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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

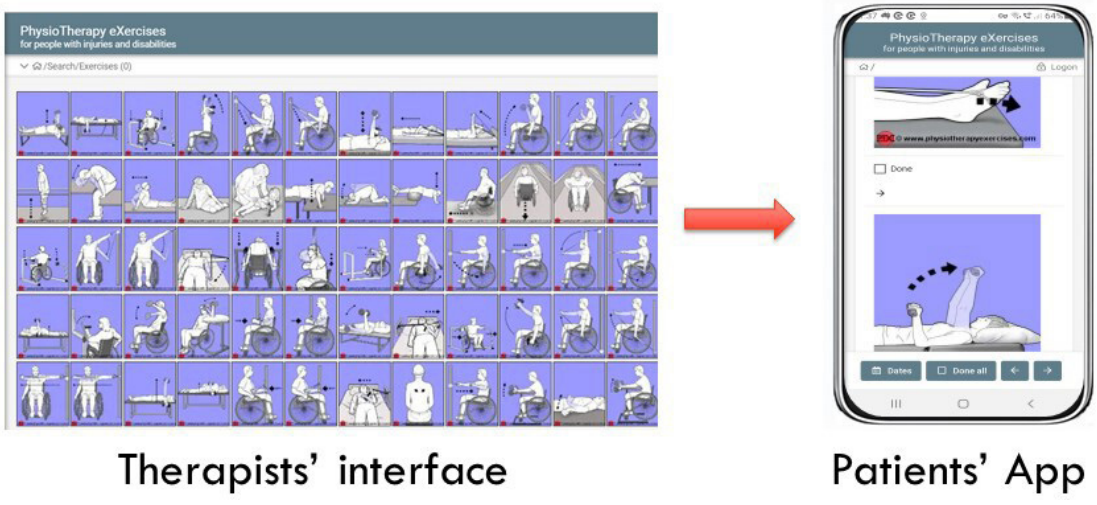

Figure 1 Freely available App developed by the authors (www.physiotherapyexercises.com).

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.

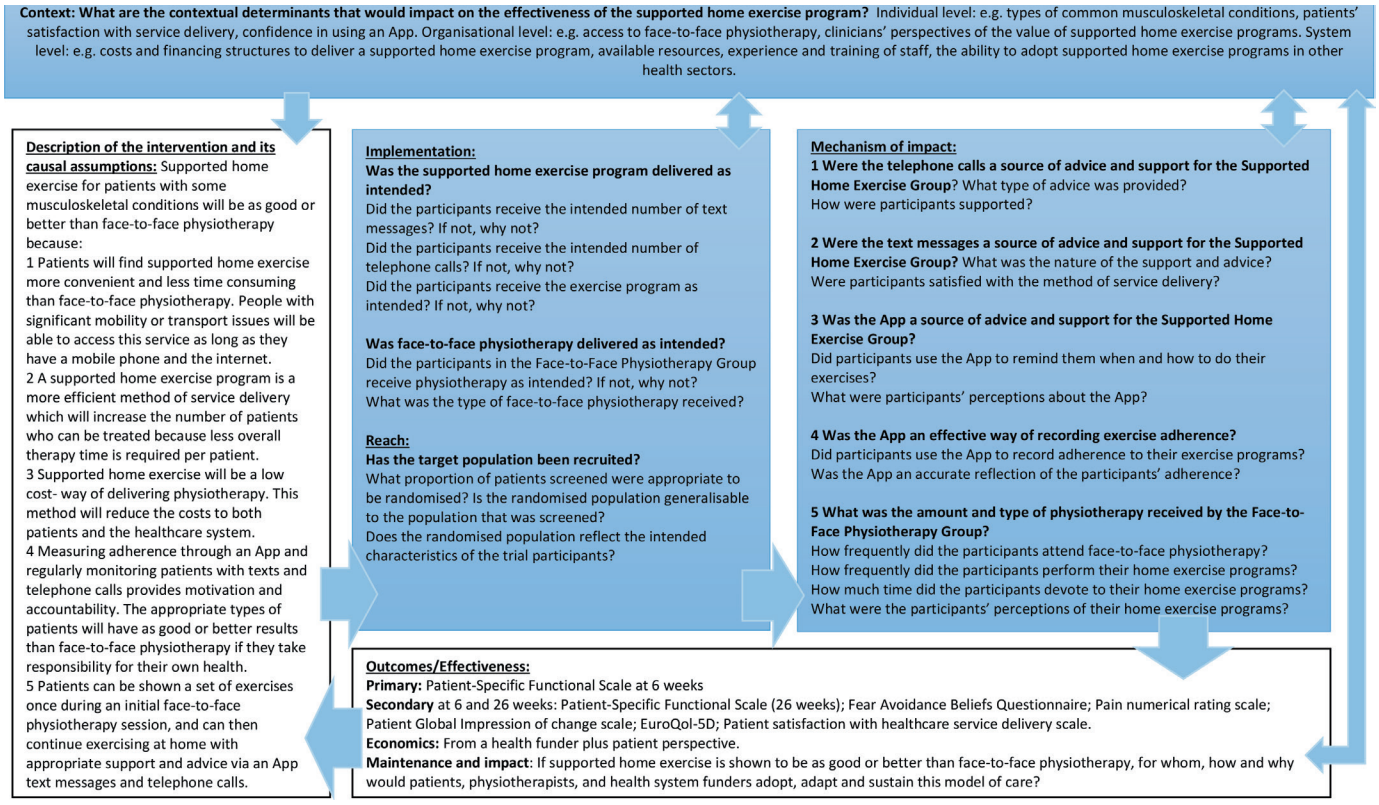

Figure 2 The process evaluation framework for the REFORM trial. The blue boxes (labelled Context, Implementation, and Mechanism of impact) depict the key components of the process evaluation which explore the contextual factors, implementation and ways in which the intervention may work. The white boxes (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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