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The effectiveness of an app with remote support to improve adherence to home exercise programs prescribed by physiotherapists: a randomised controlled trial.

Faculty of Medicine
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A thesis submitted to fulfil requirements for the degree of Master of Philosophy (Medicine).

Abstract

Question: Do people with musculoskeletal conditions better adhere to their home exercise programs (HEPs) when these are provided to them on an app with remote support compared to paper handouts?

Design: Randomised, parallel-group trial with concealed allocation and intention-to-treat analysis.

Participants: Eighty participants with upper or lower limb musculoskeletal conditions who were prescribed a 4-week HEP by a physiotherapist at a tertiary teaching hospital in Australia were recruited to the trial. Participants were randomly assigned via a computer-generated concealed block randomisation procedure to either intervention (n = 40) or control (n = 40) groups between 25/02/16 and 13/01/17.

Intervention: Participants in the intervention group received their HEPs on an app linked to www.physiotherapyexercises.com. They also received supplementary phone calls and motivational text messages. Participants in the control group received their HEPs as a paper handout.

Outcome measures: Outcome measures were collected at baseline and at 4 weeks by blinded assessors. The primary outcome was self-reported exercise adherence. Secondary outcomes included measures of function, disability, satisfaction with service delivery and assessor-reported adherence.

Results: Outcomes were available on 77 participants. Three were lost to follow up. The mean between-group difference for self-reported exercise adherence at 4-weeks was 1.3/11 points (95% CI, 0.2 to 2.3), favouring the intervention group. The mean between-group difference for the patient-specific functional scale was 0.9/11 points (95% CI, 0.1 to 1.7) in favour of the intervention group. There were no significant between-group differences for the remaining outcomes.

Conclusion: Patients with musculoskeletal conditions better adhere to their HEPs when these are provided to them on an app with remote support compared to paper handouts, however, the clinical importance of this added adherence is unclear.

1st March 2018

To whom it may concern;

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

I certify that the content of this thesis is the product of my own work only and that all the assistance received in preparing this thesis and sources have been rightfully acknowledged.

Signature:

A handwritten signature in black ink, appearing to read 'Tara E. Lambert', written in a cursive style.

Tara E. Lambert

Master of Philosophy (Medicine) Candidate

Authorship attribution statement

Chapter two of this thesis is published as:

An app with remote support achieves better adherence to home exercise programs than paper handouts in people with musculoskeletal conditions: a randomised trial. Lambert, Tara E et al. Journal of Physiotherapy, Volume 63, Issue 3, 161 – 167.

The Journal of Physiotherapy does not have a stated convention about author order. My contribution to this work was as follows:

I co-designed the study with the co-authors.

I was the Principal Investigator for the clinical trial.

I analysed data, and extracted additional data analysed by Lisa A. Harvey.

I wrote the manuscript of the published work.

Signed:



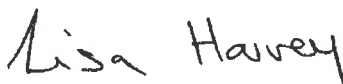
Tara E. Lambert

Date: 01. 03. 2018

Supervisors statement attesting authorship

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

Signed:



Prof Lisa A. Harvey

Date: 02.03.18

3 December 2015

A/Prof Lisa Harvey
Level 13 Kolling Building
Royal North Shore Hospital
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Dear Lisa

NSLHD reference: RESP/15/312

Title: The effectiveness of using an exercise App to improve adherence to home exercise programs prescribed by physiotherapists: a randomised controlled trial.

HREC reference: HREC/15/HAWKE/431

Thank you for your letter, dated **24 November 2015**, responding to the Northern Sydney Local Health District HREC's request for additional information/modification for the above project, which was first considered by the HREC at its meeting held on **9 November 2015**. This HREC has been accredited by NSW Ministry of Health as a Lead HREC under the model for single ethical and scientific review and Certified by the NHMRC under the National model for Harmonisation of Multicentre Ethical Review (HoMER). This lead HREC is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. No HREC members with a conflict of interest were present for review of this project.

I am pleased to advise that the Committee at an Executive meeting on **2 December 2015** has granted ethical and scientific approval of the above **single centre** project.

The project is approved to be conducted at:

- **Royal North Shore Hospital**

You are reminded that this letter constitutes *ETHICAL* and *SCIENTIFIC* approval only. You must not commence this research project at a site until a completed Site Specific Assessment Form/Access Request and associated documentation have been submitted to the site Research Governance Officer and Authorised. A copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

If a new site(s) is to be added please inform the HREC in writing and submit a Site Specific Assessment Form (SSA) to the Research Governance Officer at the new site.

The following documentation has been reviewed and approved by the HREC:

Document	Version	Date
Study Protocol	1.1	17 November 2015
Participant Information Sheet and Consent Form	1.1	17 November 2015
Case Report Forms	1.1	17 November 2015
Phone Script – 4 Weekly Follow Up	-	-
Sample SMS for App Group	1	13 October 2015

The National Ethics Application Form reviewed by the HREC was **NEAF AU/1/39D1210**

Please note the following conditions of approval:

- HREC approval is valid for **5 years** from the date of approval and expires on **2 December 2020**. The Co-ordinating Investigator is required to notify the HREC 6 months prior to this date if the project is expected to extend beyond the original approval date at which time the HREC will advise of the requirements for ongoing approval of the study.

- The Co-ordinating Investigator will provide an annual progress report to the Institution beginning in **August 2016** as well as a final study report at the completion of the project using the template available on the Research Office website. An annual report is due **every year on 30 August**.
- The Co-ordinating Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including unforeseen events that might affect continued ethical acceptability of the project and any complaints made by study participants regarding the conduct of the study.
- Proposed changes to the research protocol, conduct of the research, or length of HREC approval will be provided to the HREC for review, in the specified format.
- The HREC will be notified, giving reasons, if the project is discontinued before the expected date of completion.
- Investigators holding an academic appointment (including conjoint appointments) and students undertaking a project as part of a university course are advised to contact the relevant university HREC regarding any additional requirements for the project.

Please note it is the responsibility of the sponsor or the co-ordinating investigator of the project to register this study on a publicly available online registry (eg Australian New Zealand Clinical Trial Registry www.anzctr.org.au) if applicable.

Should you have any queries about your project please contact the Research Office, Tel: 9926 4590, email NSLHD-Research@health.nsw.gov.au.

Please quote **NSLHD reference RESP/15/312** in all correspondence.

The HREC wishes you every success in your research.

Yours sincerely



Ellie Pratt
Research Ethics Manager
NORTHERN SYDNEY LOCAL HEALTH DISTRICT

cc. Jocelyn Bowden
RESD/15/8475

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CHAPTER ONE: INTRODUCTION

In 2003, the World Health Organisation (WHO) declared:

“Increasing the effectiveness of adherence interventions may have a far greater impact on the health of the population than any improvement in specific medical treatments.”(p13)¹

Such a statement highlights that poor adherence is a problem across all health disciplines, and reinforces the necessity for health professionals to employ evidence based strategies to promote adherence and thereby optimise patient outcomes.

Within the field of physiotherapy, the concept of adherence largely relates to the undertaking of prescribed home exercise programs (HEPs).² Exercise is widely recommended and believed to be effective in treating a variety of acute and chronic musculoskeletal conditions.^{3,4} Physiotherapists tailor programs to an individual’s needs during hospital or clinic-based sessions, but the success of treatment relies on the patient’s capacity and willingness to continue with his/her program independently after face-to-face treatment has ended.^{5,6} However adherence to these programs is often poor and reduces further over time.⁷ Most importantly this negatively affects patient outcomes, but also has a significant economic impact and increases health burden through over-utilisation of services.⁸

Physiotherapists need an inexpensive and effective way of increasing adherence to HEPs that doesn’t rely solely on face-to-face appointments. The rapid development of web-based and mobile technologies such as apps may provide a platform to do this, but the limited evidence to date is largely inconclusive and therefore efficacy has not been established.

The purpose of this thesis is to determine if adherence to HEPs may be improved when they are delivered via an app compared to usual methods used by physiotherapists. This will be explored over three chapters.

The remainder of chapter one will provide a synthesis of the relevant background information and literature to-date on the effects of mobile technology and apps on adherence.

Chapter two features the published paper titled “An app with remote support achieves better adherence to HEPs than paper handouts in people with musculoskeletal conditions: a randomised trial” in the Journal of Physiotherapy. To our best knowledge, this is the first RCT to examine the effectiveness of an app on adherence in people with musculoskeletal conditions.

In chapter three, I will discuss the findings of the RCT. The aim of this chapter is to interpret the results, make conclusions based on new knowledge and make some recommendations towards future research in this field. I will also discuss some of the challenges I faced whilst conducting my research and reflect upon the things I have learnt over the course of the trial.

MUSCULOSKELETAL CONDITIONS

Musculoskeletal conditions are defined as any disorder affecting the bony skeleton, joints, muscles or connective tissues. These can be of insidious origin, such as non-specific back pain. Alternatively, these may refer to acute injuries such as those affecting soft tissues or fractures. They also include chronic conditions such as various forms of arthritis and osteoporosis.⁹

Prevalence

Musculoskeletal pain, particularly back, neck and shoulder pain, is among the most commonly experienced conditions by Australian adults.⁹ In 2013-14, the Australian Institute of Health and Welfare (AIHW) reported 521,000 admissions to Australian hospitals due to musculoskeletal conditions, not including fractures.¹⁰ This makes it the fourth most common reason for hospital admission, ranking above circulatory conditions such as heart attack and angina. Musculoskeletal problems are also the third most common reason for GP visits within Australia, accounting for 18 out of every 100 visits.¹¹

Chronic musculoskeletal conditions affect 30% of Australians, significantly contributing to the country's non-fatal burden of disease. Osteoarthritis alone is known to currently affect approximately 15% of the population, with its prevalence set to double by the year 2020 thanks to growing obesity rates and an ageing population.¹² Acute injuries such as fractures place additional demands on both inpatient and outpatient health resources. In 2013, there was a fracture reported every 3.6 minutes, or 395 fractures per day. It is projected that these figures will continue to increase as our population ages.¹³

Health economic implications of musculoskeletal conditions

Musculoskeletal conditions rank as the fourth most expensive disease group in Australia. In the most recent expenditure data, it is estimated that funds allocated to musculoskeletal conditions was at least \$5,690 million; nearly 9% of total health-care cost.¹⁴ More specifically, the burden of fracture management is estimated to be \$22.7 billion over the next 10 years. These costs include emergency

department visits, hospitalisation, rehabilitation and outpatient services; all of which make use of physiotherapy services.¹³ It is reported that in industrialised nations up to 70% of lost-work days due to medical conditions are due to musculoskeletal conditions.¹⁵

EXERCISE FOR MUSCULOSKELETAL CONDITIONS

Exercise prescription

The prescription of exercise has become the cornerstone of physiotherapy treatment for musculoskeletal conditions. Largely, this is because therapeutic exercise has a strong evidence base.^{3,16} It also offers a treatment modality that may be continued by the patient independently outside of face-to face sessions. For these reasons exercise stands as the most attractive treatment option to physiotherapists looking to provide quality, affordable and effective care.

Exercises prescribed by physiotherapists usually targets specific impairments identified after a thorough subjective and objective assessment. Typically, exercise programs for musculoskeletal conditions consist of range of motion, strengthening, stretching, and/or proprioception exercises. They may also include global reconditioning with coaching provided for graded aerobic exercise.³

Physiotherapists are skilled in their ability to tailor HEPs. They consider several important factors, including:

- a) the type and stage of an individual's condition;
- b) the appropriate dosage of exercise to prescribe (i.e., intensity and frequency); and
- c) the optimal technique for performing each exercise.²

Significant amounts of in-clinic time are spent designing and teaching these programs to patients with the expectation that they will then carry on with their programs at home.

It is imperative that patients are actively involved in the process of designing a treatment plan. A patient-centered approach should be used to ensure exercise programs are relevant to the patient's goals, and can be realistically adhered to.³ Recommendations developed by Roddy et al. for the prescription of exercises in those with hip or knee osteoarthritis state "*exercise therapy should be individualized and patient-centered taking into account factors such as age, co-morbidity and overall mobility.*"(p67)¹⁷

Exercise improves outcomes

Exercise improves patient outcomes such as pain, function, disability and social engagement.¹⁸ Hence, exercise is explicitly recommended in a number of Australian and international guidelines for specific musculoskeletal conditions. For example, Australian guidelines for the management of hip and knee osteoarthritis recommend lower limb strengthening and aerobic exercise training.^{3,4} Similarly, Australian guidelines for the treatment of acute whiplash associated disorders state that “*range of motion, low load isometric strengthening, postural and endurance exercises should be used as first line treatment.*”(p13)⁴ In the United Kingdom, the National Institute for Clinical Excellence (NICE) state that patients with low back pain should exercise daily.¹⁹ Consequently, many patients are referred to physiotherapists with the explicit purpose of being prescribed a HEPs to manage their conditions.

Research investigating the effect of therapeutic exercise on musculoskeletal conditions is extensive. A recent systematic review concluded there is moderate to strong evidence for exercise in the treatment of the five most common musculoskeletal presentations to primary care; back, neck, shoulder, knee and widespread pain.²⁰ More specifically, a systematic review with meta-analysis performed in 2013 found strong evidence to indicate that exercise therapy reduces pain and improves function for people with sub-acromial impingement of the shoulder.¹⁵ This reinforced the results of a previous systematic review on the same topic in 2009.²¹ Furthermore, an RCT comparing different treatments of sub-acromial shoulder impingement found exercise to be superior to surgical arthroscopic decompression.²² There is extensive evidence for the therapeutic effect of exercise in hip and (more so) knee osteoarthritis.²³ Several systematic reviews³ have found moderate or strong evidence for both strengthening and aerobic exercise in these conditions and these results have been reinforced by further systematic reviews with meta-analysis.²⁴⁻²⁶

Strong evidence also exists for exercise-based rehabilitation in more acute conditions. For example, patients post anterior-cruciate ligament reconstruction report greater functional outcomes in the short and

long-term after undertaking an exercise-based rehabilitation program.²⁷ In addition, patients following wrist fracture are more likely to achieve short-term functional gains when given a physiotherapist-prescribed HEP compared to advice alone.^{28,29} Of course, the achievement of these outcomes depends on a certain degree of adherence.³⁰ This will be explored in the following section.

ADHERENCE

Defining adherence

Adherence is defined by the WHO (2003) as “*the extent to which a person’s behavior... corresponds with agreed recommendations from a health care provider.*”(p19) More specific to physiotherapy,

Meichenbaum and Turk describe adherence as “*the extent to which patients undertake the clinic-based and home-based prescribed components of their physiotherapy programme.*”(p91)⁶

Importantly, we should note the difference between the terms “*adherence*” and “*compliance*” which can be used interchangeably in the literature. The term “*compliance*” implies that patients must conform to a prescribed treatment or advice, and therefore is less inclusive of the patient in goal setting and treatment planning. Adherence has become the preferred term not only to achieve consistency, but due to the inference that patient-clinician collaboration has led to the prescribed task/s.²

Conceptually, adherence may refer to different things. For example, attendance at scheduled appointments, or the accuracy and technique used to perform an exercise. Adherence can also refer to the intensity and/or frequency in which exercises are performed when unsupervised.^{1,31} For the purposes of this research, adherence refers to how often patients complete their prescribed HEPs.

Adherence to HEPs is poor

Adherence to HEPs is poor, with between 50-70% of patients reportedly not undertaking HEPs as prescribed.³¹ Furthermore, adherence to prescribed exercise programs reduces over time.^{5,32}

Poor adherence is a problem not exclusive to physiotherapy, occurring across many health disciplines.

The most advanced research in this field is adherence to medication.^{33,34} Areas where lifestyle-related behavior change is required also report problems with adherence, specifically weight loss³⁵ and smoking cessation.³⁶ The research conducted in these fields may offer some guidance to physiotherapists trying to promote greater adherence to HEPs.

The cost of poor adherence

Poor adherence results in poor patient outcomes, including greater risk of recurrence and progression towards chronic, disabling conditions.⁶ However the consequences of poor adherence are beyond that of poor outcomes for patients. There are larger, societal implications too. Poor adherence, and thus poor outcomes can often result in loss of work, further contributing to the social and economic burden posed by musculoskeletal conditions.⁸

Poor adherence is wasteful of physiotherapy resources. Failure to adhere to a treatment plan may also have a knock-on effect leading to over utilisation of health services. For example, a patient may attend the same health care provider an excessive number of times, only for the same treatment plan to be recommended. Alternatively, patients may ‘shop around’ to various, and possibly unhelpful services. This in turn increases the cost of general healthcare, with the expense passed on to both consumers and providers. Overuse of services also increases waiting times to hospital outpatient services, which is a major cause of patient inconvenience and complaints.⁶

Already, health policy is changing to deal with some of these added pressures. For example, many physiotherapy services have implemented ‘capped’ sessions especially for those presenting with a chronic complaint. At my place of work (Royal North Shore Hospital, Australia) which is also where the trial reported in this thesis was undertaken, efforts have been made to restrict the number of treatment sessions for those with chronic conditions to between four and six sessions, with a focus on long-term self-management strategies. This is commonplace across the network of metropolitan area physiotherapy services within Australia.

Meanwhile, several procedures have been observed abroad with respect to restricting face-to-face interventions. For example, in New Zealand, common musculoskeletal injuries and conditions are coded to assist clinicians in guiding their management and rehabilitation. Based on these codes, a maximum number of funded physiotherapy sessions are allocated to each condition. For example, a patient

presenting to physiotherapy with a sprained ankle will have a maximum of 10 sessions funded, after which they will have to finance any further treatment themselves.³⁷ With the ever-increasing pressure to operate cost-effective systems, such policies may soon be adopted by health services internationally.

Therefore, physiotherapists are in need of a cost-effective means to promote adherence to exercise that does not rely on face-to-face interventions.

Factors influencing adherence

Both individual and intervention related factors may influence adherence to home exercise.³⁷ It is important to understand these when discussing a new intervention aimed at improving adherence.

Individual factors relate to those introduced by the patient, which have been the focus of much of the research to date. However, intervention related factors, that is, those introduced by clinicians or health systems may be equally important.⁵

Beinert et al. conducted a systematic review in 2013 examining factors associated with increased adherence to home exercise in chronic low back pain sufferers. While the authors imply causality through the possible links between adherence and the interventions, the studies included in the review are not convincing of this. Data were extracted from eleven RCTs, however no high-quality evidence was found for any factors associated with adherence. Only moderate evidence was found for greater health locus of control influencing better adherence. Locus of control is a term used to describe the extent to which people take responsibility for any outcomes achieved. For example, people with high locus of control are likely to attribute their reduction in knee pain and improved mobility to successful weight loss and the strengthening exercises they performed. In contrast, people with low locus of control are more inclined to blame external factors such as living in an environment not amenable to home exercise. The authors also reported that better adherence might be associated with more face-to-face contact, the inclusion of a behavior change program with motivational techniques, and attendance at a program such as ‘back school.’⁵ The studies providing these data lacked detailed descriptions of the type and structure of the

interventions so it is difficult to make conclusions about these factors and their influence on adherence. Of most concern, the majority of these studies did not measure adherence in their control groups, therefore we cannot make inferences about the effects of the interventions on adherence.

A systematic review of twenty high quality RCTs conducted in 2010 sought to identify potential barriers to exercise adherence specifically in the outpatient musculoskeletal setting. This included studies with a wide variety of different musculoskeletal conditions. Barriers which are believed to have a strong association with poor adherence are summarised in the table below.³⁸

Physical	<ul style="list-style-type: none"> • Low levels of physical activity at baseline • Poor aerobic capacity • Low adherence (poor technique) during face-to-face sessions
Clinical	<ul style="list-style-type: none"> • Pain during exercise • Greater number of co-morbidities • Increased Body Mass Index
Psychological	<ul style="list-style-type: none"> • Low self-efficacy • Greater perceived number of barriers to exercise (beliefs) • Depression and/or anxiety • High degree of helplessness
Socio-demographic	<ul style="list-style-type: none"> • Cost • Poor social or family support

Table 1. Barriers to adherence.³⁸

Recognition of these factors may assist physiotherapists to effectively tailor treatment plans and work collaboratively with their patients to achieve greater adherence. When exploring an adherence-enhancing intervention, such as an exercise app, we should consider these barriers and whether the intervention can play a role in addressing them. For example, as mobile technologies have the capacity to provide feedback, send reminders and offer support this might be helpful in addressing some the psychological and socio-demographic barriers named in the table above.

Measuring adherence

Before we explore adherence-enhancing interventions, it is important to establish how adherence is measured. Adherence refers to a behavior, and is therefore very difficult to accurately measure.¹ This is a very widely researched and reported topic across the health literature, and the associated problems are not

exclusive to physiotherapy. For example, medical literature has reported ongoing problems with measuring patient adherence in people with asthma who need to regularly use prophylactic inhalers.³⁵ Much like HEPs, there are few ways of effectively measuring this adherence other than relying on patient self-reports.³⁹ There are both subjective and objective measures of adherence; each with their benefits and drawbacks. To date, there is no gold standard of measurement of adherence to home exercise.¹

Subjective measures of adherence may include questionnaires, interviews or recording tools such as diaries and logs. Mostly, they rely on patients' self-reports of adherence. While these methods may be vulnerable to obvious forms of bias, they do offer an affordable, easy to administer and time-efficient method of capturing adherence. Bollen et al. conducted a systematic review in 2014 examining different self-reported measures of adherence to unsupervised exercise and their psychometric properties. Sixty-one different measures were found within 58 studies; 29 questionnaires, 29 logs, two visual analogue scales and one tally counter. Problematically, only two of these measures had robust psychometric testing to establish validity and/or reliability. These were the Adherence to Exercise Scale for Older People (AESOP) and the Heart Failure Compliance Questionnaire. Unfortunately, neither of these instruments were appropriate for the population recruited in this clinical trial.³⁹

The most common method of self-report for home exercise is the use of paper diaries³⁸, however these have questionable validity. Researchers have previously gone to extraordinary lengths to monitor adherence through paper diaries, using electronic sensors to record each time a diary is opened. One such study by Stone et.al reported that in chronic pain patients given a diary to record adherence to management strategies, self-reported adherence was 94%. When crosschecked against that of the electronic recordings, patients were in fact only adhering 11% of the time.³⁹ This discrepancy may suggest that patients tend to 'hoard' when recording adherence in diaries. That is, patients retrospectively make entries in bulk, introducing considerable recall bias. Other means of self-report include the use of visual analogue or Likert scales to rate adherence.⁴⁰ While these types of measures have been validated for other populations or purposes, for example rating pain, there has not been robust testing of such

measures for adherence.⁶ Rather, clinicians and researchers presume these types of tools may be adapted for these purposes. This is problematic, as it jeopardises both the validity and reliability of the tool.

Subjective reports of adherence may also include assessment by others, for example, physiotherapists. However, these largely require a supervisory element and are therefore not particularly useful for home exercise adherence. These include the Sports Injury Rehabilitation Scale (SIRAS)⁴¹ and the AESOP.³⁹ Given that these tools are designed for very specific patient groups (named in their titles), neither of these were appropriate for the sample in this clinical trial.

Objective measures of adherence include simply recording the attendance rates of patients at appointments or exercise classes.³¹ However this doesn't offer any insights as to the behavior of patients at home, and whether or not they are undertaking their treatment plans once unsupervised. Medication adherence is likely the most advanced in this field, having introduced several objective measures of adherence. These include pill counters, or sensors installed in drug administering equipment such as inhalers for asthma.³⁵ The development of wearable devices coupled with smart phone technology could provide similar objective measurement for adherence to exercise. This will be discussed in more depth in a later section.

Several systematic reviews have called for the development of a standardised tool to measure adherence.³⁹ After commencing this trial, the Exercise Adherence Rating Scale (EARS) was developed by Newman-Beinert et al⁴² in an attempt to offer a standardised tool for reporting adherence to home exercise. The tool is a questionnaire with six domains and captures different elements of, and barriers to, adherence. While this tool has been validated, it remains a self-report tool. If the EARS was accepted by clinicians and researchers and widely administered, it may at least offer uniform reporting of adherence and could be used in future research examining adherence-enhancing interventions. However, the question remains whether this more complex tool offers anything more than a simple numerical scale like the one chosen for this clinical trial.

BEHAVIOUR CHANGE

There have been three important observations about poor adherence in health behaviours:

- 1) The knowledge- behaviour gap: People know what they should do and why they are supposed to do it, but they do not do it.
- 2) Translation: Things learned in face-to-face settings do not carry over into people's normal, regular routines, and;
- 3) Cessation: People stop doing something when their perception of threat or value has diminished, and do not start again.

Therefore, in order to achieve adherence to exercise, a degree of behavior change is usually required.³⁴ It is widely accepted that there are five stages of behaviour change, as well as a 'relapse' phase. This is summarised in the diagram below. This is known as the trans-theoretical model for behavior change and is utilised across many different health disciplines, including weight loss, smoking cessation and of course, prescription of physical exercise.⁴³

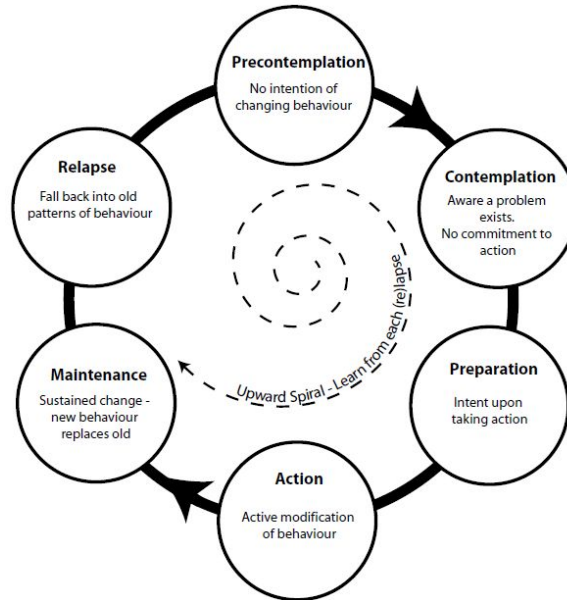


Figure 1. Stages of behavior change (<https://psychologytools.com/stages-of-change.html>).

Health care providers need to understand these principles to support their patients when prescribing HEPs. This is particularly important when referring to chronic, degenerative musculoskeletal conditions. Physiotherapists have a developing knowledge of behavior change theories, and should utilise these to encourage adherence to exercise. It has been demonstrated that the incorporation of such techniques can lead to better outcomes, including adherence. For example, a 2016 RCT found that the addition of behavior change techniques to usual care increased physical activity, spinal mobility and quality of life for sufferers of ankylosing spondylitis.⁴⁴

A summary of behavior change techniques that physiotherapists may find useful to maximise adherence along with examples has been summarised below. This has been adapted from the behavior change technique taxonomy (BCTT).⁴⁵

Domain	Techniques	Example with respect to home exercise	Domain addressed by app-delivered HEPs?
Goals and planning	Setting SMART goals Reviewing goals Planning for relapse or failure	Setting a target for walking tolerance (e.g 25 minutes). Revisit whether this goal was achieved, and re-set appropriately	
Feedback and monitoring	Recording when exercises have been completed Clinician monitoring	Using exercise diaries Use of pedometer to count daily steps Remote feedback via text-message initiated by treating physiotherapist	✓
Social support	Advise or arrange social support	Encourage patient to perform HEP during scheduled training with teammates	✓
Shaping knowledge	Advise or instruct how to perform a skill	Explain the evidence base for quadriceps strengthening in knee pain to the patient during face-to-face sessions. Then practice of quadriceps strengthening exercises refining good technique	
Natural consequences	Provide information about the consequences of engaging, or failing to engage in a new behaviour	Explain to a patient the risks of knee pain becoming chronic and disabling if they fail to strengthen the appropriate muscles.	
Comparison of behaviour	Draw attention to others performance or results	Give examples to patient of previous patients who have undertaken prescribed exercise and gone on to achieve excellent results, for example return to playing tennis	
Associations	Social or environmental cues	Place a sticker on the bathroom mirror to cue patient to perform calf raising exercise whilst brushing their teeth	✓
Repetition and substitution	Prompt rehearsal and repetition of an unwanted behavior with a wanted behaviour	Advise a patient to take the stairs if only travelling 1 floor rather than taking the lift	

Comparison of outcomes	Present information from credible sources or consider pros/cons of new behaviour	Ask the patient to prepare a pros/cons list of undertaking a lower limb strengthening program	
Reward and threat	Incentives; social, financial, outcomes	Inform patient they will be congratulated via text-message every time they log completion of exercises on an app	✓
Antecedents	Restructure of social and physical environments to facilitate behavior change	Suggest ergonomic work station review to a person suffering from neck pain	
Self- belief	Persuasion regarding capabilities, and positive 'self-talk'	Ask a patient to reflect on a time when they felt onset of pain, but they were able to settle this through the use of learnt management strategies	

Table 1. Behaviour change techniques used by physiotherapists⁴⁵ with examples. Where named domain is addressed by app delivery of HEPs marked with ✓ .

INTERVENTIONS FOR IMPROVING ADHERENCE

Previous research has shown that increasing supervised sessions with patients increases adherence.⁴⁶

Supervised sessions may be one-on-one or in group settings. There is evidence which demonstrates that the supported environment of a group session can enhance adherence and outcomes.^{32,46} Needless to say, if patients attend supervised exercise sessions where they are under the guidance of a physiotherapist, of course they are more likely to adhere. However, given the growing pressures on resources in public health, ongoing supervised exercise is not a feasible or sustainable strategy over the long-term.

Whilst it seems reasonable to assume that more face-to-face contact with physiotherapists leads to greater adherence, some studies have indicated that more supervised exercise does not lead to better patient outcomes, compared to home exercise. For example, an RCT performed in Norway in 2015 found similar improvements in pain and disability for patients treated for sub-acromial impingement of the shoulder, regardless of whether they received 6 weeks of home-based exercise or 6 weeks of supervised exercise. A mean between-group difference of 0/100 points (95% CI -14 to 14) on the Shoulder Pain and Disability Index (SPADI) was reported at follow-up.⁴⁷ Interestingly, this study also reported that participants in both groups completed more than 80% of their prescribed exercise, as recorded in diaries. The implied suggestion from the authors of this study is that so long as adherence is high, similar benefits can be achieved regardless of whether exercise is conducted in a supervised or unsupervised setting. However, without a control group it is not possible to be sure whether both groups were equally effective or equally ineffective.

More recently, a systematic review with meta-analysis demonstrated more convincing evidence for some interventions to improve adherence to exercise. This review specifically looked at people aged over 45 suffering from hip and/or knee osteoarthritis and/or low back pain. This demonstrated moderate evidence for booster-sessions with physiotherapists for increasing adherence to exercise in people with hip or knee osteoarthritis. The same study also found the use of motivational strategies (such as those mentioned in

Table 1) may increase adherence to exercise in people with chronic low back pain.⁴⁸ This echoes the findings of a 2010 Cochrane Review, which found some evidence for refresher sessions in enhancing adherence to exercise in those with chronic musculoskeletal pain. This study also found that the incorporation of specific motivational techniques such as goal setting, positive reinforcement and the development of an exercise contract may increase adherence to home-based exercise.⁴⁹ In addition, a systematic review conducted in 2016 found that the inclusion of activity monitors with feedback could positively influence adherence to home-based exercise.⁵⁰

Additionally, several qualitative studies have reported on characteristics of HEPs most likely to positively enhance adherence. For example, a 2010 study reported that patients who suffer from back and neck pain feel more inclined to undertake a HEP if their physiotherapists displayed a thorough knowledge of their condition and the known effects of exercise to them. In addition, better adherence was more likely if feedback and motivation were provided through reminders and monitoring.⁵¹

Does the MODE OF DELIVERING HEPs affect adherence?

In this section I will provide a synopsis on the research to date specifically looking at different modes of delivering HEPs and how these may influence adherence to home exercise. Somewhat surprisingly, there has been limited high quality research on this subject.

Currently, usual practice in physiotherapy involves providing patients with a paper handout containing text and/or diagrams with instructions for performing their HEPs. There is some evidence that this results in greater adherence, compared to not providing a handout at all. Schneiders et al. conducted a RCT in 1998 examining exercise adherence in people with acute low back pain. Those who received the paper handout reported a mean adherence of 71% while control group participants reported a mean adherence of 38%. This represented a mean between group difference of 33% ($p < 0.001$).⁵² However, no data were provided to determine the precision of the estimate (eg. 95% CI of the mean between-group difference).

Where paper handouts are provided, it is reported that including a diary or log sheet may serve as a reminder, and thus promote exercise adherence.⁵³

The inclusion of video or audiotapes as a mode of exercise instruction does not appear to bring added benefits to adherence or outcomes. In 2005 Schoo et al. conducted an RCT examining home exercise adherence in older adults with hip or knee osteoarthritis. When comparing those who received i) a paper brochure; ii) a paper brochure plus audiotape and; iii) a paper brochure plus videotape they reported no significant between-group differences in adherence at 4 and 8 weeks ($p = 0.69$ and 0.59).⁵⁴ This study did not provide individual-level data and utilised median percentages to calculate the p-values. Hence, a 95% confidence interval cannot be derived. This is problematic as we are unable to establish if this study had a sufficient sample size to rule out any differences between groups. Similarly, Lysack et al (2005) reported no significant differences in adherence when patients received paper-based or video-based exercise programs after total hip and knee replacement surgery.⁵⁵ Again, it was however not possible to derive an estimate of the between-group differences from the data provided in the study. Therefore, it is not clear whether this study had a sufficient sample to rule out a treatment effect and it is incorrect to assume that a non-significant finding is indicative of no treatment effect.

There is a lack of well-designed clinical trials comparing smart technology (ie smart phones and tablets) to paper-based handouts for improving adherence to HEPs. The few studies that exist have somewhat conflicting results. For example, a recent RCT in a stroke population measured adherence as a percentage from log book recordings and found no added benefit of using smart technology (video with automated reminders) compared to paper handouts (mean between-group difference 2%, 95% CI -12 to 17).⁵⁶ However more promise has been shown for these modes of delivery when they include remote self-monitoring features. For example, a 2004 RCT found that in patients with haemophilia-related knee dysfunction, internet and smart phone self-monitoring of activity levels resulted in a mean adherence of 71% compared to 33% in the control group (mean between-group difference 58%, 95% CI 39 to 77).⁵⁷

Notably, there have not been any high quality RCTs to date specifically examining the use of an app to improve adherence to HEPs in people with musculoskeletal conditions. We believe this is the first trial to compare an app with remote support to paper handouts for improving adherence to HEPs for people with musculoskeletal conditions.

TECHNOLOGY FOR PROMOTING ADHERENCE AND HEALTH OUTCOMES

Technology usage today

Reports indicate that 41% of the world's population is using the Internet today, with this rapidly rising. In Australia alone, 85% were internet users in 2015 compared to 63% in 2005. This clearly indicates a rapid upward trend in society's access to, and usage of internet-based services. Additionally, there are currently 32 million mobile phone subscriptions in Australia, meaning we utilize approximately 1.3 mobile phones per person.⁵⁸

A 2016 survey conducted across seven countries including Australia reported 33% of the population used mobile apps to access electronic health management tools. This figure has almost doubled since 2014. Additionally, 90% of app users reported they would be willing to share app data with their doctor, with 81% willing to share information with another healthcare professional. Nearly 77% of consumers felt that a wearable health device would increase engagement in their health, to which 85% of surveyed doctors agreed.⁵⁹ These figures depict a population that is equipped and ready to embrace appropriate health care interventions via mobile and web-based platforms.

Mobile technology in health

Promising results have been observed using mobile technology to elicit behavior change in health areas other than physiotherapy. Most notably, mobile technology has been demonstrated to enhance outcomes for patients with cardio-vascular disease. A large systematic review conducted in 2016 found text messaging, mobile applications and tele-monitoring all to be successful in improving outcomes for sufferers of cardiovascular disease. The authors noted particular success of those interventions that featured tailored, personalised messages and two-way engagement between patients and health professionals. They concluded that overall, text messaging seems more effective than smartphone

applications.⁶⁰ In addition, an RCT by Chow et al. demonstrated a text-messaging program led to sustained increased physical activity at 6 months in cardio-vascular disease patients.⁶¹

Another health area that has explored the potential for mobile technology widely is smoking cessation. Results of a Cochrane Review published in 2010 suggested that internet-based interventions may assist patients in quitting smoking, particularly if the information being provided is tailored to the individual and scheduled contacts with patients continue.⁶² In addition, a systematic review conducted in 2013 pooled results from two high quality trials and concluded that that mobile technology, in particular text messaging services, assist in successful smoking cessation.⁶³

Are apps the solution?

Given the widespread use of mobile technology in the population, apps are highly feasible as a mode of delivering health interventions such as HEPs. They allow patients portable access to their programs, meaning they can easily carry out their programs in different environments such as the home, gym or outdoors. The risk of losing or misplacing their exercise programs is averted, provided the patients can access their mobile device. Additionally, they allow for real-time monitoring and feedback capabilities that can include remote interaction with their physiotherapists. Such features may be regarded as motivational techniques and are known to influence adherence. All things considered, there is warranted optimism around the potential for apps to promote adherence and improve clinical outcomes in many health areas.

However, aside from the promising results mentioned above, there are insufficient data to prove the suggested benefits of apps. Unfortunately, large numbers of readily available health apps do not reflect evidence based practice, clinical guidelines or contain legitimate behavior change principles.

Development and uptake of such apps have been very fast, and medical research has not kept pace in scrutinising the efficacy of these apps. There have been particular concerns raised regarding apps targeted at mental health populations. For example, a systematic review examining the quality of apps for bipolar

disorder found that no available app reflected current treatment guidelines or self-management principles.⁶⁴

In the United Kingdom, concerns regarding the negative impact this could have on health outcomes are reflected in a policy paper outlining the National Health Schemes (NHS) intention to formulate a set of endorsed apps; based upon objective testing against cost effect, evidence based practice and usability.⁶⁵ Such practice is encouraging and may lead to better collaboration between clinicians and developers to deliver higher quality information to patients using the platform of technology.

Wearable technology

The development of wearable technology has further enhanced the capacity for monitoring exercise adherence. Step-counters such as FitBit© and StepWatch© have enabled general exercise levels to be captured and monitored, either by wearers themselves, or remotely by clinicians. There have also been reports worldwide of private stakeholders such as health insurance corporations using such technology as a means of determining individuals' health care premiums.⁶⁶ This type of technology is useful for conditions where general exercise like walking is beneficial, for example chronic low back pain or even in chronic diseases such as diabetes. However, it is limited to measuring general exercise only, not specific limb or body movements such as those required in HEPs for many musculoskeletal conditions. Much of the evidence for step-counting technologies is limited to small lab-based studies and therefore there is scope for further exploration of the validity and reliability of their use in different patient populations.

Further to this, there have been advances in technology for more specific exercise monitoring. For example, sensors integrated into commonly used equipment such as Theraband©. These sensors connect with devices via Wi-Fi or Bluetooth and calculate total activity based on the total time under tension of the Theraband©. The connection with devices like smart phones or iPads also allow for reporting of symptoms such as pain. An observational study was conducted in 2016 in adolescents suffering from

patellofemoral pain using such technology. Interestingly, the calculations found that patients only performed 15% of their prescribed exercise, despite paper diaries reflecting a mean self-reported adherence of 36%.⁶⁷

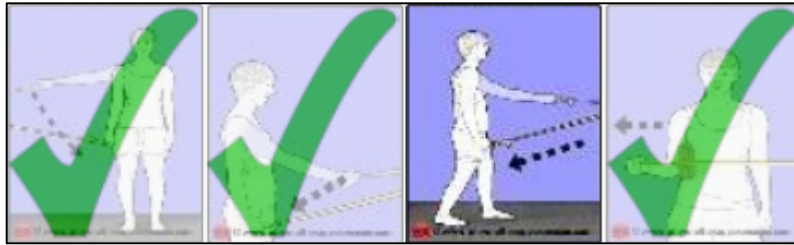
There are emerging studies of sensor technology used in the treatment of musculoskeletal conditions. For example, a pilot study conducted in 2017 used motion sensors in conjunction with a mobile app to monitor lower limb exercise and physical activity over 12 weeks. Promising results were reported. For example a mean change of 16/ 100 points (95% CI 12 to 21) on the Knee Injury and Osteoarthritis Score (KOOS) from baseline to 12 weeks.⁶⁸ However, there were several limitations such as no blinding and lack of a control group. It is therefore difficult to draw firm conclusions regarding the reported treatment effects.

While such technology shows promise, there are limitations to its implementation, particularly with respect to cost. This type of intervention requires ownership of a smart device, as well as provision of sensors (presumably by health-care providers). Set-up and maintenance of the web-based software also incurs significant costs, particularly as the software gets more sophisticated. Importantly, there remains little robust evidence, for example large RCTs, which test the effectiveness of these novel interventions. In addition, the use of wearable technology requires an extra component of adherence, that is, patients have to willingly wear the device or sensors in order to gather any useful information from them.^{69,70}

Description of www.physiotherapyexercises.com

The app used for this clinical trial is web-based software, freely available through the website www.physiotherapyexercises.com. It has been developed over a period of 15 years, largely by physiotherapists. Exercise libraries have been designed for various patient groups, varying from spinal cord injury and neurological conditions to orthopaedic and hand conditions. There are a total of 1237 exercises to select from. The program has been translated into nine languages other than English.

To explain how the program works, I will use an example. Let's assume a physiotherapist wishes to provide a HEP for a patient with a shoulder complaint.



The physiotherapist logs onto www.physiotherapyexercises.com and selects the desired exercises

Figure 2a. Selecting exercises from www.physiotherapyexercises.com from the library (Figure 2a).

Modifications can be made to the default instructions, as well as dosage instructions. For example, 10 repetitions, three times daily. Precautions, or exercise progressions may also be included.

A link to the patient's individual program is then sent to his/her email address or mobile device via text message. Once received, the patient follows this link to access his/her HEP. This is then saved to his/her mobile device where it will appear as an icon on the home screen (Figure 2b).



Figure 2b. Screenshot of www.physiotherapyexercises.com icon on phone screen.

Clicking on this icon will take the patient to his/her individual HEP (Figure 2c.) Here, the patient can log daily participation by clicking the "Done" box, which is relayed back to the treating physiotherapist.

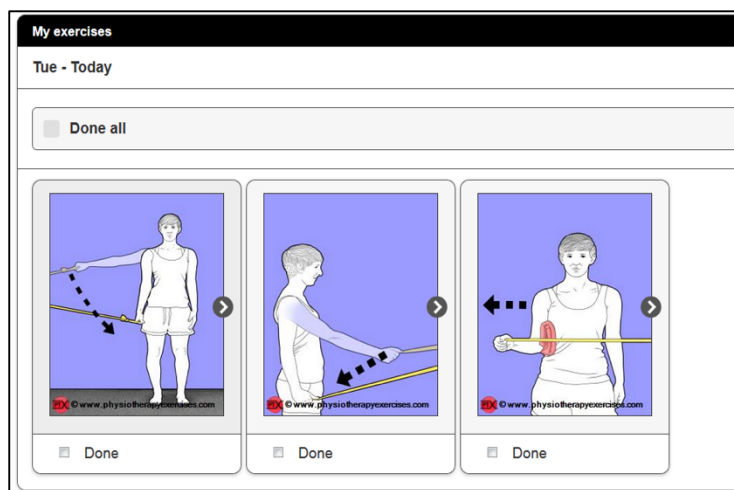


Figure 2c. Screenshot of example HEP as it appears on a mobile device


	Shoulder stretch in standing	Wk 1						✓	✓
		Wk 2	✓	✓	✓	✓	✗	✓	✓
		Wk 3	✓	✓	✓	✓	✓	✗	✓
		Wk 4	✗	✓	✓	✗	✗	✓	✓
		Wk 5	✓	✗	✓	✓	✓		

Figure 2d. Screenshot of physiotherapist monitoring capability

This enables physiotherapist monitoring (Figure 2d), which can lead to remote contact between therapists and their patients.

For example, motivational or reminder text messages can be sent out. Physiotherapists can phone their patients if they notice poor adherence, and remotely address any questions or problems patients are having performing their HEPs. A combined app, text message and telephone intervention was designed for this clinical trial, with the aim of testing a package of interventions.

SUMMARY

- Exercise is important for patient outcomes.
- Realisation of these outcomes depends on reasonable patient adherence.
- Adherence is often poor.
- Current usual practice involves the provision of paper handouts.
- The rise of technology has provided opportunity to explore novel, inexpensive ways to provide HEPs (such as apps), which may promote adherence.
- Prior to this clinical trial, there was no robust evidence to support this.
- This clinical trial aims to determine the effect of exercises delivered to patients via an app with remote support on adherence, and other outcomes such as function, disability and satisfaction with service delivery.

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CHAPTER TWO: PUBLICATION

The literature review conducted in chapter one revealed a lack of high quality trials examining the effect of apps on adherence. In particular, to the best of our knowledge, no previous clinical trials have been conducted specifically looking at the effect of an app on adherence to home exercise programs for people with musculoskeletal conditions.

This chapter contains the publication of the randomised controlled trial on which this thesis is based in the *Journal of Physiotherapy*.

Research

An app with remote support achieves better adherence to home exercise programs than paper handouts in people with musculoskeletal conditions: a randomised trial

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KEY WORDS

Patient compliance
Physical therapy modalities
Exercise therapy
Mobile applications



ABSTRACT

Question: Do people with musculoskeletal conditions better adhere to their home exercise programs when these are provided to them on an app with remote support compared to paper handouts? **Design:** Randomised, parallel-group trial with intention-to-treat analysis. **Participants:** Eighty participants with upper or lower limb musculoskeletal conditions were recruited to the trial. Each participant was prescribed a 4-week home exercise program by a physiotherapist at a tertiary teaching hospital in Australia. Participants were randomly assigned via a computer-generated concealed block randomisation procedure to either intervention (n = 40) or control (n = 40) groups. **Intervention:** Participants in the intervention group received their home exercise programs on an app linked to the freely available website www.physiotherapyexercises.com. They also received supplementary phone calls and motivational text messages. Participants in the control group received their home exercise programs as a paper handout. **Outcome measures:** Blinded assessors collected outcome measures at baseline and 4 weeks. The primary outcome was self-reported exercise adherence. There were five secondary outcomes, which captured functional performance, disability, patient satisfaction, perceptions of treatment effectiveness, and different aspects of adherence. **Results:** Outcomes were available on 77 participants. The mean between-group difference for self-reported exercise adherence at 4 weeks was 1.3/11 points (95% CI 0.2 to 2.3), favouring the intervention group. The mean between-group difference for function was 0.9/11 points (95% CI 0.1 to 1.7) on the Patient-Specific Functional Scale, also favouring the intervention group. There were no significant between-group differences for the remaining outcomes. **Conclusion:** People with musculoskeletal conditions adhere better to their home exercise programs when the programs are provided on an app with remote support compared to paper handouts; however, the clinical importance of this added adherence is unclear. **Trial registration:** ACTRN12616000066482. [Lambert TE, Harvey LA, Avdalis C, Chen LW, Jeyalingam S, Pratt CA, Tatum HJ, Bowden JL, Lucas BR (2017) An app with remote support achieves better adherence to home exercise programs than paper handouts in people with musculoskeletal conditions: a randomised trial. *Journal of Physiotherapy* 63: 161–167]

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Introduction

Home exercise programs (HEPs) are an integral component of treatment for many different types of musculoskeletal conditions, and are typically designed by physiotherapists to suit the individual needs of patients during face-to-face sessions.^{1,2} These HEPs are usually provided to patients on a paper handout.³ The prescription of HEPs encourages patients to take responsibility for their rehabilitation and self-manage their conditions over the long term.⁴ Adherence to these programs has been directly associated with improved patient outcomes;^{5,6} however, reports indicate that up to 70% of patients do not perform HEPs as prescribed and that adherence tends to decline over time.⁶

Non-adherence to HEPs can be due to patient-related factors including low motivation, pain, poor self-efficacy, limited past experience with exercise, and reduced social support. Also, the benefits of HEPs may not be immediately recognised by patients.⁷ Some researchers suggest that adherence to HEPs could be improved if physiotherapists increased their amount of face-to-face time with patients,^{8,9} but this is costly and rarely feasible given finite resources. Therefore, other solutions to improve adherence and better utilise physiotherapy resources are needed.

Whilst the research to date has addressed many patient-related factors, little attention has been directed at evaluating different modes of delivering HEPs and how this affects adherence. Those who have investigated the influence of mode of delivery on adherence

have reported mixed results. For example, studies examining the use of video or audio tapes to deliver HEPs have not demonstrated any added benefit over paper handouts or brochures.^{10–12} More recently, a randomised, controlled trial in an outpatient stroke population compared smart device technology (video and built-in reminder functions) to paper handouts, and also failed to demonstrate any difference in adherence.¹³ In contrast, a randomised, controlled trial recently reported greater adherence to HEPs delivered through mobile phones with an internet-based self-monitoring system in patients with haemophilia-related knee dysfunction.¹⁴

Given that more than 85% of Australians are internet users, with an estimated 32 million mobile phone subscriptions,¹⁵ apps are potentially highly feasible for delivering and encouraging adherence to HEPs. Promising results have already been reported with the use of apps to improve adherence and outcomes in other health areas, such as weight loss¹⁶ and diabetic management.¹⁷ There could be several reasons for this success, including the potential for apps to send alerts, motivating messages or reminders.¹⁸ In addition, it may be more convenient for patients to access their HEPs via a mobile phone or device rather than a paper handout. A recent systematic review suggested that the ability of apps to include self-monitoring systems, for example an electronic log of completed exercises, could also increase adherence in people with chronic musculoskeletal pain.¹⁹ Furthermore, patients' adherence could be positively influenced by their knowledge that their physiotherapists can remotely monitor their adherence and provide feedback via an app. Therefore, this study aimed to investigate the potential of an app to promote adherence to HEPs in an effort to optimise patient outcomes.

Therefore, the research questions for this randomised, parallel-group trial were:

1. Do people with musculoskeletal conditions better adhere to their HEPs when delivered through an app with remote support compared to paper handouts?

2. Do people with musculoskeletal conditions report better function, more improvement in their condition, less disability and greater satisfaction with healthcare service delivery when their HEPs are delivered through an app with remote support compared to paper handouts?

Method

Design

A randomised, parallel group trial was undertaken in 80 people with upper or lower limb musculoskeletal conditions (Figure 1). The study commenced on 25 February 2016 and finished on 24 February 2017. Participants were randomly assigned via a computer-generated, concealed, fixed block randomisation procedure to either intervention (n = 40) or control (n = 40) groups. Intervention group participants received their 4-week HEPs on an app with remote support, and control group participants received their HEPs on paper handouts. Data were obtained prior to randomisation by treating physiotherapists, and then 4 weeks later by blinded assessors.

Participants, therapists and centres

Participants were recruited from patients receiving physiotherapy for musculoskeletal conditions at Royal North Shore Hospital, Sydney, Australia. Patients were initially screened by one of nine experienced physiotherapists working in either the musculoskeletal outpatients, plaster room or hand therapy departments. They were included if they had an upper or lower limb injury or condition, had been provided with 4 weeks of home exercises by a physiotherapist and were expected to complete these exercises at least three times per week. Patients were only eligible for inclusion

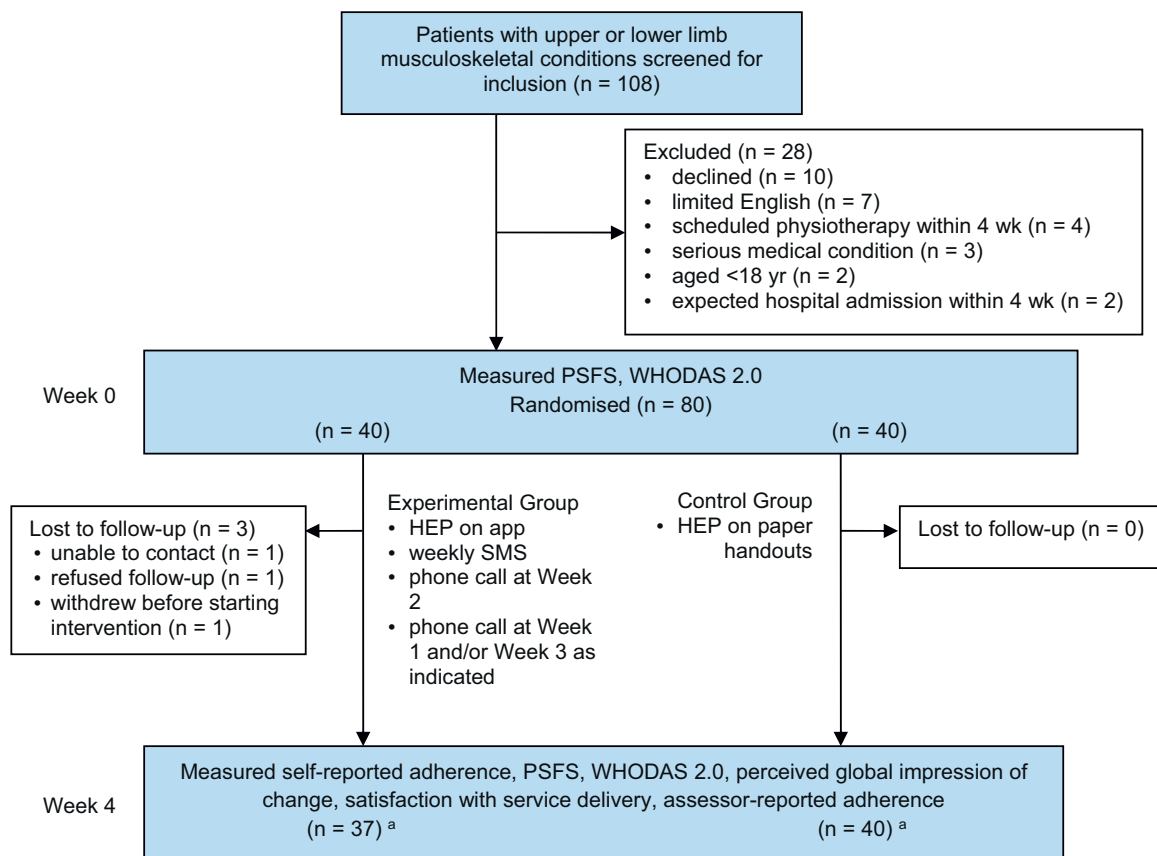


Figure 1. Design and flow of participants through the trial.

HEP = home exercise program, PSFS = Patient-Specific Functional Scale, WHODAS 2.0 = World Health Organization Disability Assessment Schedule 2.0.

^a Indicates number of participants analysed for the primary outcome. Some data were missing for some secondary outcomes; see Tables 2 to 4 for details.

if they: had access to a smart phone, tablet or computer with an active email account; were aged over 18 and able to provide informed consent; were willing to participate; and were not expected to require re-admission to hospital or further surgery during the trial period. Patients were excluded from the trial if they: were unlikely or unwilling to participate in the trial (for reasons such as serious medical conditions, cognitive impairment, psychiatric illness or drug dependency); were scheduled to receive any face-to-face physiotherapy over the course of the trial; or had limited English.

A person not involved in participant recruitment compiled a computer-generated, random allocation schedule. Participants' allocations were placed in opaque, sequentially numbered and sealed envelopes that were held offsite by an independent person to ensure that allocation was concealed. Upon successful patient screening and completion of the baseline assessment, an envelope was opened and the group allocation was revealed. At this point the participant was considered to have entered the trial.

Whilst it was not possible to blind participants, every effort was made to keep participants naïve to the details of the two groups. For example, at the time of recruitment, participants were only told that they might receive their HEPs in an alternative way to their paper handouts. They were not given any further details as to how the HEPs would be delivered or if one method was deemed superior to another.

Intervention

All participants were prescribed a 4-week HEP by their treating physiotherapist prior to randomisation. Typically, three to six exercises were prescribed and participants were instructed to complete the exercises at least once a day, three to seven times per week. The most commonly prescribed exercises were simple range of motion, strengthening and proprioception exercises. The details of the HEPs were not changed for participants of either group after randomisation. The only differences between the two groups were the mode in which the exercises were provided to participants and the additional telephone and text support provided to participants in the intervention group.

Intervention group

Participants allocated to the intervention group received their HEPs on an app associated with www.physiotherapyexercises.com, which is free web-based software used by physiotherapists worldwide for a multitude of conditions (see [Figure 2](#)). The exercises delivered through the app were identical to the exercises prescribed by each patient's treating physiotherapist prior to randomisation; however, the trial physiotherapist generated them

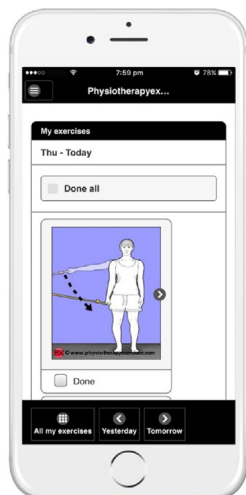


Figure 2. Example of home exercise program provided on the free www.physiotherapyexercises.com app.

from a paper copy of the original exercise program. The app was sent to participants within 1 day of randomisation by a link embedded within an email or text message. The link opened their individualised, web-based app. Subsequently, participants were phoned, informed that they were to use the app, given telephone support as they installed the app, and instructed in its use. Participants were advised to complete their exercises as recommended by their treating physiotherapist and to use the app to record adherence, which would be monitored remotely by the trial physiotherapist. They were instructed to dispose of the original paper handout of their HEP provided to them prior to randomisation. All intervention group participants were phoned again at 2 weeks, regardless of their adherence, to ensure that they understood how to use the app and provide them with an opportunity to ask any questions. In addition, those participants who had not logged any activity on their app for 7 consecutive days were phoned at 1 week and/or 3 weeks to ensure they were not experiencing difficulties using the app and to encourage them to do their exercises. The trial physiotherapist also sent out weekly motivational text messages to all participants in the intervention group stating 'keep up the hard work', 'have you logged your exercises on your app today?', or 'well done completing 4 weeks of home exercises'.

Control group

Participants allocated to the control group continued with their prescribed HEPs using the original paper handouts provided to them by their treating physiotherapist prior to randomisation. Participants in the control group did not receive any encouragement or feedback about their progress, and were not contacted again until their 4-week follow-up assessment.

Outcome measures

Assessments were taken at baseline (Week 0) for two outcomes and 4 weeks after randomisation for all outcomes by experienced and blinded physiotherapists. The baseline assessments were conducted through a face-to-face interview and the 4-week assessments were performed through a combination of telephone interview and online survey. Participants were instructed not to reveal their allocation group or method of HEP delivery to the assessor during their telephone interview at 4 weeks. There were one primary and five secondary outcomes.

Primary outcome

Self-reported exercise adherence: Participants were asked at follow-up to rate their adherence to their HEPs over the 4 weeks since randomisation on a numerical scale ranging from 0 = 'never performed my exercises' to 10 = 'always performed my exercises'. This method of capturing adherence was selected because there are few alternative ways of determining adherence that does not involve full-time surveillance.^{1,20} A similar tool has been used in previous clinical trials examining exercise adherence in musculoskeletal populations²¹ but psychometric testing has not been performed. Numerical rating scales such as this have also been widely used in medication adherence trials, and have good validity and reliability.²² A between-group difference of 2/11 points was deemed to be the minimum worthwhile treatment effect prior to commencement of the study, based on the consensus of several expert physiotherapists after taking into account the potential benefits of increased adherence to HEPs.

Secondary outcomes

The Patient-Specific Functional Scale (PSFS): This is a valid and reliable tool that is widely used by physiotherapists. It allows participants to report on their function at baseline and follow-up.²³ At baseline, participants were asked to identify up to three activities that they found difficult to perform as a result of their condition. Participants were then asked to rate each of their identified activities on a numerical scale ranging from 0 = 'unable to perform activity' to 10 = 'able to perform activity at the same level

as before the injury or problem'. At 4 weeks, the participants were asked to rate their current abilities performing the same activities they had identified at baseline. Analysis was conducted on the mean of scores for the nominated activities, with higher scores reflecting greater function.

The World Health Organization Disability Assessment Schedule (WHODAS) 2.0: This was used to determine degree of disability based on 12 items capturing mobility, self-care and community participation.²⁴ The simple scoring method was utilised, providing a total score out of 48 points,²⁵ with higher scores reflecting greater disability. These data were collected at baseline and follow-up.

Perceived global impression of change: This score was obtained at follow-up by asking participants to 'Rate the change in your condition over the past 4 weeks'. Participants were provided with a numerical scale ranging from 0 = 'a great deal worse' to 10 = 'a great deal better'. Global change scales are considered relevant instruments that are sensitive to change in both clinical and research settings.²⁶

Patient satisfaction with healthcare service: This was determined by asking the following two questions at follow-up: 'How satisfied have you been with the delivery of your home exercise program over the past 4 weeks?' and 'How satisfied have you been with the support you have received over the past 4 weeks?' Participants were instructed to rate their satisfaction on a numerical scale ranging from 0 = 'not at all satisfied' to 10 = 'extremely satisfied'.²⁷ Responses to the two questions were analysed separately.

Assessor-reported exercise adherence: The blinded assessor scored this over the phone at follow-up after asking the participants any questions deemed appropriate to formulate an opinion regarding the adherence of participants to their HEPs. The blinded assessor then provided a score on a numerical scale in response to the question 'How adherent do you think the participant has been with his/her home exercise program over the last 4 weeks?' The scale ranged from 0 = 'never did his/her exercises' to 10 = 'always did his/her exercises'.

In addition to the above outcome measures, data were collected from the intervention group for descriptive purposes. Nine questions were asked to capture participant satisfaction with the app and any barriers to its use, with five possible answers ranging from 'strongly agree' to 'strongly disagree'.

The success of blinding was determined after completion of the 4-week follow-up assessments, by asking the assessors if participants had revealed their group allocation or if they had been unblinded in any other way. Additionally, the naïvety of participants to the hypothesis of the trial was also assessed at 4 weeks. Specifically, participants were asked 'Do you think you were allocated to the better group?' They were given three possible answers: 'yes,' 'no' or 'unsure'.

Data analysis

A sample size of 80 participants was pre-determined based on a minimum worthwhile treatment effect of 2/11 points and likely SD of 3 points for self-reported exercise adherence,^{28,29} respectively, an alpha of 0.05, and a worst-case scenario of loss to follow-up of 10%. All analyses were conducted on an intention-to-treat basis. Between-group comparisons were conducted using linear regression. Baseline scores for the PSFS and WHODAS (Week 0) were included in the model to increase statistical precision. A post-hoc sensitivity analysis was performed on the primary analysis to ensure the findings were robust to the assumption of normality. For this purpose, the analysis on the primary outcome was repeated using a Wilcoxon Signed Rank Test, which is a non-parametric test that makes no assumptions about the distribution of the data. Details of the statistical analysis plan are presented in the study protocol, which is available in Appendix 1 (see eAddenda for Appendix 1). The code used to conduct the analyses in the statistical software is presented in Appendices 2 and 3 (see eAddenda for Appendices 2 and 3).

Results

Flow of participants through the study

A total of 108 patients were screened for inclusion over the duration of the trial. Of these, 80 were eligible and willing to participate and were subsequently randomised into two similar groups. The flow of participants through the trial is illustrated in Figure 1. Table 1 outlines the participants' baseline characteristics. Females represented 65% of those recruited to the trial. Participants were 18 to 88 years of age, with a mean age of 48 years (SD 17). Fractures were the most commonly treated conditions (n = 37, 46%) and the majority of participants experienced a median pain intensity of 3/10 (IQR 1 to 5) whilst performing their prescribed HEPs.

Compliance with the study protocol

Compliance with the study intervention was excellent, with 39/40 intervention group participants receiving and accessing their HEPs via the app. One participant from the intervention group dropped out of the study before commencing the intervention. Eight intervention group participants were contacted at either 1 or 3 weeks post randomisation because they had not logged activity on their app in the preceding 7 days.

Table 1
Baseline characteristics of participants.

Characteristic	Exp (n = 40)	Con (n = 40)
Age (yr), median (IQR)	56 (34 to 59)	47 (35 to 58)
Gender (M:F), n (%)	13 (33): 27 (68)	15 (38): 25 (63)
Time since injury/condition onset (mth), median (IQR)	4.5 (3.3 to 7.9)	5.3 (2.0 to 6.3)
Site of injury/condition, n (%)		
upper limb	23 (58)	17 (43)
lower limb	17 (43)	23 (58)
Injury/condition type, n (%)		
fracture	19 (48)	18 (45)
elective surgery (eg, TKR, ACL reconstruction)	7 (18)	9 (23)
soft tissue injury (eg, ankle sprain, rotator cuff tear)	10 (25)	10 (25)
other (eg, osteoarthritis)	4 (10)	3 (8)
Face-to-face physiotherapy contacts within prior 3 mth, n (%)		
1	7 (18)	4 (10)
2 to 5	19 (48)	24 (60)
6 to 10	14 (35)	9 (23)
> 10	0 (0)	3 (8)
Regular exercise (>30 mins 3 x weekly) at baseline, n (%)	32 (80)	28 (70)
Pain VAS during prescribed exercise (0 to 10), median (IQR)	3 (0.75 to 5)	2.5 (1 to 5)

Some percentages do not tally to 100 due to rounding.

ACL = anterior cruciate ligament, Con = control group, Exp = experimental group, F = female, M = male, TKR = total knee replacement, VAS = visual analogue scale.

Table 2
Mean (SD) of groups and mean (95% CI) difference between groups for all outcomes measured only at Week 4.

Outcome	Exp (n = 37)	Con (n = 40)	Exp minus Con
Self-reported exercise adherence (0 to 10)	7.8 (2.2)	6.5 (2.4)	1.3 (0.2 to 2.3)
Perceived global impression of change (0 to 10)	7.9 (1.6) ^a	7.4 (1.9) ^b	0.5 (-0.3 to 1.3)
Patient satisfaction with healthcare service (0 to 10)			
satisfaction with service delivery	8.8 (1.6)	8.5 (1.8) ^b	0.3 (-0.5 to 1.1)
satisfaction with support received	8.5 (1.9) ^a	8.1 (2.4) ^b	0.5 (-0.5 to 1.5)
Assessor-reported exercise adherence (0 to 10)	7.0 (2.2) ^c	6.7 (1.9) ^b	0.3 (-0.6 to 1.3)

Con = control group, Exp = experimental group.

^a n = 35.

^b n = 39.

^c n = 36.

Post-intervention data were missing for three participants on the primary outcome. This was mostly due to participants not being contactable at 4 weeks or declining to complete follow-up assessments. In addition, data were missing for between five and eight participants for the secondary outcomes (see Tables 2 and 3) and descriptive data (see Figure 3) due to participants declining to complete these items. Sometimes the 4-week assessment was conducted later than intended and consequently occurred a median of 5 weeks (IQR 5 to 6) after randomisation. The only reported adverse events were pain during exercise (n = 26); however, this was reported by the same participants at baseline and occurred equally within both intervention and control groups.

With regard to blinding, assessors were inadvertently unblinded in nine instances at follow-up. With regard to maintaining participant naïveté about which intervention was anticipated to be superior, 58% of the experimental group and 18% of the control group indicated that they believed they were in the superior group, with most of the remaining participants indicating that they were unsure.

Effect of HEPs provided on an app with remote support

The results for all outcomes, including between-group differences, are displayed in Tables 2 and 3. Individual participant outcome data are presented in Table 4 (see eAddenda for Table 4).

Primary outcome

The mean between-group difference for self-reported exercise adherence was 1.3/11 points (95% CI 0.2 to 2.3) in favour of the intervention group. This result was also statistically significant with the post-hoc Wilcoxon Signed Rank test ($p = 0.01$).

Secondary outcomes

There was a statistically significant between-group difference for the PSFS, with a mean between-group difference of 0.9/11 points (95% CI 0.1 to 1.7) in favour of the intervention group. However, there were no significant between-group differences for

the WHODAS 2.0 (95% CI -2.9 to 1.7), perceived global impression of change (95% CI -0.3 to 1.3), patient satisfaction with healthcare service-delivery (95% CI -0.5 to 1.1), patient satisfaction with healthcare service-support (95% CI -0.5 to 1.5) or assessor-reported exercise adherence (95% CI -0.6 to 1.3) scores.

The results of descriptive data collected from intervention group participants regarding their satisfaction with the app and its use are depicted in Figure 3. Most participants either strongly agreed or agreed with all nine domains of the questionnaire. For example, 87% of respondents found the app useful and 90% felt they would use the app to view their HEP again in the future.

Discussion

It is believed that this is the first randomised, controlled trial to examine the effect of using an app on adherence to HEPs in patients with musculoskeletal conditions.⁴ In addition, there has been little high-quality research to establish the effectiveness of such technology in the field of physiotherapy, despite a rapid uptake of apps within the health community.³⁰ Our study examined the effectiveness of delivering HEPs on an app in combination with text messaging and phone calls, with the intention of answering a pragmatic question about the effectiveness of a 'package' of interventions compared to paper handouts. Studies have shown that telephone coaching and text messaging have the ability to elicit behaviour change, which may encourage adherence²¹ and improve health outcomes.³¹ Therefore, it is not possible to know whether the same results would have been obtained if the effectiveness of the app alone had been compared to paper handouts.

The results of this study (Tables 2 and 3) indicate that participants who received their HEPs on an app with remote support reported greater adherence and greater improvements in function compared to participants who received paper handouts. A minimum worthwhile treatment effect of two points in self-reported adherence was articulated prior to commencement of the study, yet the 95% CI associated with the mean between-group

Table 3
Mean (SD) of groups, mean (SD) within-group difference and mean (95% CI) between-group difference for all outcomes measured at Week 0 and Week 4.

Outcome	Groups				Within-group difference		Between-group difference
	Week 0		Week 4		Week 4 minus Week 0		Week 4 minus Week 0
	Exp (n = 40)	Con (n = 40)	Exp (n = 36)	Con (n = 39)	Exp (n = 36)	Con (n = 39)	Exp minus Con
PSFS (0 to 10)	4.4 (1.9)	4.6 (1.9)	7.2 (1.6)	6.4 (2.1)	2.7 (2.2)	1.8 (2.0)	0.9 (0.1 to 1.7)
WHODAS 2.0 (0 to 48)	6.9 (5.4)	7.9 (6.1)	5.1 (5.1) ^a	6.5 (6.5)	-1.5 (5.0) ^a	-1.5 (5.5)	-0.6 (-2.9 to 1.7)

Con = control group, Exp = experimental group, PSFS = Patient-Specific Functional Scale, WHODAS 2.0 = World Health Organization Disability Assessment Schedule 2.0.

^a n = 35.

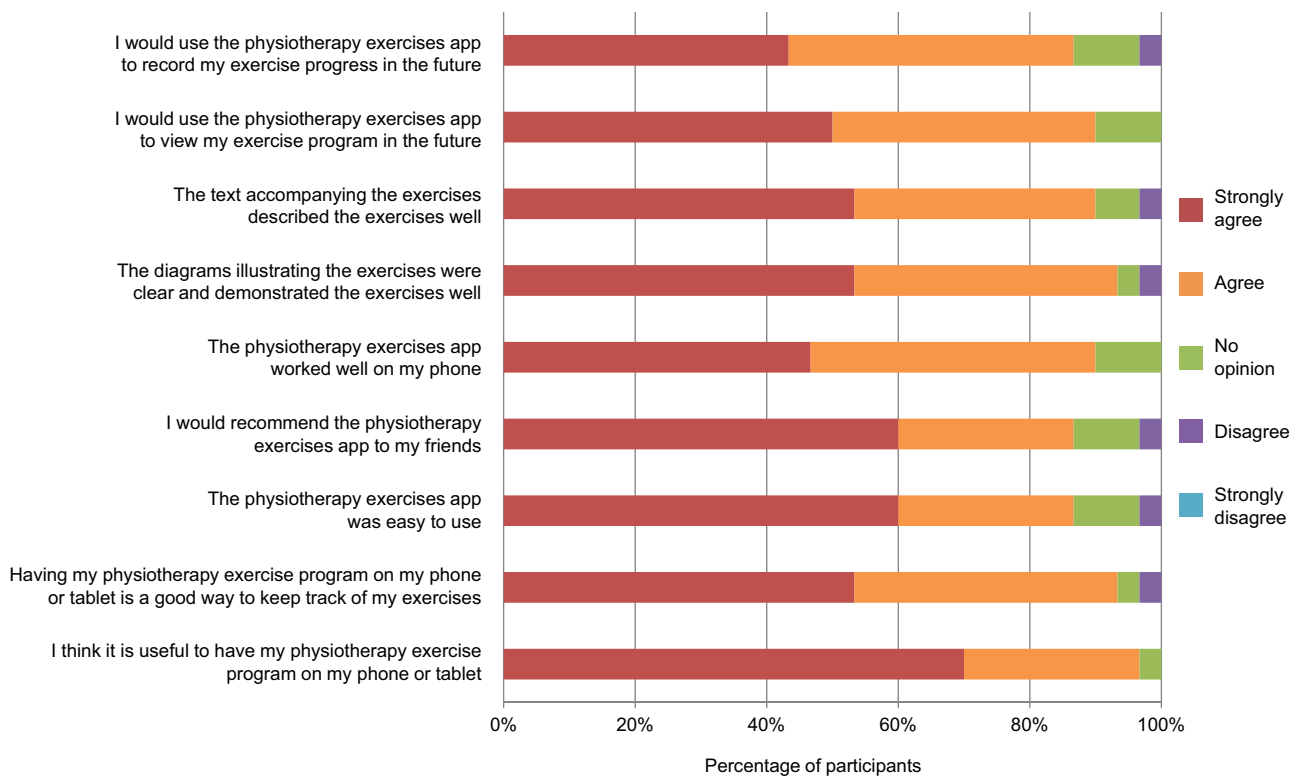


Figure 3. App satisfaction survey responses from intervention group participants (n = 32).

difference spanned this value (95% CI 0.2 to 2.3). Therefore, there is uncertainty about the clinical importance of the added adherence with the intervention. Similarly, there is uncertainty regarding the improvements in function. So together, these two sets of results do not provide convincing evidence about the superiority of HEPs provided on apps. Whether these increases in adherence and function are worth pursuing will ultimately depend on various patient, clinician and circumstantial factors, for example, patients' and therapists' computer literacy and access to mobile devices.

Importantly, the intervention group participants reported high levels of satisfaction with the app. Nearly 90% of participants strongly agreed or agreed with the nine statements about the app posed to them (see Figure 3). Of course, these data are only descriptive and may have been vulnerable to bias. Nonetheless, participants' perceptions about the benefits of using technology should be considered, particularly if HEPs can be provided through apps at no direct cost.

In the absence of any satisfactory alternate measure, the study relied on participants' self-reports of adherence. The limitations of self-report are recognised, in that individuals may overestimate (or underestimate) their own adherence.²⁰ This would be problematic if one group were to systematically overestimate (or underestimate) compared to the other. To guard against this, we attempted to keep all participants naïve to the specific purpose of the study and to the modes of delivery; however, participants were aware that we were comparing two modes of providing HEPs. The effectiveness of keeping participants naïve to the details of the study was tested by asking them at follow-up whether they felt they had been allocated to the superior group: 58% of the intervention participants and 18% of control participants indicated that they believed they were in the superior group, with most of the remaining participants indicating that they were unsure. These findings suggest that we were not very successful at keeping participants naïve to what was deemed the superior intervention, and this may have introduced bias.

In summary, providing HEPs on an app in combination with remote support increases adherence and function compared to paper handouts for people with musculoskeletal conditions, but

the clinical importance of these increases is unclear. This uncertainty probably should not discourage the use of apps for HEPs, given that physiotherapists can use freely available online software at www.physiotherapyexercises.com to generate individualised apps for their patients and users report high levels of satisfaction with it. In addition, generating individualised HEPs with the online software is probably quicker and easier than reproducing the equivalent with paper handouts (once therapists have learnt how to use the software) and provides a more professional-looking HEP that patients and therapists can use to record and monitor adherence, respectively. Regardless, there is still scope for further research about the potential benefits of apps and other similar technology for encouraging adherence to HEPs and understanding the effects on patient outcomes.

What is already known on this topic: Home exercise programs are commonly prescribed on paper for people with musculoskeletal conditions. Adherence to these programs is typically low.

What this study adds: People with musculoskeletal conditions who receive their home exercise program on an app with remote support reported greater adherence and greater improvements in function than when paper handouts were used. It remains uncertain whether this effect on adherence is clinically worthwhile. This uncertainty should not discourage the use of the app for home exercise programs, given that it: is freely available, has high user satisfaction, permits adherence monitoring, and is quick and easy to use.

eAddenda: Table 4 and Appendices 1, 2 and 3 can be found online at <http://dx.doi.org/10.1016/j.jphys.2017.05.015>.

Ethics approval: The Northern Sydney Local Health District Ethics Committee approved this study. All participants gave written informed consent before data collection began. All applicable institutional and governmental regulations concerning the use of human volunteers were followed.

Competing interests: Professor Lisa Harvey is the senior project manager of www.physiotherapyexercises.com

Source(s) of support: The research was funded by a grant from the Ramsay Research and Teaching Fund, Australia. In-kind support was provided by the Royal North Shore Hospital Physiotherapy Department.

Acknowledgements: We would like to thank the staff of the Royal North Shore Hospital Physiotherapy Department and the John Walsh Centre for Rehabilitation Research, in particular: Gary Rolls, Deborah Taylor, Patricia Evans, Raymond Jongs, Isaac Cockroft, Susan Chance, Katrina Ferguson, Joanna Prior, Rysia Pazderski, Christina Mills, Joanne Glinsky and Mohit Arora. We also wish to thank Catherine Sherrington from The George Institute for Global Health and Peter Messenger for his ongoing support of www.physiotherapyexercises.com.

Provenance: Not invited. Peer reviewed.

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CHAPTER THREE: DISCUSSION

In this chapter I will explore in more depth some of the results of my clinical trial. I will not use this section to paraphrase the discussion of the published paper but I will revisit some key points as necessary to provide context. I will also reflect upon the things I have learnt whilst conducting my clinical trial, discuss some of the challenges I faced and offer some suggestions for future research.

STUDY DESIGN

When embarking on this research, I was surprised to learn that there were no previous RCTs investigating the effects of apps on adherence to exercise in people with musculoskeletal conditions. This was surprising, as while advances in mobile technology and consumer demands drive the production of thousands of readily available health apps, medical research has not kept pace in evaluating the evidence base for app content or establishing efficacy.¹ With so little prior research in this field at the time, it was tempting to set out to answer a very broad research question, or many questions at one time. I learnt the importance of developing a clear research question, with a defined population, intervention, comparison and outcome. This helped guide important decisions throughout this study surrounding methodology, analysis and writing up my paper.

This study was designed to reduce bias. For example, study participants were randomly allocated to intervention and control groups by a computer generated, concealed procedure. Measures conducted at follow-up were conducted by assessors who were blind to group allocation. Analysis was by intention-to-treat. Whilst it was not possible to blind participants, efforts were made to keep participants naïve to the alternative intervention to prevent systematic bias.

One of the challenges at the beginning of this trial was establishing an appropriate sample size. It was difficult to find prior studies which used a comparable outcome measure to determine the likely standard deviation. The reported standard deviation of 2.4/11 points in this study ended up quite close to that

anticipated (3/11 points), but it was very difficult to know before starting the trial whether this standard deviation would be achievable. Fortunately, the confidence interval for the primary outcome (0.3 to 2.3) indicates that the sample size was sufficient to show a conclusive effect. Throughout this process I have learnt a lot about the complexity of power calculations. Similarly, it was difficult to articulate a minimum worthwhile treatment effect for the primary outcome; self-reported exercise adherence. Due to a lack of comparable studies which used the same outcome to report exercise adherence, there was very little information to base the pre-determined minimum worthwhile treatment effect of 2/11 points on. Previous studies used different scales to measure adherence² or collated various different outcomes to produce an overall adherence score. Ultimately, 2/11 points was determined by the consensus of a group of expert clinicians and researchers after carefully considering the potential benefits of introducing an app to clinical practice. However, other clinicians or researchers may have differing opinions about how much change in adherence is clinically meaningful. This will likely depend on the associated time, costs and inconvenience of employing a new intervention in their practices. I will discuss some of these factors in a later section.

This study had broad inclusion criteria. They reflect the variety of upper and lower limb conditions typically presenting to public hospital outpatient physiotherapy services and make these results generalisable. Initially there were concerns that this heterogeneity may add unwanted ‘noise’ to the data and lead to an imprecise estimate. It was considered that perhaps the type or the chronicity of patients’ conditions may influence adherence to home exercise programs (HEPs). For example, a patient undergoing rehabilitation following anterior cruciate ligament reconstruction from an acute injury may be more likely to adhere to home exercise than a person with insidious onset knee pain due to osteoarthritis. However, there was no evidence to indicate that one sub-group would preferentially achieve better outcomes with the intervention than the other. Current knowledge is that adherence relates to behaviour, and that patients with a particular pathology are not necessarily more or less adherent than another.³ The

relatively narrow 95% confidence interval for self-reported exercise adherence (0.2 to 2.3) reinforces this (Figure 1).

Although clear inclusion criteria were adhered to during recruitment, this sample was one of convenience. That is, it simply was not possible to screen every patient that presented to hospital physiotherapy services for upper or lower limb conditions for inclusion to the study. This is not ideal, and may have introduced selection bias, but is part of the reality of conducting a clinical trial in a busy hospital outpatient service. Even though clinical staff were adequately trained in recruitment, the often-busy environment and competing priorities in clinical practice meant that recruiting participants to this clinical trial was not always at the forefront of the clinicians' minds. This could be overcome if research staff were employed solely to screen all potentially eligible patients. However, this requires funding.

KEY FINDINGS

Adherence

The results of this study indicated that people who received their HEPs on an app with remote support reported greater adherence than those who received their HEPs on paper handouts (Figure 1).

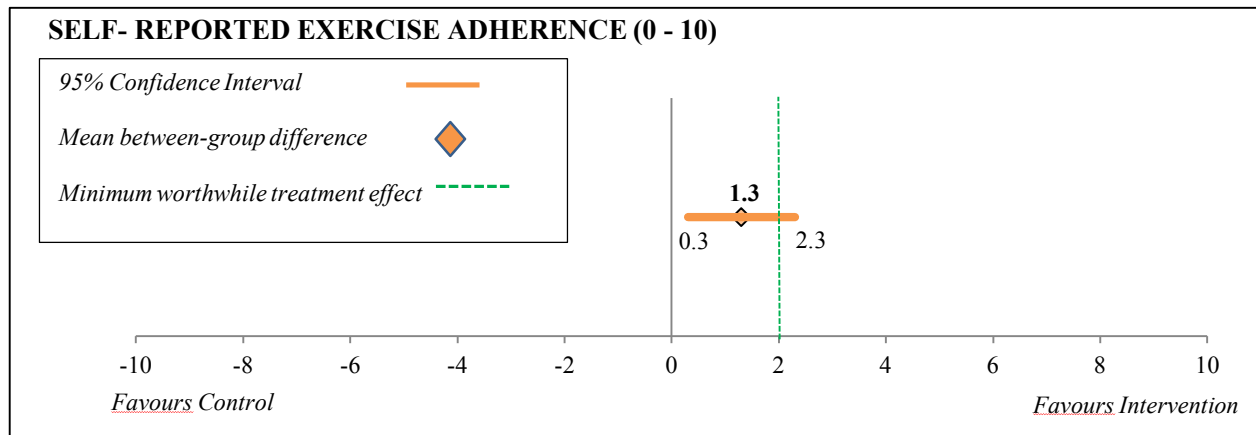


Figure 1. Self- Reported Exercise Adherence expressed on a forest plot. Mean between-group difference and 95% CI with respect to minimum worthwhile treatment effect.

While this result is statistically significant, the clinical importance is unclear. As demonstrated by the confidence interval (Figure 1), the estimated mean effect of delivering HEPs on an app with remote support in the wider population may be as low as 0.3/11 points or as high as 2.3/11 points. So, this result would only be clearly meaningful to a person who believed that a 0.3/11-point change in adherence was worthwhile.

We relied on patients' self-reports to measure adherence. We recognise that people might be inclined to over-rate (or under-rate) their own adherence with self-report. However, importantly, provided the participants were not aware of our study hypothesis this should occur equally within both groups and therefore would not systematically bias our results. Regardless, the literature on this topic concedes that there are no known, standardised measures of adherence to unsupervised exercise⁴ and therefore we must rely on self-report. Hence, we chose to use a numerical rating scale anchored at 0 and 10 to determine self-reported exercise adherence; our primary outcome. Alternatively, we could have used the adherence

data collected through the app for the intervention group. However, we had nothing equivalent for the control group and therefore could not make any between-group comparisons. The only way we could have overcome this was to ask control participants to record their adherence through a paper diary. We did not do this for two reasons. Firstly, we did not provide participants with diaries because we were concerned about contamination. That is, the mere process of recording adherence in a paper diary may influence adherence. Secondly, paper diaries are not routinely given to patients with their HEPs at the site where this trial was conducted. We designed a trial that compared our usual practice with the app to answer a pragmatic question about the benefit of introducing the app to clinical practice.

For descriptive purposes, we conducted a post-hoc analysis to test the correlation between logged rates of adherence on the app with self-reported exercise adherence scores. To do this, the number of days exercises were marked as 'done' on the app was divided by the number of days exercises were prescribed, and then converted to a percentage. As three experimental group participants were lost to follow-up, we had 37 participants to conduct this analysis on. A simple linear regression was conducted.

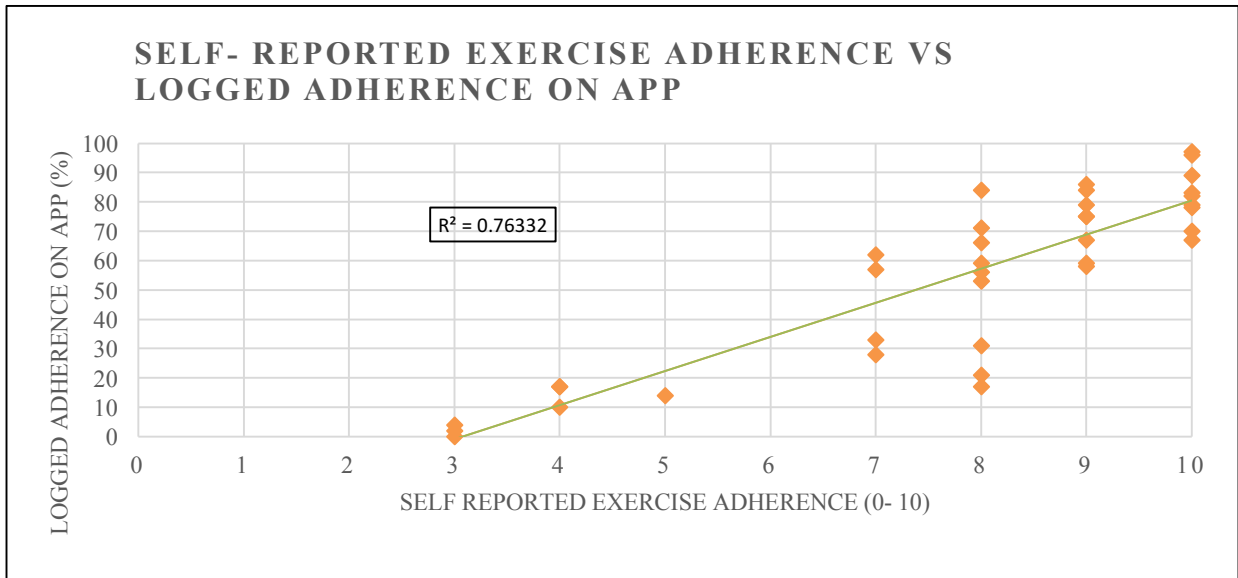


Figure 2. Correlation between self-reported exercise adherence and logged adherence captured in www.physiotherapyexercise.com app.

The line of best-fit (Figure 2) suggests the two measures of adherence are highly correlated ($R^2 = 0.76$). This suggests self-reported adherence is a satisfactory surrogate measure of adherence, but there is some evidence of systematic over-rating. For example, it appears that those who did not log any or very little adherence on their app still scored themselves more than 2/11 points for self-reported adherence. This perhaps reflects patients who did some exercise but did not log it on the app. Alternatively, perhaps these patients did very little or no exercise but over-rated their own adherence. Regardless, there is nothing to suggest this would have occurred within the intervention group and not the control group. We can only assume that such over-rating occurred equally in both groups, and therefore would not have biased our results.

The result observed for self-reported exercise adherence was not supported by the assessor-reported adherence outcome, which did not detect any significant between group difference (95% CI -0.6 to 1.3). We also conducted a post-hoc analysis to correlate the self-reported exercise adherence scores with the assessor-reported adherence scores (Figure 3). Low correlation was revealed ($R^2 = 0.30$).

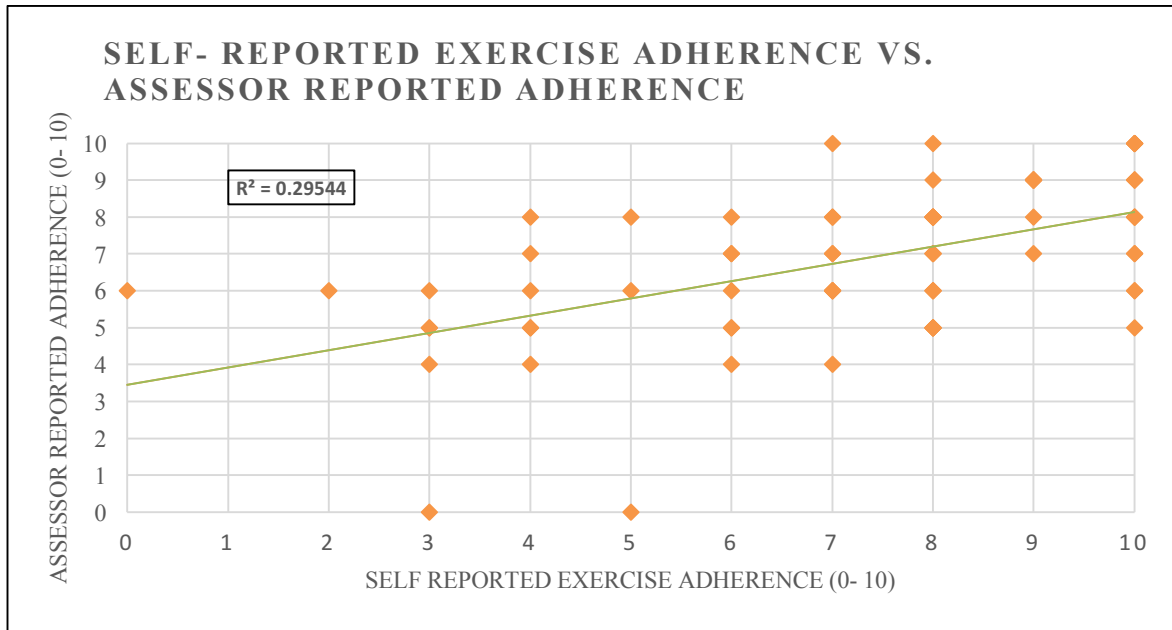


Figure 3. Correlation between self-reported exercise adherence and assessor reported adherence.

Possibly it was difficult for assessors to accurately gauge adherence over the phone, without any face-to-face contact. We were unable to use any previously validated tools such as the Sports Injury Rehabilitation Adherence Scale (SIRAS) to determine assessor-reported adherence as they require face-to-face supervision⁵ and our follow-up was conducted by telephone interview and online survey.

Interestingly, our mean (SD) reported score for assessor-reported adherence of 6.8 (2.0)/ 11 points is very similar to that reported in a large, Australian cross-sectional study exploring physiotherapists' perceptions of adherence to prescribed self-management strategies. This study reported an overall mean perceived adherence of 67% to all strategies.⁶ This may suggest that generally, physiotherapists are also inclined to over-rate their patients' level of adherence. Or, perhaps as it is impossible to know what patients do whilst unsupervised, physiotherapists tend to select a number that is somewhat moderate (e.g 6/11 points) when asked to make such judgements. Certainly in other health areas, research indicates that health professionals are often inaccurate when predicting adherence in their clients.⁷

Function

Our study also demonstrated that participants who received their HEP on an app with remote support report greater improvements in their function compared to those who received their HEP on a paper handout (between-group difference 0.9/11 points). The clinical importance of this result is unclear, as demonstrated below in the forest-plot diagram (Figure 4). As our confidence interval spanned 0.1 to 1.7 points, the estimated mean difference in function in the wider population may lie anywhere between these values. As this was chosen as a secondary outcome, no minimum worthwhile treatment effect was set prior to the study. Therefore, the clinical importance of this result remains open to interpretation.

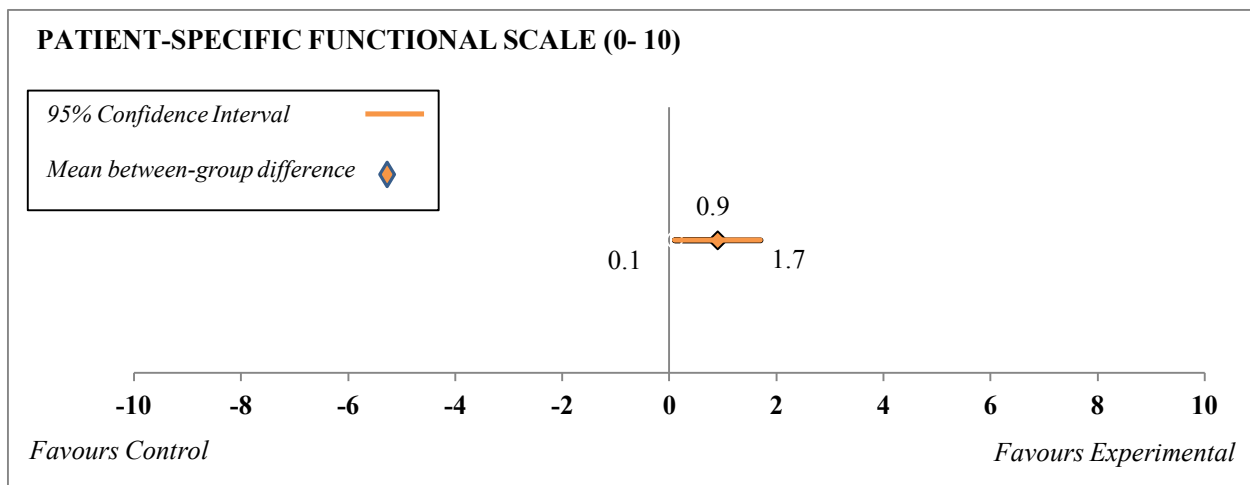


Figure 4. Result for the Patient- Specific Functional Scale, depicting the mean between-group difference and 95% confidence interval.

Disability, perceived change and satisfaction

No significant between-group differences were found for our remaining secondary outcomes which aimed to capture disability, perceived global change or satisfaction with healthcare. In hindsight, this may reflect that some of these outcomes were not appropriate for our study population. For example, the WHODAS 2.0 was selected as a measure of disability. It was selected as it is a valid, reliable and simple-to-

administer tool. The 12-item version of this tool covers domains that typically affect patients with musculoskeletal conditions and lower scores indicate less disability.⁸ It is likely that the WHODAS 2.0 did not detect a difference between groups in our sample due to its ‘floor effect.’ The inclusion criteria for our study stipulated that participants would not receive any face-to-face physiotherapy for a minimum of 4 weeks, indicating that they were at a stage of their rehabilitation which required less supervision and thus they probably had satisfactory mobility, self-care and participation at baseline. This was reflected in very low baseline scores (mean 7.55/ 60 points, SD 5.97) for all participants and left very little room for improvement to be detected. Previous studies using the WHODAS 2.0 have encountered the same issue when assessing people with a physical health condition alone.⁹ So perhaps this outcome measure was somewhat futile, and, if repeating this study in the same population group I would be inclined to eliminate this outcome, or select a more suitable tool.

No significant between-group difference was detected for perceived global impression of change. There could be several reasons for this. It is possible that the fairly short study period of 4 weeks was not long enough to detect significant changes between groups for this outcome.

Study participants who received their HEPs on the app did not conclusively report greater satisfaction with healthcare service delivery or support received than those who received paper handouts (95% CI -0.5 to 1.1) and (95% CI -0.5 to 1.5), respectively. We anticipated that intervention group participants may report greater satisfaction than those who received paper handouts as they received added remote support in the form of telephone calls and text messaging throughout the trial. However, all participants reported very high levels of satisfaction (mean 8.5/ 10 points, SD 1.9) leaving very little room for improvement at the upper end of the scale. Hence, a ceiling effect was observed for our satisfaction with service outcomes. Previous research conducted in Australia reports that generally, satisfaction with physiotherapy services is very high. For example, a 2012 prospective study of 274 people attending physiotherapy in Australia for musculoskeletal disorders reported a very high mean satisfaction score of 4.6 (95% CI 4.5 to 4.6) on a 1 to 5 scale, where 5 indicated high satisfaction. Interestingly, these high satisfaction scores did

not correlate with treatment outcomes ($r = -0.22$).¹⁰ Similar results have been observed in patients with low back pain attending primary care, including physiotherapy. A secondary review conducted in 2013 on a large longitudinal cohort study found that whilst 76% of patients were highly satisfied with their care, only 55% were satisfied with their symptoms at 12-month follow up.¹¹ So, whilst patient satisfaction is important and it is encouraging that patients presenting to physiotherapy services express high levels of satisfaction, it doesn't appear that changing the mode of HEP delivery has any additional effect on this. Therefore, caution should be exercised in presuming that high satisfaction with service leads to better patient outcomes.

BARRIERS TO TRANSLATION

In this section I will address some of the barriers I encountered when conducting my clinical trial, and discuss the implications these barriers may impose on the introduction of apps in physiotherapy practice.

Firstly, it is important to consider the technology itself. The program we used (www.physiotherapyexercises.com) is a web-based app, meaning that it can be accessed directly from the website without the need to use iTunes© or equivalent app stores. However, it requires internet connection to work. The disadvantage of this method is that if the server hosting the program goes down, users are unable to access their app. Unfortunately, this occurred during our trial for a period of 6 days. During this time, affected participants were contacted by phone and advised to continue with their HEPs to the best of their ability. They were then instructed to retrospectively log their adherence once the app was fully functional again. It is unclear whether this had an impact on the overall results in the trial; however, there are always risks of encountering technical problems when using mobile technology to deliver a health intervention. Consequently, the program has begun undergoing changes so that it will soon be available in offline mode. This will mean constant internet connection is not required for users to access their HEPs or record their participation.

Secondly, the practicalities associated with the use of the technology must be considered. This study demonstrated that an app can improve adherence and function, but this might not be enough to convince clinicians that they should use it to provide their HEPs instead of paper handouts. One of the practical issues is speed. Clinicians may experience that it is simply faster to gather a paper handout from a familiar clinical resource than it is to open an online tool, individually select the appropriate exercises for that patient and send it to the patient's mobile device. Additional time is then required to instruct a patient in the setup and use of the app. In an outpatient physiotherapy setting where patient assessment, treatment, case planning and documentation are typically expected to take place within 30 minutes, even small amounts of additional time may prove too costly to some clinicians.

Consumers seem to embrace the emergence of technology within health care; however, I have observed a gap in clinicians' attitudes towards the introduction of apps in clinical practice. While conducting this clinical trial I encountered several technology-averse clinicians reluctant to use systems which they were unfamiliar with. There are several reasons for this. Firstly, if clinicians do not have the computer literacy or confidence to utilise app technology themselves, it is difficult to expect them to effectively pass these skills on to patients. Secondly, clinicians in the public health setting are often time-poor, thus learning and familiarising with a new tool is not always prioritised, especially when there are well established tools such as paper handouts. Systems and policies must be in place to encourage learning and development and ensure clinicians are keeping pace with technological advances that are potentially meaningful to patient outcomes.

Mobile technology, including apps can be expensive for clinicians and patients. Whilst mobile technology for health is a burgeoning area in research,^{12,13} there are gaps in implementing these interventions within clinical practice. It is my experience in the public health sector that mobile interventions are currently not well funded compared with traditional face-to-face interventions. However, the program we used for our trial is free, accessed via the website www.physiotherapyexercises.com. Of course, there are other associated costs involved in using the program. For example, the time spent training physiotherapists to use the program needs to be considered. I estimate that it would take at least 4 hours of training and practice for a physiotherapist to be fully competent in providing the intervention tested in this study. In addition, providing remote support also incurs costs; both the staffing required as well as the physical costs of telephone calls and text messages. However, these associated costs need to be weighed up against the costs of poor adherence which were addressed in chapter one.

Effective communication with patients is essential to ensure the smooth running of clinical trials and clinical care, especially where remote or mobile interventions are used. However, I discovered that there are barriers to this. For example, we relied on the use of hospital phones to make contact with intervention group participants to provide remote support for the app. Unfortunately, hospital phone numbers

displayed as 'no number' on receiving phones, which many participants were reluctant to answer. This made communication difficult and inefficient. Small details like this need to be considered by service providers if interventions like tele-health and e-health are to be successful in the future.

A common belief I have encountered is that an app is only suitable for younger people. Although formal sub-group analyses have not been conducted within this study to determine a relationship between age and adherence, there is some useful information to counter this argument. The median age of participants in our intervention group was 56 (IQR 34 to 59 years), and only nine patients in this group were aged younger than 30. As our descriptive data reveals (Figure 3 in published paper, chapter two), only one of the intervention group participants disagreed that the app was easy to use. Regardless, we should bear in mind that soon the young people of today will be older, and most probably be familiar with mobile technology. It is important that physiotherapy practice reflects consumer demand and preference as technology develops.

FUTURE RESEARCH

There is large scope for further research into the potential benefits of apps in physiotherapy practice.

Undoubtedly technology will continue to develop and health services should endeavor to explore how this can enhance patient outcomes. In this section I will make some recommendations towards future research looking at the effects of apps on adherence to HEPs.

Our study examined the effects of an app with remote support, and therefore we cannot make inferences about the potential effects of an app alone, or that of remote support alone, in promoting adherence to HEPs. Future trials may wish to explore these as separate interventions, as there may be individual benefits of each. For example, text-messaging alone has shown promising results in promoting behavior change in patients with cardiovascular disease.¹⁴ In addition, telephone coaching has been shown to increase adherence to physiotherapist-prescribed interventions at 6 months in people with knee osteoarthritis, but these benefits were not maintained thereafter.¹⁵ Examining the benefits of these interventions separately in people with musculoskeletal conditions may provide some useful information, particularly for health services where providing both an app and remote support is not feasible due to various time, cost or staffing constraints.

Our trial results reflect participants' adherence to a HEP over a 4-week period. However further studies examining more persistent adherence over longer periods (e.g 6 months) of time would be useful, especially for chronic musculoskeletal conditions where ongoing self-management is important. In a New Zealand based RCT examining the effects of a text-message and internet program designed to promote adherence to medication and healthy lifestyle behaviours in cardiovascular disease, improved adherence was observed at 3 months, however gains were not maintained at 6 months.¹⁶ To date, large trials testing the effectiveness of various technologies to promote long-term adherence to behaviour changes such as exercise are lacking.

Our study offers some knowledge regarding the effects of apps on adherence to HEPs. We did not have any information on this topic prior to this study. Knowing now that apps can improve adherence to HEPs, it is important to reflect upon the significance of this. Improved adherence only matters if it corresponds to improvements in patient-centered outcomes such as function or quality- of- life. Therefore, I would suggest that future research focuses on the benefits of apps or similar technology on these outcomes, with adherence collected as a secondary outcome.

SUMMARY

The aim of this thesis was to determine the effects of exercises delivered to patients on an app with remote support compared to paper handouts. Our RCT was able to conclusively find that those who were provided with an app and remote support reported better adherence and greater improvements in function than those who received paper handouts. The clinical importance of these findings remains unclear. Nonetheless, user satisfaction with the app tested in this study was high and the costs very low. These findings should encourage further exploration into the potential benefits of apps in physiotherapy practice, particularly with regards to home exercise. I hope that the findings delivered in this thesis will provide some guidance to future research and clinical practice in physiotherapy.

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