Instrument, PSFS = Patient Specific Functional Scale, TSK = Tampa Scale for Kinesiophobia, VAS = visual analogue scale. Shaded cell = primary outcome.

[a] Lower values indicate better results and a negative between-group difference favours the experimental group.

Appendix 7: CHEERS (2022) Checklist REFORM

	Item	Guidance for Reporting	Reported in page #
TITLE			
Title	1	Identify the study as an economic evaluation and specify the interventions being compared.	1
ABSTRACT			
Abstract	2	Provide a structured summary that highlights context, key methods, results and alternative analyses.	5
INTRODUCTION			
Background and objectives	3	Give the context for the study, the study question and its practical relevance for decision making in policy or practice.	6
METHODS			
Health economic analysis plan	4	Indicate whether a health economic analysis plan was developed and where available.	doi: 10.1136/bmjopen-2020-041242.
Study population	5	Describe characteristics of the study population (such as age range, demographics, socioeconomic, or clinical characteristics).	Table 1, page 17-18
Setting and location	6	Provide relevant contextual information that may influence findings.	6
Comparators	7	Describe the interventions or strategies being compared and why chosen.	7,8
Perspective	8	State the perspective(s) adopted by the study and why chosen.	5,7,9
Time horizon	9	State the time horizon for the study and why appropriate.	12
Discount rate	10	Report the discount rate(s) and reason chosen.	8
Selection of outcomes	11	Describe what outcomes were used as the measure(s) of benefit(s) and harm(s).	7,8
Measurement of outcomes	12	Describe how outcomes used to capture benefit(s) and harm(s) were measured.	9
Valuation of outcomes	13	Describe the population and methods used to measure and value outcomes.	9
Measurement and valuation of resources and costs	14	Describe how costs were valued.	Appendix tables 1-4
Currency, price date, and conversion	15	Report the dates of the estimated resource quantities and unit costs, plus the currency and year of conversion.	8
Rationale and description of model	16	If modelling is used, describe in detail and why used. Report if the model is publicly available and where it can be accessed.	NA
Analytics and assumptions	17	Describe any methods for analysing or statistically transforming data, any extrapolation methods, and approaches for validating any model used.	NA
Characterizing heterogeneity	18	Describe any methods used for estimating how the results of the study vary for sub-groups.	NA
Characterizing distributional effects	19	Describe how impacts are distributed across different individuals or adjustments made to reflect priority populations.	NA
Characterizing uncertainty	20	Describe methods to characterize any sources of uncertainty in the analysis.	11
Approach to engagement with patients and others affected by the study	21	Describe any approaches to engage patients or service recipients, the general public, communities, or stakeholders (e.g., clinicians or payers) in the design of the study.	NA
RESULTS			
Study parameters	22	Report all analytic inputs (e.g., values, ranges, references) including uncertainty or distributional assumptions.	Table 2, Appendix tables 1-4 page 19
Summary of main results	23	Report the mean values for the main categories of costs and outcomes of interest and summarise them in the most appropriate overall measure.	Table 2 page 19
Effect of uncertainty	24	Describe how uncertainty about analytic judgments, inputs, or projections affect findings. Report the effect of choice of discount rate and time horizon, if applicable.	11 SA
Effect of engagement with patients and others affected by the study	25	Report on any difference patient/service recipient, general public, community, or stakeholder involvement made to the approach or findings of the study	NA
DISCUSSION			

Study findings, limitations, generalizability, and current knowledge	26	Report key findings, limitations, ethical or equity considerations not captured, and how these could impact patients, policy, or practice.	11, 12,13
OTHER RELEVANT INFORMATION			
Source of funding	27	Describe how the study was funded and any role of the funder in the identification, design, conduct, and reporting of the analysis	13
Conflicts of interest	28	Report authors conflicts of interest according to journal or International Committee of Medical Journal Editors requirements.	COI forms

Husereau D, Drummond M, Augustovski F, de Bekker-Grob E, Briggs AH, Carswell C, Caulley L, Chaiyakunapruk N, Greenberg D, Loder E, Mauskopf J, Mullins CD, Petrou S, Pwu RF, Staniszewska S; CHEERS 2022 ISPOR Good Research Practices Task Force. Consolidated Health Economic Evaluation Reporting Standards 2022 (CHEERS 2022) Statement: Updated Reporting Guidance for Health Economic Evaluations. BMJ. 2022;376:e067975.

Appendix 8 (Tables 1-4)

Table 1 Resource use for intervention delivery for remotely delivered physiotherapy and face-to-face physiotherapy

HEALTHCARE PROVIDER COSTS – INTERVENTION DELIVERY	Remote Care (n = 88)				Usual care (n = 89)			
Resource items	**Unit cost**	**Units per participant**	**N participants (%)**	**Total cost**	**Unit cost**	**Units per participant**	**N participants (%)**	**Total cost**
Training for REFORM staff	$34.5 per hour	5 hours to manage all trial participants	-	172.50	-	-	-	-
Trainer costs - cost of staff providing training for REFORM staff	$57.7 per hour	5 hours to provide the training	-	288.50	-	-	-	-
Visits to a physiotherapist (as part of the trial) - fees	$34.5 per hour	1 visit of duration 1 hour	88	3036.00	$34.5 per hour	3.2 visits, total duration1.86 hours	89	5701.13
Clinical space for physiotherapy (as part of the trial)	$10 per hour	1 visit duration 1 hour	88	880.00	$10 per hour	3.2 visits total duration 1.86 hours	89	1652.50
Admin costs	$40.0 per hour	.25 hours per visit	88	880.00	$40.0 per hour	3.2 visits total duration 0.8 hours	89	2860.00
Text messaging	$.1 per text message	5.4 text messages	88	47.90		-	-	-
Phone calls - received	$5.0 per phone call	1.9 calls	88	845.30		-	-	-
Phone calls - missed	$2.9 per missed phone call	3.4 calls	88	858.40	-	-	-	-
Paper copy of home exercise programs					$5 per copy	1 home exercise program	84	420.00
Server and hosting costs for the PTX exercise software	$5 unlimited access exercise App (estimated)	1	88	440.00				
TOTAL HEALTHCARE				**7448.60**				**10633.63**

PROVIDER COSTS - INTERVENTION								
Mean per patient cost				**84.64**				**119.48**

Table 2 Resource use for other healthcare during 6 weeks of intervention period in remotely delivered physiotherapy and face-to-face physiotherapy

HEALTHCARE PROVIDER COSTS – OTHER HEALTHCARE	Remote Care (n = 88)				Usual care (n = 89)			
Resource items	**Unit cost**	**Units per participant**	**N participants (%)**	**Total cost**	**Unit cost**	**Units per participant**	**N participants (%)**	**Total cost**
Visit to a GP - medical fee	$39.1 per visit	2.3 visits	22	1955.00	$39.1 per visit	2.1 visits	17	1368.50
Visit to medical specialist - medical fee	$159.4 per visit	1.2 visits	10	1912.80	$159.4 per visit	1.2 visits	13	2550.40
Visit to medical outpatient clinical/hospital doctor - medical fee	-	-	-	-	$79.7 per visit	2 visits	1	159.40
Visits to a physiotherapist (outside of trial) - fees	$34.5 per visit	2.5 visits	6	517.50	$34.5 per visit	2 visits	2	138.00
Visits to other healthcare professionals - fees	$34.5 per visit	2.4 visits	10	828.00	$34.5 per visit	1.8 visits	10	621.00
TOTAL OTHER HEALTHCARE				**5253.30**				**4837.3**
Mean per patient cost				**59.70**				**54.35**
Overall health funder costs per patient 6 weeks				**144.34**				**173.83**

Table 3 Resource use for intervention delivery in remotely delivered physiotherapy and face-to-face physiotherapy, patient perspective

	Remote Care (n = 88)				Usual care (n = 89)			
PATIENT COSTS INTERVENTION	**Unit cost**	**Units per participant**	**N participants (%)**	**Total cost**	**Unit cost**	**Units per participant**	**N participants (%)**	**Total cost**
Visits to a physiotherapist (as part of the trial) - travel costs	$.7 per km	1.0 round trip of 11.7 km per trip	88	722.77	$.7 per km	3.2 round trips of 11.7 km per trip	89	2349.01
Visits to a physiotherapist (as part of the trial) - lost in productivity	$34.8 per hour	1.8 hours per participant	88	5446.92	$34.8 per hour	5.7 hours per participant	89	17702.51
Practicing home exercises prescribed as part of the trial - lost in productivity	$34.8 per hour	2.4 hours per week for 6 weeks	71	36059.76	$34.8 per hour	2.1 hours per week for 6 weeks	84	37270.80
Medical/exercise equipment	Miscellaneous	1.3 items	6	255.00	Miscellaneous	1.1 items	12	387.00
TOTAL PATIENT COSTS - INTERVENTION				42484.45				57060.39
Mean per patient costs				482.77				648.41

Table 4 Resource use for other healthcare during 6 weeks of intervention period, patient perspective

PATIENT COSTS OTHER HEALTHCARE	Remote Care (n = 88)				Usual care (n = 89)			
General Practitioner	**Unit cost**	**Units per participant**	**N participants (%)**	**Total cost**	**Unit cost**	**Units per participant**	**N participants (%)**	**Total cost**
Visit to a GP - co payments	$30 per visit	2.3 visits	22	1500.00	$30 per visit	2.1 visits	17	1050.00
Visit to a GP - travel costs	$.7 per km	2.3 round trips of 11.7 km per trip	22	410.67	$.7 per km	2.1 round trips of 11.7 km per trip	17	287.47
Visit to a GP - lost productivity	$34.8 per hour	4 hours per participant	22	3094.84	$34.8 per hour	3.7 hours per participant	17	2166.39
Medical specialist								
Visit to a medical specialist - co payments	$64 per visit	1.2 visits	10	768.00	$64 per visit	1.2 visits	13	1024.00
Visit to a medical specialist - travel costs	$.7 per km	1.2 round trips of 11.7 km per trip	10	98.56	$.7 per km	1.2 round trips of 11.7 km per trip	13	131.41
Visit to a medical specialist - lost in productivity	$34.8 per hour	2.1 hours per participant	10	742.76	$34.8 per hour	2.1 hours per participant	13	990.35
Hospital doctor/clinic								
Visit to medical outpatient clinical/hospital doctor - travel costs	-	-	-	-	$8.2 per trip	2 trips	1	16.43
Visit to medical outpatient clinical/hospital doctor - lost in productivity	-	-	-	-	$34.8 per hour	3.6 hours per participant	1	123.79
Physiotherapist								

Visit to a physiotherapist - co payments	$20 per visit	2.5 visits	6	300.00	$20 per visit	2 visits	2	80.00
Visits to a physiotherapist (outside of trial) - travel costs	$.7 per km	2.5 round trips of 11.7 km per trip	6	123.20	$.7 per km	2 round trips of 11.7 km per trip	2	32.85
Visits to a physiotherapist (outside of trial) - lost in productivity	$34.8 per hour	4.5 hours per participant	6	928.45	$34.8 per hour	3.6 hours per participant	2	247.59
Other healthcare professional								
Visit to a other healthcare professional - co payments	$20 per visit	2.4 visits	10	480.00	$20 per visit	1.8 visits	10	360.00
Visits to other healthcare professionals - travel costs	$.7 per km	2.4 round trips of 11.7 km per trip	10	197.12	$.7 per km	1.8 round trips of 11.7 km per trip	10	147.84
Visits to other healthcare professionals - lost in productivity	$34.8 per hour	4.3 hours per participant	10	1485.52	$34.8 per hour	3.2 hours per participant	10	1114.14
PATIENT COSTS – OTHER HEALTHCARE				**10129.12**				**7772.26**
Mean per patient costs				**115.10**				**87.32**
Overall mean patient costs 6 weeks				**597.87**				**735.73**

Appendix 9: Table 5 Mean (SD) utility scores measured with the EQ-5D-5L for patients in delivered physiotherapy and face-to-face physiotherapy, measured at baseline, 6 and 26 weeks.

	Remote care		Usual care	
Time	**N**	**Mean (SD)**	**N**	**Mean (SD)**
Baseline	88	0.692 (0.263)	89	0.650 (0.291)
6 weeks	87	0.778 (0.202)	88	0.752 (0.250)
26 weeks	71	0.748 (0.289)	79	0.750 (0.289)

Appendix 10: **Table 6 Costs and sources**

Reference costs for healthcare and other resource use.

Item	Unit cost	Source
Training for REFORM staff	$34.50 per hour	NSW Award for health professionals (Level 1, year 2 as per 01/7/2022) https://www.health.nsw.gov.au/careers/conditions/Awards/health-professional.pdf
Trainer costs - cost of staff providing training for REFORM staff	$57.70 per hour	NSW Award for health professionals (Level 4, year 2 as per 01/7/2022) https://www.health.nsw.gov.au/careers/conditions/Awards/health-professional.pdf
Visits to a physiotherapist (as part of the trial) - fees	$34.50 per hour	Source: https://www.health.nsw.gov.au/careers/conditions/Awards/health-professional.pdf
Clinical space for physiotherapy (as part of the trial)	$10.00 per hour	Estimate of $10.00 per hour to rent a clinical room.
Admin costs	$40.00 per hour	Estimate of $40.00 per hour in salary
The text message	$0.10 per text message	Based on the monthly subscription cost of sending text messages through a local provider
Scheduled phone calls at week 2 and week 4 which were picked up	$5.00 per phone call	Estimate of the cost of the phone call and the therapists' time.
Additional missed phone calls at week 2 and week 4 - therapists' time	$2.90 per missed phone call	Estimate of the cost of 5 minutes of therapists' time per failed call.
Server and hosting costs for the PTX exercise software	$5.00 per copy of home exercise program	Estimate is based on the cost of running the App divided by the total number of users to attain an estimate of the cost per user.

Item	Unit cost	Source
Provision of a paper copy of home exercise programs	$5.00 per copy of home exercise program	Estimated $5.00 per home exercise program covers the cost of the software license and printing.
Visit to a GP - medical fee	$39.10 per visit	Medicare Benefits Scheme - General Practitioner Attendances, Level B - Item 23 (Source: http://www.mbsonline.gov.au/internet/mbsonline/publishing.nsf/Content/E528C73047125137CA258797000C9597//MBSBook%201%20March%202022-v2.pdf)
Visit to medical specialist - medical fee	$159.40 per visit	Medicare Benefits Scheme - Consultant Physician - Item 116 (Source: http://www.mbsonline.gov.au/internet/mbsonline/publishing.nsf/Content/E528C73047125137CA258797000C9597//MBSBook%201%20March%202022-v2.pdf)
Visit to medical outpatient clinical/hospital doctor - medical fee	$79.70 per visit	Medicare Benefits Scheme - General Practitioner Attendances, Level C - Item 36 (Source: http://www.mbsonline.gov.au/internet/mbsonline/publishing.nsf/Content/E528C73047125137CA258797000C9597//MBSBook%201%20March%202022-v2.pdf)
Visits to a physiotherapist (outside of trial) - fees	$34.50 per visit	NSW Award for health professionals (Level 1, year 2 as per 01/7/2022) (Source: https://www.health.nsw.gov.au/careers/conditions/Awards/health-professional.pdf)
Visits to other healthcare professionals - fees	$34.50 per visit	NSW Award for health professionals (Level 1, year 2 as per 01/7/2022) (Source: https://www.health.nsw.gov.au/careers/conditions/Awards/health-professional.pdf)
Visits to a physiotherapist (as part of the trial) - travel costs	$0.70 per km	2020 to 2022 as per Australian Tax Office (Source: https://www.ato.gov.au/Business/Income-and-deductions-for-business/Deductions/Deductions-for-motor-vehicle-expenses/Cents-per-kilometre-method/)
Visits to a physiotherapist (as part of the trial) - lost in productivity	$34.80 per hour	Source: https://www.abs.gov.au/statistics/labour/earnings-and-working-conditions/average-weekly-earnings-australia/nov-2022

Item	Unit cost	Source
Practicing home exercises prescribed as part of the trial - lost in productivity	$34.80 per hour	Source: https://www.abs.gov.au/statistics/labour/earnings-and-working-conditions/average-weekly-earnings-australia/nov-3127.
Medical/exercise equipment	Miscellaneous	Various costs provided by participants
Visit to a GP - co payments	$30.00 per visit	Estimated $30.00 per visit to a GP that was not covered by Medicare
Visit to a GP - travel costs	$0.70 per km	2020 to 2022 as per Australian Tax Office (Source: https://www.ato.gov.au/Business/Income-and-deductions-for-business/Deductions/Deductions-for-motor-vehicle-expenses/Cents-per-kilometre-method/)
Visit to a GP - lost productivity	$34.80 per hour	Source: https://www.abs.gov.au/statistics/labour/earnings-and-working-conditions/average-weekly-earnings-australia/nov-2022)
Visit to a medical specialist - co payments	$64.00 per visit	Estimated $64.00 per visit to a medical specialist that was not covered by Medicare
Visit to a medical specialist - travel costs	$0.70 per km	2020 to 2022 as per Australian Tax Office (Source: https://www.ato.gov.au/Business/Income-and-deductions-for-business/Deductions/Deductions-for-motor-vehicle-expenses/Cents-per-kilometre-method/)
Visit to a medical specialist - lost in productivity	$34.80 per hour	Source: https://www.abs.gov.au/statistics/labour/earnings-and-working-conditions/average-weekly-earnings-australia/nov-2022
Visit to medical outpatient clinical/hospital doctor - travel costs	$8.20 per trip	2020 to 2022 as per Australian Tax Office (Source: https://www.ato.gov.au/Business/Income-and-deductions-for-business/Deductions/Deductions-for-motor-vehicle-expenses/Cents-per-kilometre-method)

Item	Unit cost	Source
Visit to medical outpatient clinical/hospital doctor - lost in productivity	$34.80 per hour	Source: https://www.abs.gov.au/statistics/labour/earnings-and-working-conditions/average-weekly-earnings-australia/nov-2022
Visit to a physiotherapist - co payments	$20.00 per visit	Estimated $20.00 per visit to a physio that was not covered by Medicare
Visits to a physiotherapist (outside of trial) - travel costs	$0.70 per km	2020 to 2022 as per Australian Tax Office (Source: https://www.ato.gov.au/Business/Income-and-deductions-for-business/Deductions/Deductions-for-motor-vehicle-expenses/Cents-per-kilometre-method/)
Visits to a physiotherapist (outside of trial) - lost in productivity	$34.80 per hour	Source: https://www.abs.gov.au/statistics/labour/earnings-and-working-conditions/average-weekly-earnings-australia/nov-2022
Visit to another healthcare professional - co payments	$20.00 per visit	Estimated $20.00 per visit to a healthcare provider that was not covered by Medicare
Visits to other healthcare professionals - travel costs	$0.70 per km	2020 to 2022 as per Australian Tax Office (Source: https://www.ato.gov.au/Business/Income-and-deductions-for-business/Deductions/Deductions-for-motor-vehicle-expenses/Cents-per-kilometre-method/)
Visits to other healthcare professionals - lost in productivity	$34.80 per hour	Source: https://www.abs.gov.au/statistics/labour/earnings-and-working-conditions/average-weekly-earnings-australia/nov-2022

*All costs are reported in 2022 Australian dollars.