BMJ Open

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

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2020-041242
Article Type:	Protocol
Date Submitted by the Author:	04-Jun-2020
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Keywords:	Telemedicine < BIOTECHNOLOGY & BIOINFORMATICS, Musculoskeletal disorders < ORTHOPAEDIC & TRAUMA SURGERY, REHABILITATION MEDICINE, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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

Trial Registration:

This trial is registered at the Australian and New Zealand Clinical trial registry. It will be conducted in accordance with the NHMRC National Statement on Ethical Conduct in Human Research (2018) and the Note for Good Clinical Practice (CPMP/ICH-135/95).

Protocol version:

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

Funding:

This project has received funding through Australia's Medical Research Future Fund (MRFF) Rapid Applied Research Translation Program grant awarded to Sydney Health Partners.

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ABSTRACT

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

Method: The aim of this single-blind randomised controlled non-inferiority trial is to determine whether a supported home exercise programme is as good as or better than face-to-face physiotherapy for the treatment of musculoskeletal conditions. Two hundred and ten participants will be recruited from four public hospitals in Sydney, Australia. Participants will be randomised to either the Supported Home Exercise Group or the Face-to-face Physiotherapy group. Participants allocated to the Supported Home Exercise Group will initially receive one face-to-face session with the trial physiotherapist and will then be managed remotely for the next 6 weeks. Participants allocated to the Face-to-face Physiotherapy Group will receive a course of physiotherapy as typically provided in Sydney government hospitals. The primary outcome is function measured by the Patient Specific Functional Scale at 6 weeks. There will be 9 secondary outcomes measured at 6 and 26 weeks. Separate analyses will be conducted on each outcome and all analyses will be conducted on an intention-to-treat basis. A health economic evaluation will be conducted from a health funder plus patient perspective.

Results: Recruitment commenced in March 2019 and it is anticipated that the trial will be completed by September 2021.

Conclusion: This trial will investigate two different models of physiotherapy care for people with musculoskeletal conditions.

Strengths and limitations of this study:

- The results of this trial will inform cost-effective models of physiotherapy care and will be particularly relevant in the 2019/2020 Coronavirus pandemic because we need alternate ways of delivering physiotherapy that minimises face-to-face contact.
- The trial has many design features important for minimising bias including concealed allocation, blinded assessors and intention-to-treat analysis. In addition, it is highly pragmatic involving 4 public hospitals in Sydney. This increases its external validity.
- Although the 6-and 26-week assessments are blinded, it is not possible to blind the clinicians or the participants.
- The results of this trial will be most applicable to the provision of physiotherapy in public hospitals as no participants from the private physiotherapy sector will be included.

INTRODUCTION

Musculoskeletal conditions are common and include back pain, hip and knee osteoarthritis, whiplash-associated disorders and ankle sprains. Together musculoskeletal conditions cause 21% of the total years lived with disability (second only to mental illness), placing a great burden on world health (1). In 2015 an estimated 30% of all people had at least one musculoskeletal condition in Australia. This figure is reported to be as high as 72% for people aged over 75(2). These conditions cost $9.2 billion in health services and $7.4 billion in lost productivity (1, 3, 4).

Exercise, support and advice are considered core components of management for many musculoskeletal conditions (5-8). Exercise, support and advice are typically provided by physiotherapists through regular face-to-face treatments. However, exercise can be provided remotely as part of a home exercise program while support and advice can be provided via the telephone. There is initial evidence from trials and systematic reviews to suggest that different forms of remotely-provided physiotherapy can be used to manage a variety of musculoskeletal conditions safely and effectively (5, 9-17). A move away from reliance on face-to-face physiotherapy has many potential benefits. Adopting new technologies and strategies into physiotherapy management will allow for the delivery of timely and accessible care to those who are in remote or rural locations, and those who have significant mobility issues. Another benefit for this method of physiotherapy is its low cost which might enhance cost-effectiveness from a funder and patient perspective. Increasing remote access and decreasing the cost of physiotherapy may have the added benefit of decreasing the burden on the public health system by decreasing waiting times for publicly funded outpatient physiotherapy.

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

The trial will be highly pragmatic with broad inclusion criteria to capture a range of musculoskeletal conditions for which exercise, support and advice are the basis of evidence-based care. The aim is to determine whether a supported home exercise program is as effective or better, than a course of face-to-face physiotherapy. This will be determined with one primary outcome and 9 secondary outcomes. An economic analysis will be run alongside the trial to assess the affordability and value for money of this model of care from a health funder plus patient perspective. A process evaluation

will also be completed in order to understand the feasibility of delivering physiotherapy through supported home exercise programs and to explore the perspectives of patients, healthcare professionals and key stakeholders about different models of delivering physiotherapy.

METHODS AND ANALYSIS

Design:

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

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

Participants:

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

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

- is 18 years or over and able to provide informed consent in writing
- has a musculoskeletal condition. Examples include:
    - back/neck pain
    - hip or knee osteoarthritis
    - whiplash-associated disorders
    - ankle sprains
    - post fracture
    - sporting injury
    - post hip or knee replacement
- is seeking physiotherapy treatment at the participating hospital
- can speak and read English to provide informed consent
- is able to participate for 6 weeks and will be available for 6 and 26-week follow up assessments

- has access to a smart phone with internet connection
- is identified by the hospital physiotherapists or trial physiotherapist (study coordinator) to have a condition appropriate for treatment with exercise, support and advice.

A person will be excluded if he or she:

- is pregnant
- has a mental illness which may affect adherence to the trial protocol
- is deemed to be at a high risk of falling with home exercises
- is at a clinical risk without Face-to-Face physiotherapy
- is on a post-operative exercise regime prescribed by a surgeon

Public and patient involvement:

Over a 20-year period, patients and the public were involved in the development of the exercise App (www.physiotherapyexercises.com) upon which this trial is based. The primary outcome measure was designed by other researchers with input from patients. All participants for this trial are patients on a waiting list for outpatient physiotherapy in one of the four public hospitals involved in this trial. All participants will be asked to give written informed consent before being randomised. In order to include the participants' perspective in the results of this trial, an outcome measure asking the participants to self-report their satisfaction with service delivery will be included. A secondary process evaluation will also explore participants' opinions and experiences of the intervention and trial. Participants will be able to access the published results of this trial.

Recruitment strategy and time frame:

Recruitment started in March 2019 and currently 101 participants have been randomised. Recruitment was however temporarily ceased on 9 March 2020 because of the COVID-19 pandemic. It will recommence once it is considered safe and appropriate by the investigators and participating sites and will continue until 210 participants have been recruited (see Appendix Table 1 for the timeline of study pre COVID-19).

Assignment of intervention:

A secure random allocation schedule has been computer-generated by an independent researcher and is stored off site on a REDcap database. Randomisation is blocked and stratified by site and duration since onset of injury (less than 12 weeks versus more than 12 weeks). The allocation schedule is concealed from potential participants and from all staff associated with the trial. Randomisation will occur once a participant has been screened, provided consent and completed

the baseline assessment. A trial staff member responsible for coordinating the treatments will log onto REDcap to retrieve the participant's allocation. Participants' assignments will not be disclosed to the blinded assessors or all but two Investigators. Eligible participants are randomised into one of two groups namely:

1. **The Supported Home Exercise Group**. Participants initially receive one face-to-face session with the trial physiotherapist but are then managed remotely for the next 6 weeks.

2. **The Face-to-face Physiotherapy Group**. Participants receive a course of face-to-face physiotherapy by a hospital physiotherapist.

Interventions:

1. Supported Home Exercise Group: Participants allocated to the Supported Home Exercise Group initially receive one face-to-face session with the trial physiotherapist and then will be managed remotely for the next 6 weeks. During the initial session, the trial physiotherapist will assess the patient and then prescribe an individualised 6-week home exercise program consisting of a battery of 5 to 10 exercises. This will be delivered to patients' mobile devices using a freely available exercise-prescribing App that authors LAH, JG and colleagues have developed (www.physiotherapyexercises.com). The number of repetitions and sets of exercises will be determined by the trial physiotherapist. Participants will be asked to complete their exercises at least once every day for the intervention period of 6 weeks. Participants will record exercise adherence on their App. These data will be automatically transferred to a password protected section of the website which is accessed by the trial physiotherapist to remotely monitor exercise adherence. The trial physiotherapist will provide ongoing support through weekly text messages. The purpose of these text messages is to encourage adherence to the prescribed exercises and provide the participants with encouragement and support. These text messages are generated from a pre-paid website and are scheduled to be sent each week to the participants in the Supported Home Exercise Group. The messages are not individualised but are designed to be motivating and to remind participants to continue their exercises. Participants cannot respond to these text messages (See Appendix Table 2 for examples of the text messages). The participants will also receive a telephone call from the trial physiotherapist at 2 and 4 weeks to ensure adherence and provide feedback, support and advice. Participants will be telephoned more frequently if their exercise adherence is poor. Participants are also able to contact the trial physiotherapist on a study mobile phone number or via email at any time. The trial physiotherapist has the option of providing an additional face-to-face physiotherapy session if she has any concerns about a participant's progress,

safety or wellbeing that she may become aware of from conversations with the participant over the telephone or from any other trial or hospital staff.

2. Face-to-Face Physiotherapy Group: Participants allocated to the Face-to-Face Physiotherapy Group will receive a course of physiotherapy as typically provided in Sydney government hospitals. This will be provided by the hospital physiotherapists and could involve up to three sessions per week for up to 6 weeks or group classes. The number of sessions per week and duration of the course of physiotherapy for each participant will be determined by the hospital physiotherapist and may be gradually decreased and completed during the intervention period if a participant recovers. This approach has been adopted to mimic usual practice. The type of physiotherapy provided during the face-to-face sessions will be determined by the hospital physiotherapist and may include any combination of manual therapy, advice, exercise and occasional electrotherapy. In this way, the trial will be pragmatic and will provide a real-life comparison of the two models of care. The number and type of therapy provided will be recorded and reported (see Appendix Table 3 for a detailed description of the intervention as per the TIDier guidelines).

Outcome measures:

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

The primary outcome will be:

Function as measured by the Patient-Specific Functional Scale at 6 weeks. This outcome measure is sensitive to changes that are important to patients and is used across many different types of musculoskeletal conditions including cervical spine, knee and lower back pain (17). Participants are asked at baseline to identify up to five functional activities that are most important to them and which they find difficult to perform. Participants are then asked to rate each activity at baseline and 6 weeks on an 11-point scale. The scale ranges from zero to ten and indicates the level of difficulty participants have with each activity due to their condition. Zero indicates that they are unable to perform the activity and 10 indicates that they are able to perform the activity at pre-injury level. Scores for each activity are summed and expressed as a percentage of the total possible score for the participant (determined by the number of identified activities) (17, 18).

The secondary outcomes will be:

The Patient-Specific Functional Scale at 26 weeks. See above for details.

Fear of movement and re-injury measured using the Tampa Scale for Kinesiophobia (TSK) at 6 and 26 weeks. The TSK is a multi-item instrument that quantifies fear of movement and re-injury. Participants are asked to score 17 items on a scale of 1-4, where a score of 1 indicates "*strongly disagree*" and a score of 4 indicates "*strongly agree*". Item 4, 8, 12 and 16 are reversed where 1 indicates *"strongly agree"* and 4 indicates *"strongly disagree".* This instrument has high reliability (19, 20).

Pain measured using a 0-10 Numerical Rating Scale (NRS) at 6 and 26 weeks. Participants are asked to rate their average pain over the past 24 hours on a 0-10 numerical rating scale anchored at each end with "*no pain*" and "*worst pain imaginable*". The NRS for pain measurement is a valid and reliable tool for measuring acute and chronic pain (21).

Patient Global Impression of Change at 6 and 26 weeks. Participants are asked to rate the change in their condition on a numerical scale. This scale ranges from negative seven to positive seven anchored in the middle and at each end with "*no change*", "*very much worse*" and "*very much better*", respectively.

Patient satisfaction with healthcare service delivery at 6 weeks. Participants are asked to rate their satisfaction with the care they have received for their musculoskeletal condition on an 11-point numerical scale. This scale ranges from zero to ten anchored at each end with "*complete dissatisfaction*" and "*complete satisfaction*" with the delivery of healthcare service.

Health-related quality of life measured using the EuroQol-5D at 6 and 26 weeks. This validated questionnaire has been used in a wide range of musculoskeletal conditions and requires the participant to rate their level of problems in five dimensions including mobility, self-care, usual activities, pain and anxiety/depression. Utility based quality of life will be derived from the Australian valuation of this instrument for use in the cost-utility analysis.

Functional performance measured with the Function Component of the Later Life Function and Disability Instrument at 6 and 26 weeks. This standardised 32-item instrument captures participants' perceptions about their abilities to perform discrete actions or activities (e.g. unscrew the lid of a jar; put on and take off a coat or jacket). It is suitable for adults of all ages even though it was specifically designed for adults in later life. This instrument has good validity and has been recommended for self-reported data collection (22). The full assessment also captures life performing tasks and limitations on performing life performance tasks but only the Functional Performance aspect of the assessment will be used. Participants are asked to rate their difficulties

performing each of the 32 actions or activities on a 5-point scale ranging from "*none*" (i.e., no difficulties performing the activity) to "*can't do*". Scores will be transformed into a 0 to 100 summary score where a high score indicates a higher level of functioning (23).

Frequency of performing life tasks measured with the Disability Component of the Later Life Function and Disability Instrument at 6 and 26 weeks*.* This standardised 16-item instrument captures participants' perceptions about the frequency with which they perform socially defined life tasks such as visiting friends and family in their homes, taking part in recreational activities, and traveling with overnight stays (22, 23). Participants are asked "*to what extent they [do you] feel limited in doing a particular task*". They are provided with the following options: "*completely*", "*a lot*", "*somewhat*", "*a little*", and "*not at all*". Scores will be transformed into a 0 to 100 summary score where a high scores indicates a higher level of functioning (23).

Limitations in capability of performing life tasks measured with the Disability Component of the Later Life Function and Disability Instrument at 6 and 26 weeks. This standardised 16-item instrument captures participants' perceptions about their limitations in performing socially defined life tasks such as visiting friends and family in their homes, taking part in recreational activities and traveling with overnight stays (22). Participants are asked "*how often do they (1) do a particular task*". They are provided with the following options: "*very often*", "*often*", "*once in a while*", "*almost never*", and "*never*". Scores will be transformed into a 0 to 100 summary score where a high score indicates a higher level of functioning (23).

Sample size:

A sample size of 210 people is required to provide 80% power to rule out a 1.5 point between group difference assuming a 15% loss to follow up, a standard deviation of 2(18), a 15% treatment dropout rate and a correlation between baseline and final scores of 0.5 (an effect size of 0.75 points was used in the power calculation to account for the non-inferiority design) (24).

Data analysis:

Statistical plan: Data analysis and dissemination of results will occur after the database has been cleaned and locked. All analyses will be conducted on an intention-to-treat basis with these performed and interpreted blinded to treatment group according to a pre-specified statistical analysis plan. Separate analyses will be conducted on each outcome. Between-group comparisons of each outcome will be conducted using regression models in which the outcome will be a linear function of a dummy-coded variable representing group membership (Supported Home Exercise Group or Face-to-face Physiotherapy Group) and a dummy-coded variable for stratum, specifically

site and duration since onset of injury (less than 12 weeks versus more than 12 weeks). Baseline scores will be included in the model to increase statistical precision. If more than 5% of data are missing for a particular analysis, multiple imputation will be used to account for missing data provided the missing at random assumption appears plausible.

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

Economic evaluation: The economic evaluation will compare the supported home exercise program with face-to-face physiotherapy and will be conducted from a health funder plus patient perspective, since patients will contribute time and money to the treatments. If supported home exercise is statistically non-inferior to face-to-face physiotherapy, then a cost-minimisation analysis will be conducted; otherwise a cost-effectiveness analysis for the primary and secondary outcomes, patient function at 6 weeks and 26 weeks will be conducted. A trial-based cost-utility analysis, for quality of life outcomes at 26 weeks will also be conducted. The cost of delivering the physiotherapy intervention in the two arms of the trial will be determined using standard micro-costing methods. All costs will be collected during the trial period and valued in 2020 Australian dollars. Health funder costs will include physiotherapists' time and materials where appropriate. Other healthcare utilisation (e.g visits to doctors, exercise physiologists, masseurs) will be determined by patient self-report. Patient costs will include the costs associated with the time to: attend the face-to-face sessions with the physiotherapist (including travel time), receive the telephone calls from the trial physiotherapist and to complete the prescribed home exercise program. The cost of any equipment purchased will also be included. As in all economic evaluations, the costs captured in this study are likely to be skewed, so nonparametric bootstrap methods will be used for hypothesis testing and interval estimation. In the cost-utility analysis, patient outcomes will be measured in quality adjusted life years (QALYs) at 26 weeks, using a standard instrument, the EQ-5D-5L. The incremental cost-effectiveness ratio (ICER) will be determined in AUD per QALY gained. Bootstrapped cost-effect pairs will be plotted on an incremental cost–effectiveness plane and a cost-effectiveness acceptability curve will be generated for the probability of being cost-effective at different thresholds. The robustness of the ICERs will be tested through multiple one-way sensitivity analyses.

Data collection:

Baseline data will be collected on paper case report forms (CRFs) and then entered into an electronic database (REDcap) by the trial physiotherapist. The data at 6 and 26 weeks will be collected in one of four ways. Most participants will be guided while they use an online data collection form or the assessor will take responses from participants over the telephone and enter them into the online data collection form for the participant. If the participant prefers a paper copy to be sent in the mail then the assessor will take responses from the participant over the telephone and enter them into the data base while the participants reads the questions from the paper copy. Participants will also be given the option to complete the assessment on paper and return the completed forms via an included prepaid envelope. The final option of data collection will allow the participant to complete the online assessment independently by receiving a link via email and completing the questions online without any assistance from the assessor.

Data storage:

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

Data confidentiality:

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

Trial monitoring:

The study will be overseen and monitored by the research staff who will examine study procedures, ensure data quality and monitor compliance with the study protocol. All protocol violations will also be recorded. An independent Data Safety Monitoring Board will not be used for this trial and an interim analysis will not be conducted because the intervention is unlikely to cause harm and the trial is not sufficiently large enough to warrant stopping it early on the grounds of futility. Ethical

approval was obtained on the 17 March 2017 from the Northern Sydney Local Health District HREC, trial number HREC/16HAWKE/431-RESP/16/287.

If a serious adverse event (SAE occurs at any time from randomisation until completion of the 26-week assessment, the trial physiotherapist will record all the relevant information regarding the event including the type of event, the start and stop dates, the action taken and the cause of the event (24). It will be reported to the Principal Investigator within 24 hours and reported immediately to the Ethics Committee irrespective of group allocation. It will also be detailed in the annual report (25). If a SAE has a significant safety issue (SSI), a report will be made to the Principal Investigator within 72 hours and the trial will be modified to eliminate the safety issue. In contrast, data on the type of adverse event (AE) will be recorded but not immediately reported to the Ethics Committee. These data will be collected for both groups by asking participants at 6 and 26 weeks to recall any events related to their condition or the intervention.

Provenance:

This trial is registered at the Australian and New Zealand Clinical trial registry. It will be conducted in accordance with the NHMRC National Statement on Ethical Conduct in Human Research (25) and the Note for Good Clinical Practice (CPMP/ICH-135/95) (26). Not commissioned, peer reviewed for ethical and funding approval prior to submission.

Trial status:

The first participant was randomised on 19/03/2019, and it was anticipated that the last participant will be recruited at the end of Dec 2020. However, due to the global COVID-19 pandemic, recruitment was stopped on the 9 March 2020. Recruitment will recommence as soon as it is safe to do so. The most recent version of the protocol is V.1.2 dated November 2019.

Dissemination plan:

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

Acknowledgements and Funding:

The authors acknowledge support from the health professionals, patients and staff at each of the sites. This project has received funding through the Medical Research Future Fund (MRFF) Rapid Applied Research Translation Program grant awarded to Sydney Health Partners.

Contributors:

LAH, JG, HW, JC, CM, CS, MJ, MF and AH were responsible for the design of the intervention and the trial. LAH, JG, HW, MF, BL, AH, DT, IS and MJ secured funding. AH is responsible for the economics analysis. TL, JC, HW, AB, JC, KD and BP are responsible for collecting data. LS, JC, IS, BP, DW, KD, AB, MT, MJ and HW are responsible for the sites. All authors have read and approved the final manuscript.

Competing Interests:

None Declared.

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APPENDIX:

Table 1: Timeline for the study (pre COVID-19)

Phase	**Objective**	**Planned Completion Date**
Preparation	Finalise protocol Submit to ethics Finalise CRF Complete Database	From October 2016
Recruitment	Commence Recruitment	April 2019
Dissemination	Publish Protocol	March 2020
Recruitment and data collection	Continue recruitment Collect data from 6 week and 26-week assessments Recruit 100% of participants	April 2019 to Dec 2020
Analysis	Clean and lock data base Complete Analysis Submit papers for publication	From Jun 2021
Dissemination	Present results at seminars, conferences Disseminate results into policy and practice	From Sep 2021

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

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

Table 3: Description of the intervention based on the TIDieR checklist.

Checklist Item	**Intervention group**	**Control group**
	Setting: Home	*Setting*: Out patients
Brief Name:	Supported Home Exercises Group	Face-to-Face Group.
Why:	Exercise, support and advice are considered core components of management for most musculoskeletal conditions. Exercise can be provided remotely as part of a home exercise program while support and advice can be provided over the telephone.	Pragmatic trial design
What:		
Materials for Therapists	A detailed protocol outlining the trial procedures. Knowledge on accessing and devising and exercise programme using www.physiotherapyexercises.com and creating an App to monitor adherence. Programming test messages using a website. Study phone for follow up phone calls.	A detailed protocol. Providing physiotherapy in a public hospital outpatient setting.
Materials for Participants	Device such as a smart phone or tablet. Access to the internet. Participants are provided with an exercises programme and an App to monitor adherence.	Participants are provided with outpatient usual care.
Who provided	Trial physiotherapist who is a PhD candidate at University of Sydney.	Physiotherapists employed at the study site hospitals.

How	Initial face-to-face session for assessment and exercise prescription.	Face-to-face physiotherapy consisting of usual care.
Where	Initially on site in a study hospital in the outpatient department, then in the participants' home environment.	Onsite at a study hospital in the outpatient department.
When and How much?	One initial session lasting approximately one hour Participants are asked to exercise on their own each day. The trial physiotherapist will call at week 2 and week 4 to monitor adherence and give support and advice.	One initial session lasting approximately one hour. Regular face-to-face physiotherapy sessions of up to one hour per session. The frequency is determined by the treating physiotherapist but can be up to 3 times per week
Tailoring:	Each participant is prescribed an individualised exercise programme following an initial assessment by the trial physiotherapist.	Determined by the outpatient physiotherapist.
Modifications:	To date approximately half of the required number of participants has been randomised. No modifications have been made.	Some modifications were made to usual care due to COVID-19 restrictions. Telehealth was the only treatment option for a small number of participants while restrictions were in place.
Trial Fidelity:	Regular communication between the investigators and the sites, double data entry, team meetings and reviews of the protocol will ensure trial fidelity.	Data detailing the type of treatments and number of sessions will be used to assess usual care.

Table 4: Visit schedule for Study

	Enrolment	B/L Assessment	Allocation							Week 6 Assessment	HEQs	Week 26 Assessment
	Day -7 to 0	Day 0	Day 0	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 6	Week 6	Week 26
Visit Activity		Clinic								Ph	Ph	Ph
Eligibility	✓											
Informed Consent	✓											
Randomisation allocation			✓									
Face-to-face Physiotherapy				✓	✓	✓	✓	✓	✓		✓	
Supported Home Exercise				✓ (Text)	✓ (Text/ ph)	✓ (Text)	✓ (Text/ ph)	✓ (Text)	✓ (Text)		✓	
ASSESSMENTS												
PSFS		✓								✓		✓
TSK		✓								✓		✓
Pain		✓								✓		✓
PGIC		✓								✓		✓
PSHCSD		✓								✓		✓
EuroQol-5D		✓								✓		✓
LLFDI – function		✓								✓		✓
LLFDI – disability (freq)		✓								✓		✓
LLFDI – disability (capability)		✓								✓		✓
AEs										✓		✓

Abbreviations: *PSFS: Patient specific functional scale. TSK: Tampa Scale for Kinesiophobia. PGIC: Patient Global impression of Change. PSHCSD: Patient Satisfaction with Health Care Service Delivery. LLFDI: Late Life Function and Disability Instrument. AEs: Adverse Events. PH: Phone. B/L: Baseline. HEQs: Health Economics Questions.*

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry
	2b	All items from the World Health Organization Trial Registration Data Set
Protocol version	3	Date and version identifier
Funding	4	Sources and types of financial, material, and other support
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors
	5b	Name and contact information for the trial sponsor
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)
Introduction		
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention
	6b	Explanation for choice of comparators
Objectives	7	Specific objectives or hypotheses
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions

Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial
Methods: Data collection, management, and analysis		
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)
Methods: Monitoring		
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed

	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor

Ethics and dissemination

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions
	31b	Authorship eligibility guidelines and any intended use of professional writers
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code

Appendices

Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ g doi bm g Published March Page of

RESEARCH METHODS & REPORTING

Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide

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Abstract

Without a complete published description of interventions, clinicians and patients cannot reliably implement interventions that are shown to be useful, and other researchers cannot replicate or build on research findings. The uality of description of interventions in publications, however, is remarkably poor. To improve the completeness of reporting, and ultimately the replicability, of interventions, an international group of experts and stakeholders developed the Template for Intervention Description and Replication (TIDieR) checklist and guide. The process involved a literature review for relevant checklists and research, a Delphi survey of an international panel of experts to guide item selection, and a face to face panel meeting. The resultant 12 item TIDieR checklist (brief name, why, what (materials), what (procedure), who provided, how, where, when and how much, tailoring, modifications, how well (planned), how well (actual)) is an extension of the CONSORT 2010 statement (item 5) and the SPIRIT 2013 statement (item 11). While the emphasis of the checklist is on trials, the guidance is intended to apply across all evaluative study designs. This paper presents the TIDieR checklist and guide, with an explanation and elaboration for each item, and examples of good reporting. The TIDieR checklist and guide should improve the reporting of interventions and make it easier for authors to structure accounts of their interventions, reviewers and editors to assess the descriptions, and readers to use the information.

Introduction

The evaluation of interventions is a major research activity, yet the quality of descriptions of interventions in publications remains remarkably poor. Without a complete published description of the intervention, other researchers cannot replicate or build on research findings. For effective interventions,

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Extra material supplied by the author (see http://www.bmj.com/content/348/bmj.g1687?tab=related#datasupp)

Appendix 1: Existing checklists and literature used in generation of the Delphi survey items
Appendix 2: Main profession of Delphi survey respondents
Appendix 3: The TIDieR (template for intervention description and replication) checklist
Appendix 4: Examples of different formats that can be used to describe and/or provide study intervention materials

clinicians, patients, and other decision makers are left unclear about how to reliably implement the intervention. Intervention description involves more than providing a label or the ingredients list. Key features—including duration, dose or intensity, mode of delivery, essential processes, and monitoring—can all influence efficacy and replicability but are often missing or poorly described. For complex interventions, this detail is needed for each component of the intervention. For example, a recent analysis found that only 11% of 262 trials of cancer chemotherapy provided complete details of the trial treatments.[1] The most frequently missing elements were dose adjustment and "premedications," but 16% of trials omitted even the route of drug administration. The completeness of intervention description is often worse for non-pharmacological interventions: one analysis of trials and reviews found that 67% of descriptions of drug interventions were adequate compared with only 29% of non-pharmacological interventions.[2] A recent study of 137 interventions, from 133 trials of non-drug interventions, found that only 39% of interventions were described adequately in the primary paper or any references, appendices, or websites.[3] This increased, albeit to only 59%, by contacting authors for additional information—a task almost no clinicians and few researchers have time to undertake.

The Consolidated Standards of Reporting Trials (CONSORT) 2010 statement[4] currently suggests in item 5 that authors should report on "The interventions for each group with sufficient details to allow replication, including how and when they were actually administered." This is appropriate advice, but further guidance seems to be needed: despite endorsement of the CONSORT statement by many journals, reporting of interventions is deficient. The problem arises partly from lack of awareness among authors about what comprises a good description and partly from lack of attention by peer reviewers and editors.[5]

A small number of CONSORT extension statements contain expanded guidance about describing interventions, such as non-pharmacological interventions,[6] and specific categories of interventions, such as acupuncture and herbal interventions.[7 8] The guidance for content of trial protocols, SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials), provides some recommendations for describing interventions in protocols.[9] More generic and comprehensive guidance is needed along with robust ways to implement such guidance. We developed an extension of item 5 of the CONSORT 2010 statement and item 11 of the SPIRIT 2013 statement in the form of a checklist and guidance entitled TIDieR (Template for Intervention Description and Replication), with the objective of improving the completeness of reporting, and ultimately the replicability, of interventions. This article describes the methods used to develop and obtain consensus for this checklist and, for each item, provides an explanation, elaboration, and examples of good reporting. While the emphasis of the checklist is on trials, the guidance is intended to apply across all evaluative study designs, such as trials, case-control studies, and cohort studies.

Methods for development of the TIDieR checklist and guide

Development of the checklist followed the methodological framework for developing reporting guidelines suggested by the EQUATOR Network.[10] In collaboration with the CONSORT steering group, we established a TIDieR steering committee (PPG, TCH, IB, RM, RP). The committee generated a list of 34 potential items from relevant CONSORT checklists and checklists for reporting discipline-specific or particular categories of interventions. The group also reviewed other sources of guidance on intervention reporting identified from a thorough search of the literature, followed by a forward and backward citation search (see appendix 1).

We then used a two round modified Delphi consensus survey method[11] involving a broad range of expertise and stakeholders. In the first round, each of the 34 items generated by the steering committee was rated by survey participants as "omit," "possible," "desirable," or "essential" to include in the final checklist. From the first round, some items were reworded and combined, and then the ranked items were divided into three groups for the second round. The first group contained 13 items with the highest rankings (rated as "essential" by ≥70% participants or "essential or desirable" by ≥85%), and participants were advised that these would be included in the checklist unless strong objection to their inclusion was received in the second round. The second group contained 13 items with moderate rankings ("essential or desirable" by ≥65%); participants were asked to rate each of these again as "omit," "possible," "desirable," or "essential." The third group contained three items with low rankings, and participants were advised that these items would be removed unless strong objection to their omission was received in the second round. In both rounds, participants could also suggest additional items, comment on item wording, or provide general comments.

Delphi participants (n=125) were authors of research on describing interventions, clinicians, authors of existing reporting guidelines, clinical trialists, methodologists or statisticians with expertise in clinical trials, and journal editors (see appendix 2). They were invited by email to complete the two rounds of the web based survey. The response rate was 72% (n=90) for the first round. Only those who completed round one and were willing to participate in round two were invited to participate in round two. The response rate for round two was 86% (74 of 86 invited).

After the two Delphi rounds, 13 items were included in the draft checklist, and 13 moderately rated items were retained for further discussion at the in person meeting. The results of the Delphi survey were reported at a two day consensus meeting on 27-28 March 2013, in Oxford, UK. Thirteen invited experts, representing a range of health disciplines (see author list) and with expertise in the development of trial, methodological, and/or reporting guidelines, attended and are all authors of this paper. The meeting began with a review of the literature on intervention reporting, followed by a report of the Delphi process, the draft checklist of 13 items, and rankings of and comments about the additional 13 moderately rated items. Meeting participants discussed the proposed items and agreed which should be included and the wording of each item.

After the meeting, the checklist was distributed to the participants to ensure it reflected the decisions made, and this explanation and elaboration document was drafted. This was then piloted with 26 researchers who were authoring papers of intervention studies and minor clarifications were made in the elaboration of some items.

Scope of the TIDieR checklist and guide for describing interventions

The overarching purpose of the TIDieR checklist is to prompt authors to describe interventions in sufficient detail to allow their replication. The checklist contains the minimum recommended items for describing an intervention. Authors

should provide additional information where they consider it necessary for the replication of an intervention.

Most TIDieR items are relevant for most interventions and applicable to even apparently simple drug interventions, which are sometimes poorly described.[2] If we consider the elements of an evaluation of an intervention—the population, intervention, comparison, outcome ("PICO")—TIDieR can be seen as a guide for reporting the intervention and comparison (and co-interventions, when relevant) elements of a study. Other elements (such as population, outcomes) and methodological features are covered by CONSORT 2010 or SPIRIT 2013 items for randomised trials and by other checklists (such as the STROBE statement[12]) for alternate study designs. They have not been duplicated as part of the TIDieR checklist.

The order in which items are presented in the checklist does not necessarily reflect the order in which information should be presented. It might also be possible to combine a number of items from the checklist into one sentence. For example, information about what materials (item 3) and what processes (item 4) can be combined (example 3c).

We emphasise that our definition of "intervention" extends to describing the intervention received by the comparison group/s in a study. Control interventions and co-interventions are often particularly poorly described; "usual care" is not a sufficient description. When a controlled study is reported, authors should describe what participants in the control group received with the same level of detail used to describe the intervention group, within the limits of feasibility. Full understanding of the comparison group care can help to explain the observed efficacy of an intervention, with greater apparent effect sizes being potentially found when control group care is minimal.[13] Describing the care that each group received will usually require the replication of the checklist for each group in a study.

As well as describing which interventions (or control conditions) were delivered to different groups, authors should also explain legitimate variants of the intervention. Authors might find it helpful to locate their trial on the pragmatic explanatory continuum.[14] If, for example in a pragmatic trial, authors expect there to be variants in aspects of the intervention (for instance, in the "usual care" group across various centres), those variants should be described under the appropriate checklist items.

We recognise that limitations (such as format and length) for journals that are only paper based can sometimes preclude inclusion of all intervention information in the primary paper (that is, the paper that is reporting the main results of the intervention evaluation). The information that is prompted by the TIDieR checklist might therefore be reported in locations beyond the primary paper itself, including online supplementary material linked to the primary paper, a published protocol and/or other published papers, or a website. Authors should specify the location of additional detail in the primary paper (for example, "online appendix 2 for the training manual," "available at www...," or "details are in our published protocol"). When websites provide further details, URLs that are designed to remain stable over time are essential.

The TIDieR checklist explanation and elaboration

The items included in the checklist are shown in table 1⇓. The complete checklist is available in appendix 3 and a Word version, which authors and reviewers can fill out, is available on the EQUATOR Network website (www.equator-network.org/reporting-guidelines/tidier/). An explanation for each item is given below, along with examples of good reporting. Citations for the examples are in table 2.⇓

Item 1. Brief name: Provide the name or a phrase that describes the intervention

Examples:

- 1a. Single . . . dose of dexamethasone
- 1b. TREAD (TREAtment of Depression with physical activity) study
- 1c. Internet based, nurse led vascular risk factor management programme promoting self management

Explanation—Precision in the name, or brief description, of an intervention enables easy identification of the type of intervention and facilitates linkage to other reports on the same intervention. Give the intervention name (examples 1a, 1b), explaining any abbreviations or acronyms in full (example 1b), or a short (one or two line) statement of the intervention without elaboration (example 1c).

Item 2. Why: Describe any rationale, theory, or goal of the elements essential to the intervention

Examples:

- 2a. Dexamethasone (10 mg) or placebo was administered 15 to 20 minutes before or with the first dose of antibiotic. . . Studies in animals have shown that bacterial lysis, induced by treatment with antibiotics, leads to inflammation in the subarachnoid space, which may contribute to an unfavourable outcome [references]. These studies also show that adjuvant treatment with anti-inflammatory agents, such as dexamethasone, reduces both cerebrospinal fluid inflammation and neurologic sequelae [references]
- 2b. Self management of oral anticoagulant therapy may result in a more individualised approach, increased patient responsibility, and enhanced compliance, which may lead to improvement in the regulation of anticoagulation
- 2c. The TPB [Theory of Planned Behaviour] informed the hypothesised mediators of intention and physical activity that were targeted in the intervention program: instrumental and affective attitude, subjective norm and perceived behavioural control
- 2d. We chose a 5° wedge because greater wedging is less likely to be tolerated by the wearer [reference] and is difficult to accommodate within a normal shoe

Explanation—Inclusion of the rationale, theory, or goals that underpin an intervention, or the components of a complex intervention,[15] can help others to know which elements are essential, rather than optional or incidental. For example, the colour of capsules used in a pharmacological intervention is likely to be an incidental, not essential, contributor to the intervention's efficacy and hence reporting of this is not necessary. In some reports, the term "active ingredient" is used and refers to the components within an intervention that can be specifically linked to its effect on outcomes such that, if they were omitted, the intervention would be ineffective.[16] The known or supposed mechanism of action of the active component/s of the intervention should be described.

Example 2a illustrates the rationale for treating bacterial meningitis with dexamethasone in addition to an antibiotic. Behaviour change and implementation interventions might require different forms of description, but the basic principles are the same. It might, alongside an account of the components

of the intervention, also be appropriate to describe the intervention in terms of its theoretical basis, including its hypothesised mechanisms of action (examples 2b, 2c).[17-19] The rationale behind an important element of an intervention can sometimes be pragmatic and relate to acceptability of the intervention by participants (example 2d).

Item 3. What (materials): Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (for example, online appendix, URL)

Examples:

- 3a. The educational package included a 12-minute cartoon . . . The presentation of the cartoon was complemented by classroom discussions, display of the same poster that was used for the control group [see figure in appendix 4], dissemination of a pamphlet summarising the key messages delivered in the cartoon, and drawing and essay writing competitions to reinforce the messages . . . The cartoon can be accessed at NEJM.org or at [URL provided]. A specific teacher training workshop was held before commencement of the trial (for details, see the protocol, available at NEJM.org)
- 3b. The intervention group received a behaviour change counselling training programme called the Talking Lifestyle learning programme that took practitioners through a portfolio-driven set of learning activities. Precise details of both intervention content and the training programme can be found in [URL, login and password provided]. . . Box 1 provides a more detailed description of the components of the training programme
- 3c. The "local" group received a sonographically guided injection of 2 mL (10 mg/mL) triamcinolone (Kenacort-T, Bristol-Myers Squibb) and 5 mL (10 mg/mL) lidocaine hydrochloride (Xylocaine, AstraZeneca) to the subacromial bursa and an intramuscular injection of 4 mL (10 mg/mL) lidocaine hydrochloride to the upper gluteal region

Explanation—A full description of an intervention should describe what different physical and information materials were used as part of the intervention (this typically will not extend to study consent forms unless they provide written instructions about the intervention that are not provided elsewhere). Intervention materials are the most commonly missing element of intervention descriptions.[3] This list of materials can be regarded as comparable with the "ingredients" required for a recipe. It can include materials provided to participants (example 3a), training materials used with the intervention providers (examples 3a, 3b), or the surgical device or pharmaceutical drug used and its manufacturer (example 3c). For some interventions, it might be possible to describe the materials and the procedures (item 4) together (examples 3c, 4c). If the information is too long or complex to describe in the primary paper, alternative options and formats for providing the materials should be used (see appendix 4 for some examples) and details of where they can be obtained (examples 3a, 3b) should be provided in the primary paper.

Item 4. What (procedures): Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities

Examples:

- 4a. The TREPP [transrectus sheath preperitoneal] technique can be performed under spinal anaesthesia. To reach the PPS [preperitoneal space], a 5 cm straight incision is made about 1 cm above the pubic bone. The anterior rectus sheath is opened, as is the underlying fascia transversalis [figure]. After retraction of the muscle fibres medially, the inferior epigastric vein and artery are identified and retracted medially as well
- 4b. . . . identified a suitable vein for cannulation. The overlying skin was wiped with an alcohol swab and allowed to dry, as per standard operating procedures. The principal investigator then administered the allocated spray from a distance of about 12 cm for two seconds. This technique avoided "frosting up" of vapocoolant on the skin. Liquid spray on the skin was allowed to evaporate for up to 10 seconds. The area was again wiped with an alcohol swab and cannulation proceeded immediately. Cannulation had to be carried out within 15 seconds of administration of the spray
- 4c. . . . three periods of exercise each lasting 5 min, supervised by a physiotherapist. The first period consisted of 2 min of indoor jogging, 1 min of stair climbing (three floors), and 2 min of cycling on an ergometer. Resistance on the ergometer was adjusted to ensure that the participant's respiratory rate was elevated during the 2 min of cycling. At the end of the first period, the patient performed several prolonged and brief expiratory flow accelerations with open glottis, the forced expiratory technique, and finally cough and sputum expectoration. These clearance manoeuvres were performed over 1.5 min. The second period consisted of 1 min of stretching repeated five times, followed by the same expiratory manoeuvres for 1.5 min, as described above. The third period consisted of continuous jumping on a small trampoline. It included 2 min of jumping, 2 min of jumping while throwing and catching a ball, and 1 min of jumping while hitting a tossed ball. This was again followed by expiratory manoeuvres for 1.5 min. The entire regimen was followed by 40 min rest
- 4d. All health workers doing outpatient consultations in the intervention group received text messages about malaria case management for 6 months . . . The key messages addressed recommendations from the Kenyan national malaria guidelines and training manuals [references]
- 4e. Onsite activities were implemented by hospital personnel responsible for quality improvement initiatives . . . Standard communication channels were used, including group specific computer based training modules and daily electronic documentation by nursing staff for all groups. On-site training in bathing with chlorhexidine-impregnated cloths was provided to hospitals assigned to a decolonisation regimen . . . Nursing directors performed at least three quarterly observations of bathing, including questioning staff about protocol details. Investigators hosted group specific coaching teleconferences at least monthly to discuss implementation, compliance, and any new potentially conflicting initiatives

Explanation—Describe what processes, activities, or procedures the intervention provider/s carried out. Continuing the recipe metaphor used above, this item refers to the "methods" section

of a recipe and where intervention materials ("ingredients") are involved, describes what is to be done with them. "Procedure" can refer to the sequence of steps to be followed (examples 3c, 4b) and is a term used by some disciplines, particularly surgery, and includes, for example, preoperative assessment, optimisation, type of anaesthesia, and perioperative and postoperative care, along with details of the actual surgical procedure used (example 4a). Examples of processes or activities include referral, screening, case finding, assessment, education, treatment sessions (example 4c), telephone contacts (example 4d), etc. Some interventions, particularly complex ones, might require additional activities to enable or support the intervention to occur (in some disciplines these are known as implementation activities), and these should also be described (example 4e). Elaboration about how to report interventions where the procedure is not the same for all participants is provided at item 9 (tailoring).

Item 5. Who provided: For each category of intervention provider (for example, psychologist, nursing assistant), describe their expertise, background and any specific training given

Examples:

- 5a. Only female counsellors were included in this rural area, after consultation with the village chiefs, because it would not have been deemed culturally appropriate for men to counsel women without their husband present . . . Selection criteria for lay counsellors included completion of 12 years of schooling, residence in the intervention area, and a history of community work
- 5b. The procedure is simple, uses existing surgical skills, and has a short learning curve, with the manufacturers recommending at least five mentored cases before independently practising. All surgeons involved in the study will have completed this training and will have carried out over five procedures prior to recruiting to the study
- 5c. Therapists received at least one day of training specific to the trial from an experienced CBT [cognitive behaviour therapy] therapist and trainer and weekly supervision from skilled CBT supervisors at each centre. . . The intervention was delivered by 11 part time therapists in the three sites who were representative of those working within NHS psychological services [reference]. Ten of the 11 therapists were female, their mean age was 39.2 years (SD 8.1), and they had practised as a therapist for a mean of 9.7 years (8.1) . . . Nine of the 11 therapists delivered 97% of the intervention and, for these nine, the number of patients per therapist ranged from 13 (6%) to 41 (18%)
- 5d. . . . brief lifestyle counselling was practised with trained actors and tape recorded. The competency of counselling was checked using the behaviour change counselling index [reference]. Only practitioners who reached a required standard (agreed by inter-rater consensus between three independent clinical assessors) were approved to deliver brief lifestyle counselling in the trial

Explanation—The term "intervention provider" refers to who was involved in providing the intervention (for example, by delivering it to recipients or undertaking specific tasks). This is important in circumstances where the providers' expertise and other characteristics (example 5a) could affect the outcomes of the intervention. Important issues to address in the description might include the number of providers involved in delivering or undertaking the intervention; their disciplinary background (for example, nurse, occupational therapist, colorectal surgeon, expert patient); what pre-existing specific skills, expertise, and experience providers required and if and how these were verified; details of any additional training specific to the intervention that needed to be given to providers before (example 3b) and/or during the study (example 5c); and if competence in delivering the intervention was assessed before (example 5d) or monitored throughout the study and whether those deemed lacking in competence were excluded (example 5d) or retrained. Other information about providers could include whether the providers were doing the intervention as part of their normal role (example 3b) or were specially recruited as providers for purposes of the study (example 5c); whether providers were reimbursed for their time or provided with other incentives (if so, what) to deliver the intervention as part of the study, and whether such time or incentives might be needed to replicate the intervention.

Item 6. How: Describe the modes of delivery (such as face to face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group

Examples:

- 6a. . . . sessions . . . held weekly and facilitated in groups of 6-12 by . . .
- 6b. Drugs were delivered by . . . members of the [Reproductive and Child Health] trekking teams . . . teams visited each of the study villages . . .
- 6c. The text messaging intervention, SMS Turkey, provided six weeks of daily messages aimed at giving participants skills to help them quit smoking. Messages were sent in an automated fashion, except two days and seven days after the initial quit day
- 6d. . . . made their own appointments online . . . Participants and therapists typed free text into the computer, with messages sent instantaneously; no other media or means of communication were used
- 6e. . . . three 1 hour home visits (televisits) by a trained assistant . . . ; participants' daily use of an in-home messaging device . . . .. that was monitored weekly by the teletherapist; and five telephone intervention calls between the teletherapist and the participant . . .

Explanation—Specify whether the intervention was provided to one participant at a time (such as a surgical intervention) or to a group of participants and, if so, the group size (example 6a). Also describe whether it was delivered face to face (example 6b), by distance (such as by telephone, surface mail, email, internet, DVD, mass media campaign, etc) as in examples 6c, 6d, or a combination of modes (example 6e). When relevant, describe who initiated the contact (example 6c), and whether the session was interactive (example 6d) or not (example 6c), and any other delivery features considered essential or likely to influence outcome.

Item 7. Where: Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features

Examples:

- 7a. . . . medication . . . and a spacer (as appropriate) were delivered to the school nurse for directly observed therapy

on the days on which the child attended school. . . An additional canister of preventive medication was delivered to the child's home to use on weekends and other days the child did not attend school, and the child's caregiver was shown proper administration technique

- 7b. Women were recruited from three rural and one peri-urban antenatal clinic in Southern Malawi . . . tablets were taken under supervision at the clinic
- 7c. . . . participants for the . . telehealth trial, across three sociodemographically distinct regions in England (rural Cornwall, rural and urban Kent, and urban Newham in London) comprising four primary care trusts. . . Control participants had no telehealth or telecare equipment installed their homes for the duration of the study. A Lifeline pendant (a personal alarm) plus a smoke alarm linked to a monitoring centre were not, on their own, sufficient to classify as telecare for current purposes
- 7d. Most births in African countries occur at home, especially in rural areas . . . They identified pregnant women and made five home visits during and after pregnancy . . . Peer counsellors lived in the same communities, so informal contacts to make arrangements for visits were common. . . counsellors were . . . given a bicycle, T shirt. . .
- 7e. This paper contains a box, titled "Key features of healthcare systems in Northern Ireland and Republic of Ireland," which summarises relevant aspects of general practices such as funding, registration, and access to free prescriptions

Explanation—In some studies the intervention can be delivered in the same location where participants were recruited and/or data were collected and details might therefore already be included in the primary paper (for example, as in item 4b of CONSORT 2010 statement if reporting a trial). If, however, the intervention occurred in different locations, this should be specified. At its simplest level, the location might be, for example, in the participants' home (example 7a), residential aged care facility, school (example 7a), outpatient clinic (example 7b), inpatient hospital room, or a combination of locations (example 7a). Features or circumstances about the location can be relevant to the delivery of the intervention and should be described (examples 7e). For example, they might include the country (example 7b), type of hospital or primary care (example 7c), publicly or privately funded care, volume of activity, details of the healthcare system, or the availability of certain facilities or equipment (examples 7c, 7d, 7e). These features can impact on various aspects of the intervention such as its feasibility (example 7d) or provider or participant adherence and are important for those considering replicating the intervention.

Item 8. When and how much: Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose

Examples:

- 8a. . . . a loading dose of 1 g of tranexamic acid infused over 10 min, followed by an intravenous infusion of 1 g over 8 h
- 8b. They received five text messages a day for the first five weeks and then three a week for the next 26 weeks
- 8c. . . . . exercise three times a week for 24 weeks. . . Participants began with 15 minutes of exercise and increased to 40 minutes by week eight . . . Between weeks eight and 24, attempts to increase exercise intensity were made at least weekly either by increasing treadmill speed or by increasing the treadmill grade. Participants with leg symptoms were encouraged to exercise to near maximal leg symptoms. Asymptomatic participants were encouraged to exercise to a level of 12 to 14 . . . . on the Borg rating of perceived exertion scale [reference]
- 8d. . . . delivered weekly one hour sessions in the woman's home, for up to eight weeks . . . starting at around eight weeks postnatally

Explanation—The type of information needed about the "when and how much" of the intervention will differ according to the type of intervention. For some interventions some aspects will be more important than others. For example, for pharmacological interventions, the dose and scheduling is often important (example 8a); for many non-pharmacological interventions, the "how much" of the intervention is instead described by the duration and number of sessions (examples 8b, 8c). For multiple session interventions, the schedule of the sessions is also needed (example 8b) and if the number of sessions, their schedule, and/or intensity was fixed (examples 8b, 4c, 6a) or if it could be varied according to rules and if so, what they were (example 8c). Tailoring of the intervention to individuals or groups of individuals is elaborated on in item 9 (tailoring). For some interventions, as part of the "when" information, detail about the timing of the intervention in relation to relevant events might also be important (for example, how long after diagnosis, first symptoms, or a crucial event did the intervention start) (example 8d). As described below in item 12, the "amount" or dose of intervention that participants actually received might differ from the amount intended. This detail should be described, usually in the results section (examples 12a-c).

Item 9. Tailoring: If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how

Examples:

- 9a. Those allocated to the intervention arm followed an intensive stepped programme of management, with mandatory visits to their doctor at weeks 6, 10, 14, and 18 after randomisation to review their blood pressure and to adjust their treatment if needed according to prespecified algorithms [provided in supplementary appendix]
- 9b. All patients received laparoscopic mini-gastric bypass surgery. . . The bypass limb was adjusted according to the preoperative BMI of the patient. A 150 cm limb was used for BMI 35, with a 10 cm increase in the bypass limb with every BMI category increase, instead of using a fixed limb for all patients
- 9c. Participants began exercising at 50% of their 1 rm [repetition maximum]. Weights were increased over the first five weeks until participants were lifting 80% of their 1 rm. Weights were adjusted after each monthly 1 rm and as needed to achieve an exercise intensity of a rating of perceived exertion of 12 to 14
- 9d. Stepped-care decisions for patients . . . were guided by responses to the nine item patient health questionnaire [reference], administered at each treatment visit and formally evaluated at eight week intervals. Patients who

did not show prespecified improvement were offered the choice of switching treatments (for example, from problem solving therapy to medication), adding the other treatment, or intensifying the original treatment choice, based on the treatment team's recommendation (for details, see [reference])

Explanation—In tailored interventions, not all participants receive an identical intervention. Interventions can be tailored for several reasons, such as titration to obtain an appropriate "dose" (example 9a); participant's preference, skills, or situation (example 9b); or it may be an intrinsic element of the intervention as with increasing intensity of an exercise (example 9c). Hence, a brief rationale and guide for tailoring should be provided, including any variables/constructs used for participant assessment (examples 9b, 9c) and subsequent tailoring. Tailoring can occur at several stages and authors should describe any decision points and rules used at each point (example 9d). If any decisional or instructional materials are used, such as flowcharts, algorithms or dosing nomograms, these should be included, referenced (example 9d), or their location provided (example 9a).

Item 10. Modifications: If the intervention was modified during the course of the study, describe the changes (what, why, when, and how)

Examples:

- 10a. A mixture of general practitioners and practice care nurses delivered 95% of screening and brief intervention activity in this trial. . . Owing to this slow recruitment, research staff who had delivered training in study procedures supported screening and brief intervention delivery in 10 practices and recruited 152 patients, which was 5% of the total number of trial participants
- 10b. Computers with slow processing units and poor internet connections meant that seven general practitioners never got functional software; they used a structured paper version that was faxed between the research team and general practitioner after each appointment

Explanation— This item refers to modifications that occur at the study level, not individual tailoring as described in item 9. Unforeseen modifications to the intervention can occur during the course of the study, particularly in early studies. If this happens, it is important to explain what was modified, why and when modifications occurred, and how the modified intervention differed from the original (example 10a—modification to who provided the intervention; example 10b— modification in the materials). Modifications sometimes reflect changing circumstances. In other studies, they can show learning about the intervention, which is important to transmit to the reader and others to prevent unnecessary repetition of errors during attempts to replicate the intervention. If changes to the intervention occurred between the published protocol or published pilot study and the primary paper, these changes should also be described.

Item 11. How well (planned): If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them

Examples:

- 11a. Pathologists were trained to identify lateral spread of tumour according to the protocol [reference]. The results of histopathological examination of the specimens were reviewed by a panel of supervising pathologists and a quality manager
- 11b. Staff in the study sites were trained initially, and therapy supervision was provided by weekly meetings between therapists and investigators. Cognitive therapy sessions were taped with the participant's consent so that participants could be asked to listen to the tapes as part of their homework and to assist supervision. During the course of the trial a sample of 80 tapes was rated according to the cognitive therapy scale-revised [reference] and the cognitive therapy for at risk populations adherence scale [reference] to ensure rigorous adherence to the protocol throughout the duration of the trial. These tapes were drawn from both early and late phases of therapy and included participants from each year of recruitment
- 11c. Adherence to trial medication was assessed by means of self reported pill counts collected during follow-up telephone calls. These data were categorised as no pills taken, hardly any taken (1-24% of prescribed doses), some taken (25-49%), most taken (50-74%), or all taken (75-100%)
- 11d. Training will be delivered independently in each of the three regional study centres. All trainers will adhere to a single training protocol to ensure standardised delivery of the training across centres. Training delivery will be planned and rehearsed jointly by all trainers using role play and peer review techniques. In addition, the project manager will act as an observer during the first two training sessions in each centre and will provide feedback to trainers with a view to further standardising the training [note, this example is from a protocol]

Explanation—Fidelity refers to the degree to which an intervention happened in the way the investigators intended it to[20] and can affect the success of an intervention.[21] The terms used to describe this concept vary among disciplines and include treatment integrity, provider or participant adherence, and implementation fidelity. This item—and item 12—extends beyond simple receipt of the intervention (such as how many participants were issued with the intervention drug or exercises) and refers to "how well" the intervention was received or delivered (such as how many participants took the drug/did the exercises, how much they took/did, and for how long). Depending on the intervention, fidelity can apply to one or more parts of the intervention, such as training of providers (examples 11a, 11b, 11d), delivery of the intervention (example 11b), and receipt of the intervention (example 11c). The types of measures used to determine intervention fidelity will also vary according to the type of intervention. For example, in simple pharmacological interventions, assessing fidelity often focuses on recipients' adherence to taking the drug (example 11b). In complex interventions, such as rehabilitation, psychological, or behaviour change interventions, however, assessment of fidelity is also more complex (example 11b). There are various preplanned strategies and tools that can be used to maintain fidelity before delivery of the intervention (example 11d) or during the study (example 11b). If any strategies or tools were used to maintain fidelity, they should be clearly described. Any materials used as part of assessing or maintaining fidelity should be included, referenced, or their location provided.

Item 12: How well (actual): If intervention adherence or fidelity was assessed, describe

the extent to which the intervention was delivered as planned

Examples:

- 12a. The mean (SD) number of physiotherapy sessions attended was 7.5 (1.9). Seven patients (9%) completed less than four physiotherapy sessions; the reasons included non-attendance, moving interstate, or recovery from pain. Of patients in the physiotherapy groups, 70% were compliant with their home exercise program during at least five of seven weeks
- 12b. The EE [early exercise] group reported an adherence rate of 73% at [time] T2 and 75.7% at [time] T3, and the CE [delayed exercise] group reported 86.7% adherence at T3 . . . with the early exercise EE group reporting disease and treatment related barriers to exercise during their cancer treatment ("week of chemotherapy" 14%; "fatigue" 10%); or life related barriers ("illness eg, colds or flu" 16%; "family obligations" 13%)"
- 12c. A total of 214 participants (78%) reported taking at least 75% of the study tablets; the proportion of patients who reported taking at least 75% of the tablets was similar in the two groups
- 12d. The integrity of the psychological therapy was assessed with the cognitive therapy rating scale [reference] to score transcripts of 40 online sessions for patients who had completed at least five sessions of therapy. With use of computer generated random numbers, at least one such patient was selected for each therapist. For these patients, either session six or the penultimate session was rated by two independent CBT [cognitive behaviour therapy]-trained psychologists, who gave mean ratings of 31 (SD between therapists 9) and 32 (13) of 72

Explanation— For various reasons, an intervention, or parts of it, might not be delivered as intended, thus affecting the fidelity of the intervention. If this is assessed, authors should describe the extent to which the delivered intervention varied from the intended intervention. This information can help to explain study findings, minimise errors in interpreting study outcomes, inform future modifications to the intervention, and, when fidelity is poor, can point to the need for further studies or strategies to improve fidelity or adherence.[22 23] For example, there might be some aspects of the intervention that participants do not like and this could influence their adherence. The way in which the intervention fidelity is reported will reflect the measures used to assess it (examples 12a-d), as described in item 11.

Discussion

Who should use TIDieR?

We describe a short list of items that we believe can be used to improve the reporting of interventions and make it easier for authors to structure accounts of their interventions, reviewers and editors to assess the descriptions, and readers to use the information. Consistent with the CONSORT 2010 and SPIRIT 2013 statements, we recommend that interventions are described in enough detail to enable replication, and recommend that authors use the TIDieR checklist to achieve this. As inclusion of all intervention details is not always possible in the primary paper of a study, the TIDieR checklist encourages authors to indicate that they have reported each of the items and to state where this information is located (see appendix 3).

The number of checklist items reported is improved when journals require checklist completion as part of the submission process.[24] We encourage journals to endorse the use of the TIDieR checklist, in a similar way to CONSORT and related statements. This can be done by modifying their author instructions, publishing an editorial about intervention reporting, and including a link to the checklist on their website. Few journals currently provide specific guidance about how to report interventions.[25] A small number have editorial policies stating that they will not publish trials unless intervention protocols or full details are available.[26] We encourage other journals to consider adopting similar policies. Any links provided by journals and authors should be reliable and enduring. Stable depositories for descriptions of interventions are also required, and their development needs the contribution and collaboration of all stakeholders in the research community (such as researchers, journal editors, publishers, research funding bodies).

Authors might also want to be guided by the TIDieR items when describing interventions in systematic reviews so that readers of reviews have access to full details of any intervention (or at least details about where to obtain further information) that they want to replicate after reading the review.

Using TIDieR in conjunction with the CONSORT and SPIRIT Statements

For authors submitting reports of randomised trials, we suggest using the TIDieR in conjunction with the CONSORT checklist: when authors complete item 5 of the CONSORT checklist, they should insert "refer to TIDieR checklist" and provide a separate completed TIDieR checklist. For journals that adopt this recommendation, their instructions to authors will need to be modified accordingly and their editors and reviewers made aware of the change. Similarly, for authors submitting protocols of trials, the TIDieR checklist can be referred to when dealing with item 11 of the SPIRIT 2013 checklist. One point of difference is that two TIDieR items (items 10 and 12) are not applicable to intervention reporting in protocols because they cannot be completed until the study is complete. This is noted on the TIDieR checklist. Published protocols are likely to grow in importance as a source of information about the intervention and use of TIDieR in conjunction with the SPIRIT 2013 statement can facilitate this. For authors of study designs other than randomised trials, TIDieR can be used alone as a standalone checklist or in conjunction with the relevant statement for that study design (such as the STROBE statement[12]). We acknowledge that describing complex interventions well can be challenging and that for some particularly complex interventions, a checklist, such as TIDieR, could go some way towards assisting with intervention reporting but might not be able to capture the full complexity of these interventions.

We recognise that adhering to the TIDieR checklist might increase the word count of a paper, particular if the study protocol is not publicly available. We believe this might be necessary to help improve the reporting of studies generally and interventions specifically. As journals recognise the importance of well reported studies and fully described methods, and many move to a model of online only, or a hybrid of printed and online with posting of the full study protocol, this might become less of a barrier to quality reporting. For example, the Nature Publishing Group recently removed word limits on the methods section of submitted papers and advises that: "If more space is required to describe the methods completely, the author should include the 300-word section 'Methods Summary' and provide an additional 'Methods' section at the end of the text, following the figure legends. This Methods section will appear in the

online . . . version of the paper, but will not appear in the printed issue. The Methods section should be written as concisely as possible but should contain all elements necessary to allow interpretation and replication of the results."[27]

Conclusion

The TIDieR checklist and guide should assist authors, editors, peer reviewers, and readers. Some authors might perceive this checklist as another time consuming hurdle and elect to seek publication in a journal that does not endorse reporting guidelines. There is a large evidence base indicating that the quality of reporting of health research is unacceptably poor. Properly endorsed and implemented reporting guidelines offer a way for publishers, editors, peer reviewers, and authors to do a better job of completely and transparently describing what was done and found.[28] Doing so will help reduce wasteful research[29 30] and increase the potential impact of research on health.

We are grateful to everyone who responded to the Delphi survey and for their thoughtful comments. We also thank Nicola Pidduck (Department of Primary Care Health Sciences, Oxford University) for her assistance in organising the consensus meeting in Oxford.

Contributors: PPG and TCH initiated the TIDieR group and led the organising of the Delphi survey and consensus meeting, in conjunction with the other members of the steering group (IB, RM, and RP). TCH led the writing of the paper. All authors contributed to the drafting and revision of the paper and approved the final version. TCH and PPG are guarantors.

Funding: There was no explicit funding for the development of this checklist and guide. The consensus meeting in March 2013 was partially funded by a NIHR Senior Investigator Award held by PPG. TCH is supported by a National Health and Medical Research Council of Australia (NHMRC)/Primary Health Care Research Evaluation and Development Career Development Fellowship (1033038) with funding provided by the Australian Department of Health and Ageing. PPG is supported by a NHMRC Australia Fellowship (527500). DGA is supported by a programme grant from Cancer Research UK (C5529). MDW is supported by a Wellcome Trust Senior Investigator award (WT097899MA).

Competing interests: All authors have completed the Unified Competing Interest form at www.icmje.org/coi disclosure.pdf (available on request from the corresponding author) and declare: RM is employed by NETSCC, part of the National Institute for Health Research (NIHR) in England. NETSCC manages on behalf of NIHR the NIHR Journals Library, a suite of five open access journals providing an important and permanent archive of research funded by the National Institute for Health Research. The NIHR Journals Library places great value on reporting the full results of funded research and so is likely to be a user of TIDieR, as it is of other reporting guidelines. VB was the Chief Editor of PLOS Medicine at the time of the consensus meeting and initial drafting of this paper. HM is an assistant editor at BMJ but was not involved in any decision making regarding this paper.

Provenance and peer review: Not commissioned; externally peer reviewed.

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Accepted: 04 February 2014

Cite this as: *BMJ g*

BMJ Publishing Group Ltd

Summary points

- Without a complete published description of interventions, clinicians and patients cannot reliably implement effective interventions
- The uality of description of interventions in publications, regardless of type of intervention, is remarkably poor
- The Template for Intervention Description and Replication (TIDieR) checklist and guide has been developed to improve the completeness of reporting, and ultimately the replicability, of interventions
- TIDieR can be used by authors to structure reports of their interventions, by reviewers and editors to assess completeness of descriptions, and by readers who want to use the information

Tables

Table 1| **Items included in the Template for Intervention Description and Replication (TIDieR) checklist: information to include when describing an intervention. Full version of checklist provides space for authors and reviewers to give location of the information (see appendix 3)**

Item No	Item
Brief name	
1	Provide the name or a phrase that describes the intervention
Why	
2	Describe any rationale, theory, or goal of the elements essential to the intervention
What	
3	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (such as online appendix, URL)
4	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities
Who provided	
5	For each category of intervention provider (such as psychologist, nursing assistant), describe their expertise, background, and any specific training given
How	
6	Describe the modes of delivery (such as face to face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group
Where	
7	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features
When and How Much	
8	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity, or dose
Tailoring	
9	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how
Modifications	
10	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how)
How well	
11	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them
12	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned

If checklist is completed for a protocol, these items are not relevant to protocol and cannot be described until study is complete.

Table 2| **List of references for the examples used**

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BMJ Open

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

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2020-041242.R1
Article Type:	Protocol
Date Submitted by the Author:	07-Dec-2020
Complete List of Authors:	Withers, Hannah; The University of Sydney, Kolling Institute; The University of Sydney, Kolling Instititue Glinsky, Joanne; The University of Sydney, Kolling Institute Chu, Jackie; The University of Sydney, Kolling Institute Jennings, Matthew; South Western Sydney Local Health District, Physiotherapy Hayes, Alison; The University of Sydney, School of Public Health Starkey, Ian; Blacktown & Mount Druitt Hospital, Physiotherapy Department Palmer, Blake; Blacktown & Mount Druitt Hospital, Physiotherapy Department Szymanek, Lukas; Campbelltown Hospital, Physiotherapy Cruwys, Jackson; Campbelltown Hospital, Physiotherapy Wong, David; Liverpool Hospital, Physiotherapy Duong, Kitty; Liverpool Hospital, Physiotherapy Barnett, Anne; Bankstown Hospital, Physiotherapy Tindall, Matthew; Bankstown Hospital, Physiotherapy Lucas, Barbara; Royal North Shore Hospital, Physiotherapy Lambert, Tara; Royal North Shore Hospital, Physiotherapy Sherrington, Catherine; University of Sydney, Sydney School of Public Health Maher, Christopher; The University of Sydney, Institute for Musculoskeletal Health Ferreira, Manuela; University of Sydney Institute of Bone and Joint Research, Taylor, Deborah; Royal North Shore Hospital, Physiotherapy Harvey, Lisa; The University of Sydney, Kolling Institute
Primary Subject Heading:	Rehabilitation medicine
Secondary Subject Heading:	Evidence based practice, Health policy, Rehabilitation medicine
Keywords:	Telemedicine < BIOTECHNOLOGY & BIOINFORMATICS, Musculoskeletal disorders < ORTHOPAEDIC & TRAUMA SURGERY, REHABILITATION MEDICINE, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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

Trial Registration:

This trial is registered at the Australian and New Zealand Clinical trial registry. It will be conducted in accordance with the NHMRC National Statement on Ethical Conduct in Human Research (2018) and the Note for Good Clinical Practice (CPMP/ICH-135/95).

Protocol version:

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

Funding:

This project has received funding through Australia's Medical Research Future Fund (MRFF) Rapid Applied Research Translation Program grant awarded to Sydney Health Partners, grant number N/A.

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ABSTRACT

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

Methods and Analysis: The aim of this single-blind randomised controlled non-inferiority trial is to determine whether a supported home exercise programme is as good as or better than face-to-face physiotherapy for the treatment of musculoskeletal conditions. Two hundred and ten participants will be recruited from four public hospitals in Sydney, Australia. Participants will be randomised to either the Supported Home Exercise Group or the Face-to-face Physiotherapy group. Participants allocated to the Supported Home Exercise Group will initially receive one face-to-face session with the trial physiotherapist and will then be managed remotely for the next 6 weeks. Participants allocated to the Face-to-face Physiotherapy Group will receive a course of physiotherapy as typically provided in Sydney government hospitals. The primary outcome is function measured by the Patient Specific Functional Scale at 6 weeks. There will be 9 secondary outcomes measured at 6 and 26 weeks. Separate analyses will be conducted on each outcome and all analyses will be conducted on an intention-to-treat basis. A health economic evaluation will be conducted from a health funder plus patient perspective.

Ethics and Dissemination

Ethical approval was obtained on the 17 March 2017 from the Northern Sydney Local Health District HREC, trial number HREC/16HAWKE/431-RESP/16/287. The results of this study will be submitted for publication to peer-reviewed journals and be presented at national and international conferences.

Recruitment commenced in March 2019 and it is anticipated that the trial will be completed by September 2021. This trial will investigate two different models of physiotherapy care for people with musculoskeletal conditions.

Strengths and limitations of this study:

- The results of this trial will inform cost-effective models of physiotherapy care and will be particularly relevant in the 2019/2020 Coronavirus pandemic because we need alternate ways of delivering physiotherapy that minimises face-to-face contact.
- The trial has many design features important for minimising bias including concealed allocation, blinded assessors and intention-to-treat analysis.
- This trial is highly pragmatic involving 4 public hospitals in Sydney which increases its external validity.
- Although the 6-and 26-week assessments are blinded, it is not possible to blind the clinicians or the participants.
- The results of this trial will be most applicable to the provision of physiotherapy in public hospitals as no participants from the private physiotherapy sector will be included.

INTRODUCTION

Musculoskeletal conditions are common and include back pain, hip and knee osteoarthritis, whiplash-associated disorders and ankle sprains. Together musculoskeletal conditions cause 21% of the total years lived with disability (second only to mental illness), placing a great burden on world health (1). In 2015 an estimated 30% of all people had at least one musculoskeletal condition in Australia. This figure is reported to be as high as 72% for people aged over 75. In 2008-9, costs attributed to musculoskeletal conditions were an estimated $5.7 billion(2, 3).

Exercise, support and advice are considered core components of management for many musculoskeletal conditions (4-7). Exercise, support and advice are typically provided by physiotherapists through regular face-to-face treatments. However, exercise can be provided remotely as part of a home exercise program while support and advice can be provided via the telephone. There is initial evidence from trials and systematic reviews to suggest that different forms of remotely-provided physiotherapy can be used to manage a variety of musculoskeletal conditions safely and effectively (4, 8-16). A move away from reliance on face-to-face physiotherapy has many potential benefits. Adopting new technologies and strategies into physiotherapy management will allow for the delivery of timely and accessible care to those who are in remote or rural locations, and those who have significant mobility issues. Another benefit for this method of physiotherapy is its low cost which might enhance cost-effectiveness from a funder and patient perspective. Increasing remote access and decreasing the cost of physiotherapy may have the added benefit of decreasing the burden on the public health system by decreasing waiting times for publicly funded outpatient physiotherapy.

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

The trial will be highly pragmatic with broad inclusion criteria to capture a range of musculoskeletal conditions for which exercise, support and advice are the basis of evidence-based care. The aim is to determine whether a supported home exercise program is as effective or better, than a course of face-to-face physiotherapy. This will be determined with one primary outcome and 9 secondary outcomes. An economic analysis will be run alongside the trial to assess the affordability and value

for money of this model of care from a health funder plus patient perspective. A process evaluation will also be completed in order to understand the feasibility of delivering physiotherapy through supported home exercise programs and to explore the perspectives of patients, healthcare professionals and key stakeholders about different models of delivering physiotherapy.

METHODS AND ANALYSIS

Design:

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

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

Participants:

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

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

- is 18 years or over and able to provide informed consent in writing
- has a musculoskeletal condition. Examples include:
    - back/neck pain
    - hip or knee osteoarthritis
    - whiplash-associated disorders
    - ankle sprains
    - post fracture
    - sporting injury
    - post hip or knee replacement
- is seeking physiotherapy treatment at the participating hospital
- can speak and read English to provide informed consent

- is able to participate for 6 weeks and will be available for 6 and 26-week follow up assessments
- has access to a smart phone with internet connection
- is identified by the hospital physiotherapists or trial physiotherapist (study coordinator) to have a condition appropriate for treatment with exercise, support and advice.

A person will be excluded if he or she:

- is pregnant
- has a mental illness which may affect adherence to the trial protocol. This will be determined in consultation with the treating physiotherapists and a review of past medical history.
- is deemed to be at a high risk of falling with home exercises
- is at a clinical risk without Face-to-Face physiotherapy
- is on a post-operative exercise regimen prescribed by a surgeon

Public and patient involvement:

Over a 20-year period, patients and the public were involved in the development of the exercise App (www.physiotherapyexercises.com) upon which this trial is based. The primary outcome measure was developed in 1995 (16) with input from patients. All participants for this trial are patients on a waiting list for outpatient physiotherapy in one of the four public hospitals involved in this trial. All participants will be asked to give written informed consent before being randomised. In order to include the participants' perspective in the results of this trial, an outcome measure asking the participants to self-report their satisfaction with service delivery will be included. A secondary process evaluation will also explore participants' opinions and experiences of the intervention and trial. Participants will be able to access the published results of this trial.

Recruitment strategy and time frame:

Recruitment started in March 2019 and currently 101 participants have been randomised. Recruitment was however temporarily ceased on 9 March 2020 because of the COVID-19 pandemic. It will recommence once it is considered safe and appropriate by the investigators and participating sites and will continue until 210 participants have been recruited (see Appendix Table 1 for the timeline of study pre COVID-19).

Potential participants will be screened according to the inclusion/exclusion criteria from the waiting list of each outpatient physiotherapy department. This process will be completed by either the treating physiotherapists or admin staff of the department over the telephone. If appropriate,

patients will be given an appointment to attend the outpatient department to complete the consent, baseline assessment and randomisation.

Assignment of intervention:

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

1. **The Supported Home Exercise Group**. Participants initially receive one face-to-face session with the trial physiotherapist but are then managed remotely for the next 6 weeks.
2. **The Face-to-face Physiotherapy Group**. Participants receive a course of face-to-face physiotherapy by a hospital physiotherapist.

Interventions:

1. Supported Home Exercise Group: Participants allocated to the Supported Home Exercise Group initially receive one face-to-face session with the trial physiotherapist and then will be managed remotely for the next 6 weeks. During the initial session, the trial physiotherapist will assess the patient and then prescribe an individualised 6-week home exercise program consisting of a battery of 5 to 10 exercises. This will be delivered to patients' mobile devices using a freely available exercise-prescribing App that authors LAH, JG and colleagues have developed (www.physiotherapyexercises.com). The number of repetitions and sets of exercises will be determined by the trial physiotherapist. Participants will be asked to complete their exercises at least once every day for the intervention period of 6 weeks. Participants will record exercise adherence on their App. These data will be automatically transferred to a password-protected section of the website which is accessed by the trial physiotherapist to remotely monitor exercise adherence. The trial physiotherapist will provide ongoing support through weekly text messages. The purpose of these text messages is to encourage adherence to the prescribed exercises and provide the participants with encouragement and support. These text messages are generated from a pre-paid website and are scheduled to be sent each week to the participants in the Supported

Home Exercise Group. The messages are not individualised but are designed to be motivating and to remind participants to continue their exercises. Participants cannot respond to these text messages (See Appendix Table 2 for examples of the text messages). The participants will also receive a telephone call from the trial physiotherapist at 2 and 4 weeks to ensure adherence and provide feedback, support and advice. Participants will be telephoned more frequently if their exercise adherence is poor. Participants are also able to contact the trial physiotherapist on a study mobile phone number or via email at any time. The trial physiotherapist has the option of providing an additional face-to-face physiotherapy session if she has any concerns about a participant's progress, safety or wellbeing that she may become aware of from conversations with the participant over the telephone or from any other trial or hospital staff.

2. Face-to-Face Physiotherapy Group: Participants allocated to the Face-to-Face Physiotherapy Group will receive a course of physiotherapy as typically provided in Sydney government hospitals. This will be provided by the hospital physiotherapists and could involve up to three sessions per week for up to 6 weeks or group classes. The number of sessions per week and duration of the course of physiotherapy for each participant will be determined by the hospital physiotherapist and may be gradually decreased and completed during the intervention period if a participant recovers. This approach has been adopted to mimic usual practice. The type of physiotherapy provided during the face-to-face sessions will be determined by the hospital physiotherapist and may include any combination of manual therapy, advice, exercise and occasional electrotherapy. In this way, the trial will be pragmatic and will provide a real-life comparison of the two models of care. The number of sessions and type of therapy provided will be recorded and reported (see Appendix Table 3 for a detailed description of the intervention as per the TIDier guidelines).

Participants in both groups are permitted to continue with any co concomitant treatments for any co morbidities. They are asked to not have any other physiotherapy for their musculoskeletal condition(s) in addition to what is provided by the treating therapist of both groups for the 6-week intervention period.

Outcome measures:

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

The primary outcome will be:

Function as measured by the Patient-Specific Functional Scale at 6 weeks. This outcome measure is sensitive to changes that are important to patients and is used across many different types of musculoskeletal conditions including cervical spine, knee and lower back pain (16). Participants are asked at baseline to identify up to five functional activities that are most important to them and which they find difficult to perform. Participants are then asked to rate each activity at baseline and 6 weeks on an 11-point scale. The scale ranges from zero to ten and indicates the level of difficulty participants have with each activity due to their condition. Zero indicates that they are unable to perform the activity and 10 indicates that they are able to perform the activity at pre-injury level. Scores for each activity are summed and expressed as a percentage of the total possible score for the participant (determined by the number of identified activities) (16, 17).

The secondary outcomes will be:

The Patient-Specific Functional Scale at 26 weeks. See above for details.

Fear of movement and re-injury measured using the Tampa Scale for Kinesiophobia (TSK) at 6 and 26 weeks. The TSK is a multi-item instrument that quantifies fear of movement and re-injury. Participants are asked to score 17 items on a scale of 1-4, where a score of 1 indicates "*strongly disagree*" and a score of 4 indicates "*strongly agree*". Item 4, 8, 12 and 16 are reversed where 1 indicates *"strongly agree"* and 4 indicates *"strongly disagree".* This instrument has high reliability (18, 19).

Pain measured using a 0-10 Numerical Rating Scale (NRS) at 6 and 26 weeks. Participants are asked to rate their average pain over the past 24 hours on a 0-10 numerical rating scale anchored at each end with "*no pain*" and "*worst pain imaginable*". The NRS for pain measurement is a valid and reliable tool for measuring acute and chronic pain (20).

Patient Global Impression of Change at 6 and 26 weeks. Participants are asked to rate the change in their condition on a numerical scale. This scale ranges from negative seven to positive seven anchored in the middle and at each end with "*no change*", "*very much worse*" and "*very much better*", respectively.

Patient satisfaction with healthcare service delivery at 6 weeks. Participants are asked to rate their satisfaction with the care they have received for their musculoskeletal condition on an 11-point numerical scale. This scale ranges from zero to ten anchored at each end with "*complete dissatisfaction*" and "*complete satisfaction*" with the delivery of healthcare service.

Health-related quality of life measured using the EuroQol-5D at 6 and 26 weeks. This validated questionnaire has been used in a wide range of musculoskeletal conditions and requires the

participant to rate their level of problems in five dimensions including mobility, self-care, usual activities, pain and anxiety/depression. Utility based quality of life will be derived from the Australian valuation of this instrument for use in the cost-utility analysis.

Functional performance measured with the Function Component of the Later Life Function and Disability Instrument at 6 and 26 weeks. This standardised 32-item instrument captures participants' perceptions about their abilities to perform discrete actions or activities (e.g. unscrew the lid of a jar; put on and take off a coat or jacket). It is suitable for adults of all ages even though it was specifically designed for adults in later life. This instrument has good validity and has been recommended for self-reported data collection (21). The full assessment also captures life performing tasks and limitations on performing life performance tasks but only the Functional Performance aspect of the assessment will be used. Participants are asked to rate their difficulties performing each of the 32 actions or activities on a 5-point scale ranging from "*none*" (i.e., no difficulties performing the activity) to "*can't do*". Scores will be transformed into a 0 to 100 summary score where a high score indicates a higher level of functioning (22).

Frequency of performing life tasks measured with the Disability Component of the Later Life Function and Disability Instrument at 6 and 26 weeks. This standardised 16-item instrument captures participants' perceptions about the frequency with which they perform socially defined life tasks such as visiting friends and family in their homes, taking part in recreational activities, and traveling with overnight stays (21, 22). Participants are asked "*to what extent they feel limited in doing a particular task*". They are provided with the following options: "*completely*", "*a lot*", "*somewhat*", "*a little*", and "*not at all*". Scores will be transformed into a 0 to 100 summary score where a high scores indicates a higher level of functioning (22).

Limitations in capability of performing life tasks measured with the Disability Component of the Later Life Function and Disability Instrument at 6 and 26 weeks. This standardised 16-item instrument captures participants' perceptions about their limitations in performing socially defined life tasks such as visiting friends and family in their homes, taking part in recreational activities and traveling with overnight stays (21). Participants are asked "*how often do they (1) do a particular task*". They are provided with the following options: "*very often*", "*often*", "*once in a while*", "*almost never*", and "*never*". Scores will be transformed into a 0 to 100 summary score where a high score indicates a higher level of functioning (22).

Sample size:

A sample size of 210 people is required to provide 80% power for a non-inferiority margin (delta) of -1.5 points (where a positive between-group difference favours the Supported Home Exercise Group

assuming a 15% loss to follow up, a standard deviation of 2 (17), a 15% treatment dropout rate, a correlation between baseline and final scores of 0.5 and a conservative estimate that the between-group difference favours the Face-to-Face Group by 0.75 points.

Data analysis:

Statistical plan: Data analysis and dissemination of results will occur after the database has been cleaned and locked. All analyses will be conducted on an intention-to-treat basis with these performed and interpreted blinded to treatment group according to a pre-specified statistical analysis plan. Separate analyses will be conducted on each outcome. Between-group comparisons of each outcome will be conducted using regression models in which the outcome will be a linear function of a dummy-coded variable representing group membership (Supported Home Exercise Group or Face-to-face Physiotherapy Group) and a dummy-coded variable for stratum, specifically site and duration since onset of injury (less than 12 weeks versus more than 12 weeks). Baseline scores will be included in the model to increase statistical precision. If more than 5% of data are missing for a particular analysis, multiple imputation will be used to account for missing data provided the missing at random assumption appears plausible.

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

Other analyses: The results of all other analyses will be presented as point estimates (with 95% CI) and will not be interpreted with respect to non-inferiority margins (deltas) or statistical significance but instead used to aid the interpretation of the results of the non-inferiority analysis of the primary outcome at 6 weeks. We will not make any adjustments for multiple comparisons however we will interpret these findings cautiously taking into account the number of outcomes and the two endpoints.

Economic evaluation: The economic evaluation will compare the supported home exercise program with face-to-face physiotherapy and will be conducted from a health funder plus patient perspective, since patients will contribute time and money to the treatments. If supported home exercise is statistically non-inferior to face-to-face physiotherapy, then a cost-minimisation analysis will be conducted; otherwise a cost-effectiveness analysis for the primary and secondary outcomes, patient function at 6 weeks and 26 weeks will be conducted. A trial-based cost-utility analysis, for

quality of life outcomes at 26 weeks will also be conducted. The cost of delivering the physiotherapy intervention in the two arms of the trial will be determined using standard micro-costing methods. All costs will be collected during the trial period and valued in 2020 Australian dollars. Health funder costs will include physiotherapists' time and materials where appropriate. Other healthcare utilisation (e.g visits to doctors, exercise physiologists, masseurs) will be determined by patient self-report. Patient costs will include the costs associated with the time to: attend the face-to-face sessions with the physiotherapist (including travel time), receive the telephone calls from the trial physiotherapist and to complete the prescribed home exercise program. The cost of any equipment purchased will also be included. As in all economic evaluations, the costs captured in this study are likely to be skewed, so nonparametric bootstrap methods will be used for hypothesis testing and interval estimation. In the cost-utility analysis, patient outcomes will be measured in quality adjusted life years (QALYs) at 26 weeks, using a standard instrument, the EQ-5D-5L. The incremental cost-effectiveness ratio (ICER) will be determined in AUD per QALY gained. Bootstrapped cost-effect pairs will be plotted on an incremental cost–effectiveness plane and a cost-effectiveness acceptability curve will be generated for the probability of being cost-effective at different thresholds. The robustness of the ICERs will be tested through multiple one-way sensitivity analyses.

Data collection:

Baseline data will be collected on paper case report forms (CRFs) and then entered into an electronic database (REDcap) by the trial physiotherapist. The data at 6 and 26 weeks will be collected in one of four ways. Most participants will be guided while they use an online data collection form or the assessor will take responses from participants over the telephone and enter them into the online data collection form for the participant. If the participant prefers a paper copy to be sent in the mail then the assessor will take responses from the participant over the telephone and enter them into the data base while the participants reads the questions from the paper copy. Participants will also be given the option to complete the assessment on paper and return the completed forms via an included prepaid envelope. The final option of data collection will allow the participant to complete the online assessment independently by receiving a link via email and completing the questions online without any assistance from the assessor.

Data storage:

All information collected for this trial will have identifying information removed and will be kept confidential and secure. All files containing participants' personal details will remain at the site where they are collected. The original CRFs will be stored centrally on completion of the trial and will only contain the participants' ID code. Electronically transcribed data will be stored on the REDcap

system managed by the University of Sydney. Access to data will only be granted to the Principal Investigators and other research staff directly involved in the study. All source documents and trial documentation will be kept in a secure location by the investigators for 15 years or the appropriate retention period according to local regulations.

Data confidentiality:

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

Trial monitoring:

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

If a serious adverse event (SAE occurs at any time from randomisation until completion of the 26-week assessment, the trial physiotherapist will record all the relevant information regarding the event including the type of event, the start and stop dates, the action taken and the cause of the event (23). It will be reported to the Principal Investigator within 24 hours and reported immediately to the Ethics Committee irrespective of group allocation. It will also be detailed in the annual report (24). If a SAE has a significant safety issue (SSI), a report will be made to the Principal Investigator within 72 hours and the trial will be modified to eliminate the safety issue. In contrast, data on the type of adverse event (AE) will be recorded but not immediately reported to the Ethics Committee. These data will be collected for both groups by asking participants at 6 and 26 weeks to recall any events related to their condition or the intervention.

Provenance:

This trial is registered at the Australian and New Zealand Clinical trial registry. It will be conducted in accordance with the NHMRC National Statement on Ethical Conduct in Human Research (24) and the

Note for Good Clinical Practice (CPMP/ICH-135/95) (25, 26). Not commissioned, peer-reviewed for ethical and funding approval prior to submission.

Trial status:

The first participant was randomised on 19/03/2019, and it was anticipated that the last participant will be recruited at the end of Dec 2020. However, due to the global COVID-19 pandemic, recruitment was stopped on the 9 March 2020. Recruitment will recommence as soon as it is safe to do so. The most recent version of the protocol is V.1.2 dated November 2019.

Dissemination plan:

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

Acknowledgements and Funding:

The authors acknowledge support from the health professionals, patients and staff at each of the sites. This project has received funding through the Medical Research Future Fund (MRFF) Rapid Applied Research Translation Program grant awarded to Sydney Health Partners. Grant number N/A.

Contributors:

LAH, JG, HW, JC, CM, CS, MJ, MF and AH were responsible for the design of the intervention and the trial. LAH, JG, HW, MF, BL, AH, DT, IS and MJ secured funding. AH is responsible for the economics analysis. TL, JC, HW, AB, JC, KD and BP are responsible for collecting data. LS, JC, IS, BP, DW, KD, AB, MT, MJ and HW are responsible for the sites. All authors have read and approved the final manuscript.

Competing Interests:

None Declared.

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APPENDIX:

Table 1: Timeline for the study (pre COVID-19)

Phase	**Objective**	**Planned Completion Date**
Preparation	Finalise protocol Submit to ethics Finalise CRF Complete Database	From October 2016
Recruitment	Commence Recruitment	April 2019
Dissemination	Publish Protocol	March 2020
Recruitment and data collection	Continue recruitment Collect data from 6 week and 26-week assessments Recruit 100% of participants	April 2019 to Dec 2020
Analysis	Clean and lock data base Complete Analysis Submit papers for publication	From Jun 2021
Dissemination	Present results at seminars, conferences Disseminate results into policy and practice	From Sep 2021

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

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

Table 3: Description of the intervention based on the TIDieR checklist.

Checklist Item	**Intervention group**	**Control group**
	Setting: Home	*Setting*: Out patients
Brief Name:	Supported Home Exercises Group	Face-to-Face Group.
Why:	Exercise, support and advice are considered core components of management for most musculoskeletal conditions. Exercise can be provided remotely as part of a home exercise program while support and advice can be provided over the telephone.	Pragmatic trial design
What:		
Materials for Therapists	A detailed protocol outlining the trial procedures. Knowledge on accessing and devising and exercise programme using www.physiotherapyexercises.com and creating an App to monitor adherence. Programming test messages using a website. Study phone for follow up phone calls.	A detailed protocol. Providing physiotherapy in a public hospital outpatient setting.
Materials for Participants	Device such as a smart phone or tablet. Access to the internet. Participants are provided with an exercises programme and an App to monitor adherence.	Participants are provided with outpatient usual care.
Who provided	Trial physiotherapist who is a PhD candidate at University of Sydney.	Physiotherapists employed at the study site hospitals.

How	Initial face-to-face session for assessment and exercise prescription.	Face-to-face physiotherapy consisting of usual care.
Where	Initially on site in a study hospital in the outpatient department, then in the participants' home environment.	Onsite at a study hospital in the outpatient department.
When and How much?	One initial session lasting approximately one hour Participants are asked to exercise on their own each day. The trial physiotherapist will call at week 2 and week 4 to monitor adherence and give support and advice.	One initial session lasting approximately one hour. Regular face-to-face physiotherapy sessions of up to one hour per session. The frequency is determined by the treating physiotherapist but can be up to 3 times per week
Tailoring:	Each participant is prescribed an individualised exercise programme following an initial assessment by the trial physiotherapist.	Determined by the outpatient physiotherapist.
Modifications:	To date approximately half of the required number of participants has been randomised. No modifications have been made.	Some modifications were made to usual care due to COVID-19 restrictions. Telehealth was the only treatment option for a small number of participants while restrictions were in place.
Trial Fidelity:	Regular communication between the investigators and the sites, double data entry, team meetings and reviews of the protocol will ensure trial fidelity.	Data detailing the type of treatments and number of sessions will be used to assess usual care.

Table 4: Visit schedule for Study

	Enrolment	B/L Assessment	Allocation							Week 6 Assessment	HEQs	Week 26 Assessment
	Day -7 to 0	Day 0	Day 0	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 6	Week 6	Week 26
Visit Activity		Clinic								Ph	Ph	Ph
Eligibility	✓											
Informed Consent	✓											
Randomisation allocation			✓									
Face-to-face Physiotherapy				✓	✓	✓	✓	✓	✓		✓	
Supported Home Exercise				✓ (Text)	✓ (Text/ ph)	✓ (Text)	✓ (Text/ ph)	✓ (Text)	✓ (Text)		✓	
ASSESSMENTS												
PSFS		✓								✓		✓
TSK		✓								✓		✓
Pain		✓								✓		✓
PGIC		✓								✓		✓
PSHCSD		✓								✓		✓
EuroQol-5D		✓								✓		✓
LLFDI – function		✓								✓		✓
LLFDI – disability (freq)		✓								✓		✓
LLFDI – disability (capability)		✓								✓		✓
AEs										✓		✓

Abbreviations: *PSFS: Patient specific functional scale. TSK: Tampa Scale for Kinesiophobia. PGIC: Patient Global impression of Change. PSHCSD: Patient Satisfaction with Health Care Service Delivery. LLFDI: Late Life Function and Disability Instrument. AEs: Adverse Events. PH: Phone. B/L: Baseline. HEQs: Health Economics Questions.*

SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry
	2b	All items from the World Health Organization Trial Registration Data Set
Protocol version	3	Date and version identifier
Funding	4	Sources and types of financial, material, and other support
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors
	5b	Name and contact information for the trial sponsor
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)
Introduction		
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention
	6b	Explanation for choice of comparators
Objectives	7	Specific objectives or hypotheses
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions

Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial
Methods: Data collection, management, and analysis		
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)
Methods: Monitoring		
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed

	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor

Ethics and dissemination

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions
	31b	Authorship eligibility guidelines and any intended use of professional writers
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code

Appendices

Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

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

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2020-041242.R2
Article Type:	Protocol
Date Submitted by the Author:	24-Feb-2021
Complete List of Authors:	Withers, Hannah; The University of Sydney, Kolling Institute; The University of Sydney, Kolling Instititue Glinsky, Joanne; Kolling Institute of Medical Research, Kolling Institute Chu, Jackie; Kolling Institute of Medical Research, Kolling Institute Jennings, Matthew; South Western Sydney Local Health District, Physiotherapy Hayes, Alison; The University of Sydney, School of Public Health Starkey, Ian; Blacktown & Mount Druitt Hospital, Physiotherapy Department Palmer, Blake; Blacktown & Mount Druitt Hospital, Physiotherapy Department Szymanek, Lukas; Campbelltown Hospital, Physiotherapy Cruwys, Jackson; Campbelltown Hospital, Physiotherapy Wong, David; Liverpool Hospital, Physiotherapy Duong, Kitty; Liverpool Hospital, Physiotherapy Barnett, Anne; Bankstown Hospital, Physiotherapy Tindall, Matthew; Bankstown Hospital, Physiotherapy Lucas, Barbara; Royal North Shore Hospital, Physiotherapy Lambert, Tara; Royal North Shore Hospital, Physiotherapy Sherrington, Catherine; University of Sydney, Sydney School of Public Health Maher, Christopher; The University of Sydney, Institute for Musculoskeletal Health Ferreira, Manuela; University of Sydney Institute of Bone and Joint Research, Taylor, Deborah; Royal North Shore Hospital, Physiotherapy Harvey, Lisa; The University of Sydney, Kolling Institute
Primary Subject Heading:	Rehabilitation medicine
Secondary Subject Heading:	Evidence based practice, Health policy, Rehabilitation medicine
Keywords:	Telemedicine < BIOTECHNOLOGY & BIOINFORMATICS, Musculoskeletal disorders < ORTHOPAEDIC & TRAUMA SURGERY, REHABILITATION MEDICINE, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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

Trial Registration:

This trial is registered at the Australian and New Zealand Clinical trial registry. It will be conducted in accordance with the NHMRC National Statement on Ethical Conduct in Human Research (2018) and the Note for Good Clinical Practice (CPMP/ICH-135/95).

Protocol version:

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

Funding:

This project has received funding through Australia's Medical Research Future Fund (MRFF) Rapid Applied Research Translation Program grant awarded to Sydney Health Partners, grant number N/A.

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ABSTRACT

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

Methods and Analysis: The aim of this single-blind randomised controlled non-inferiority trial is to determine whether a supported home exercise programme is as good as or better than face-to-face physiotherapy for the treatment of musculoskeletal conditions. Two hundred and ten participants will be recruited from four public hospitals in Sydney, Australia. Participants will be randomised to either the Supported Home Exercise Group or the Face-to-face Physiotherapy group. Participants allocated to the Supported Home Exercise Group will initially receive one face-to-face session with the trial physiotherapist and will then be managed remotely for the next 6 weeks. Participants allocated to the Face-to-face Physiotherapy Group will receive a course of physiotherapy as typically provided in Sydney government hospitals. The primary outcome is function measured by the Patient Specific Functional Scale at 6 weeks. There will be 9 secondary outcomes measured at 6 and 26 weeks. Separate analyses will be conducted on each outcome and all analyses will be conducted on an intention-to-treat basis. A health economic evaluation will be conducted from a health funder plus patient perspective.

Ethics and Dissemination

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

Strengths and limitations of this study:

- The intervention that is being investigated minimises reliance on face-to-face treatments and as such is highly relevant to the current COVID-19 pandemic.
- The trial has many design features important for minimising bias including concealed allocation, blinded assessors and intention-to-treat analysis.
- This trial is highly pragmatic involving 4 public hospitals in Sydney which increases its external validity.
- Although the 6-and 26-week assessments are blinded, it is not possible to blind the clinicians or the participants.
- The results of this trial will be most applicable to the provision of physiotherapy in public hospitals as no participants from the private physiotherapy sector will be included.

INTRODUCTION

Musculoskeletal conditions are common and include back pain, hip and knee osteoarthritis, whiplash-associated disorders and ankle sprains. Together musculoskeletal conditions cause 21% of the total years lived with disability (second only to mental illness), placing a great burden on world health (1). In 2015 an estimated 30% of all people had at least one musculoskeletal condition in Australia (2). This figure is reported to be as high as 72% for people aged over 75(3). In 2008-9, costs attributed to musculoskeletal conditions were an estimated $5.7 billion (4, 5).

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

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

The trial will be highly pragmatic with broad inclusion criteria to capture a range of musculoskeletal conditions for which exercise, support and advice are the basis of evidence-based care. The aim is to determine whether a supported home exercise program is as effective or better, than a course of face-to-face physiotherapy. This will be determined with one primary outcome and nine secondary

outcomes. An economic analysis will be run alongside the trial to assess the affordability and value for money of this model of care from a health funder plus patient perspective. A process evaluation will also be completed in order to understand the feasibility of delivering physiotherapy through supported home exercise programs and to explore the perspectives of patients, healthcare professionals and key stakeholders about different models of delivering physiotherapy.

METHODS AND ANALYSIS

Design:

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

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

Participants:

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

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

- is 18 years or over and able to provide informed consent in writing
- has a musculoskeletal condition. Examples include:
    - back/neck pain
    - hip or knee osteoarthritis
    - whiplash-associated disorders
    - ankle sprains
    - post fracture
    - sporting injury
    - post hip or knee replacement
- is seeking physiotherapy treatment at the participating hospital
- can speak and read English to provide informed consent

- is able to participate for 6 weeks and will be available for 6 and 26-week follow up assessments
- has access to a smart phone with internet connection
- is identified by the hospital physiotherapists or trial physiotherapist (study coordinator) to have a condition appropriate for treatment with exercise, support and advice.

A person will be excluded if he or she:

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

Public and patient involvement:

Over a 20-year period, patients and the public were involved in the development of the exercise App (www.physiotherapyexercises.com) upon which this trial is based. The primary outcome measure was developed in 1995 (18) with input from patients. All participants for this trial are patients on a waiting list for outpatient physiotherapy in one of the four public hospitals involved in this trial. All participants will be asked to give written informed consent before being randomised. In order to include the participants' perspective in the results of this trial, an outcome measure asking the participants to self-report their satisfaction with service delivery will be included. A secondary process evaluation will also explore participants' opinions and experiences of the intervention and trial. A separate manuscript is being prepared to explain the protocol for the process evaluation. Participants will be able to access the published results of this trial.

Recruitment strategy and time frame:

Recruitment started in March 2019 and currently 101 participants have been randomised. Recruitment was however temporarily ceased on 9 March 2020 because of the COVID-19 pandemic. It will recommence once it is considered safe and appropriate by the investigators and participating sites and will continue until 210 participants have been recruited (see Appendix Table 1 for the timeline of study).

Potential participants will be screened according to the inclusion/exclusion criteria from the waiting list of each outpatient physiotherapy department. This process will be completed by either the

treating physiotherapists or administrative staff of the department over the telephone. If appropriate, patients will be given an appointment to attend the outpatient department to complete the consent, baseline assessment and randomisation.

Assignment of intervention:

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

1. **The Supported Home Exercise Group**. Participants initially receive one face-to-face session with the trial physiotherapist but are then managed remotely for the next 6 weeks.
2. **The Face-to-face Physiotherapy Group**. Participants receive a course of face-to-face physiotherapy by a hospital physiotherapist.

Interventions:

1. Supported Home Exercise Group: Participants allocated to the Supported Home Exercise Group initially receive one face-to-face session with the trial physiotherapist and then will be managed remotely for the next 6 weeks. During the initial session, the trial physiotherapist will assess the patient and then prescribe an individualised 6-week home exercise program consisting of a battery of 5 to 10 exercises. This will be delivered to patients' mobile devices using a freely available exercise-prescribing App that authors LAH, JG and colleagues have developed (www.physiotherapyexercises.com). The number of repetitions and sets of exercises will be determined by the trial physiotherapist. Participants will be asked to complete their exercises at least once every day for the intervention period of 6 weeks. Participants will record exercise adherence on their App. These data will be automatically transferred to a password-protected section of the website which is accessed by the trial physiotherapist to remotely monitor exercise adherence. The trial physiotherapist will provide ongoing support through weekly text messages. The purpose of these text messages is to encourage adherence to the prescribed exercises and provide the participants with encouragement and support. These text messages are generated from

a pre-paid website and are scheduled to be sent each week to the participants in the Supported Home Exercise Group. The messages are not individualised but are designed to be motivating and to remind participants to continue their exercises. Participants cannot respond to these text messages (See Appendix Table 2 for examples of the text messages). The participants will also receive a telephone call from the trial physiotherapist at 2 and 4 weeks to ensure adherence and provide feedback, support and advice. Participants will be telephoned more frequently if their exercise adherence is poor. Participants are also able to contact the trial physiotherapist on a study mobile phone number or via email at any time. The trial physiotherapist has the option of providing an additional face-to-face physiotherapy session if she has any concerns about a participant's progress, safety or wellbeing that she may become aware of from conversations with the participant over the telephone or from any other trial or hospital staff. Details about all additional text and phone calls with the Intervention participants will be recorded including the number of text messages and the number and duration of telephone calls. In addition, the number of failed attempts to contact participants by telephone will be recorded. Detailed notes will also be kept regarding participants' adherence to their exercise programs, and any advice and support given. Participants will also be asked to report on whether or not they received the weekly auto-generated text messages.

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

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

Outcome measures:

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

The primary outcome will be:

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

The secondary outcomes will be:

The Patient-Specific Functional Scale at 26 weeks. See above for details.

Fear of movement and re-injury measured using the Tampa Scale for Kinesiophobia (TSK) at 6 and 26 weeks. The TSK is a multi-item instrument that quantifies fear of movement and re-injury. Participants are asked to score 17 items on a scale of 1-4, where a score of 1 indicates "*strongly disagree*" and a score of 4 indicates "*strongly agree*". Item 4, 8, 12 and 16 are reversed where 1 indicates *"strongly agree"* and 4 indicates *"strongly disagree".* This instrument has high reliability (22, 23).

Pain measured using a 0-10 Numerical Rating Scale (NRS) at 6 and 26 weeks. Participants are asked to rate their average pain over the past 24 hours on a 0-10 numerical rating scale anchored at each end with "*no pain*" and "*worst pain imaginable*". The NRS for pain measurement is a valid and reliable tool for measuring acute and chronic pain (24).

Patient Global Impression of Change at 6 and 26 weeks. Participants are asked to rate the change in their condition on a numerical scale. This scale ranges from negative seven to positive seven anchored in the middle and at each end with "*no change*", "*very much worse*" and "*very much better*", respectively.

Patient satisfaction with healthcare service delivery at 6 weeks. Participants are asked to rate their satisfaction with the care they have received for their musculoskeletal condition on an 11-point numerical scale. This scale ranges from zero to ten anchored at each end with "*complete dissatisfaction*" and "*complete satisfaction*" with the delivery of healthcare service.

Health-related quality of life measured using the EuroQol-5D at 6 and 26 weeks*.* This validated questionnaire has been used in a wide range of musculoskeletal conditions and requires the participant to rate their level of problems in five dimensions including mobility, self-care, usual activities, pain and anxiety/depression. Utility based quality of life will be derived from the Australian valuation of this instrument for use in the cost-utility analysis.

Functional performance measured with the Function Component of the Later Life Function and Disability Instrument at 6 and 26 weeks. This standardised 32-item instrument captures participants' perceptions about their abilities to perform discrete actions or activities (e.g. unscrew the lid of a jar; put on and take off a coat or jacket). It is suitable for adults of all ages even though it was specifically designed for adults in later life. This instrument has good validity and has been recommended for self-reported data collection (25). The full assessment also captures life performing tasks and limitations on performing life performance tasks but only the Functional Performance aspect of the assessment will be used. Participants are asked to rate their difficulties performing each of the 32 actions or activities on a 5-point scale ranging from "*none*" (i.e., no difficulties performing the activity) to "*can't do*". Scores will be transformed into a 0 to 100 summary score where a high score indicates a higher level of functioning (26).

Frequency of performing life tasks measured with the Disability Component of the Later Life Function and Disability Instrument at 6 and 26 weeks*.* This standardised 16-item instrument captures participants' perceptions about the frequency with which they perform socially defined life tasks such as visiting friends and family in their homes, taking part in recreational activities, and traveling with overnight stays (25, 26). Participants are asked "*to what extent they feel limited in doing a particular task*". They are provided with the following options: "*completely*", "*a lot*", "*somewhat*", "*a little*", and "*not at all*". Scores will be transformed into a 0 to 100 summary score where a high scores indicates a higher level of functioning (26).

Limitations in capability of performing life tasks measured with the Disability Component of the Later Life Function and Disability Instrument at 6 and 26 weeks. This standardised 16-item instrument captures participants' perceptions about their limitations in performing socially defined life tasks such as visiting friends and family in their homes, taking part in recreational activities and traveling with overnight stays (25). Participants are asked "*how often do they (1) do a particular*

task". They are provided with the following options: "*very often*", "*often*", "*once in a while*", "*almost never*", and "*never*". Scores will be transformed into a 0 to 100 summary score where a high score indicates a higher level of functioning (26).

Sample size:

A sample size of 210 people is required to provide 80% power for a non-inferiority margin (delta) of -1.5 points on the primary outcome (PSFS) where a positive between-group difference favours the Supported Home Exercise Group assuming a 15% loss to follow up, a standard deviation of 2 (21), a 15% treatment dropout rate, a correlation between baseline and final scores of 0.5 and a conservative estimate that the between-group difference favours the Face-to-Face Group by 0.75 points.

Data analysis:

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

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

Other analyses: The results of all other analyses will be presented as point estimates (with 95% CI) and will not be interpreted with respect to non-inferiority margins (deltas) or statistical significance but instead used to aid the interpretation of the results of the non-inferiority analysis of the primary outcome at 6 weeks. We will not make any adjustments for multiple comparisons however we will interpret these findings cautiously taking into account the number of outcomes and the two endpoints. Between-group comparisons of each outcome will be conducted using regression models in which the outcome will be a linear function of a dummy-coded variable representing group membership (Supported Home Exercise Group or Face-to-face Physiotherapy Group) and a dummy-coded variable for stratum, specifically site and duration since onset of injury (less than 12 weeks versus more than 12 weeks). Baseline scores will be included in the model to increase statistical

precision. If more than 5% of data are missing for a particular analysis, multiple imputation will be used to account for missing data provided the missing at random assumption appears plausible.

Economic evaluation: The economic evaluation will compare the supported home exercise program with face-to-face physiotherapy and will be conducted from a health funder plus patient perspective, since patients will contribute time and money to the treatments. If supported home exercise is statistically non-inferior to face-to-face physiotherapy, then a cost-minimisation analysis will be conducted; otherwise a cost-effectiveness analysis for the primary and secondary outcomes, (patient function at 6 weeks and 26 weeks) will be conducted. A trial-based cost-utility analysis, for quality of life outcomes at 26 weeks will also be conducted. The cost of delivering the physiotherapy intervention in the two arms of the trial will be determined using standard micro-costing methods. All costs will be collected during the trial period and valued in 2021 Australian dollars. Health funder costs will include physiotherapists' time and materials where appropriate. Other healthcare utilisation (e.g visits to doctors, exercise physiologists, masseurs) will be determined by patient self-report. Patient costs will include the costs associated with the time to: attend the face-to-face sessions with the physiotherapist (including travel time), receive the telephone calls from the trial physiotherapist and to complete the prescribed home exercise program. The cost of any equipment purchased will also be included. As in all economic evaluations, the costs captured in this study are likely to be skewed, so nonparametric bootstrap methods will be used for hypothesis testing and interval estimation. In the cost-utility analysis, patient outcomes will be measured in quality adjusted life years (QALYs) at 26 weeks, using a standard instrument, the EQ-5D-5L. The incremental cost-effectiveness ratio (ICER) will be determined in AUD per QALY gained. Bootstrapped cost-effect pairs will be plotted on an incremental cost–effectiveness plane and a cost-effectiveness acceptability curve will be generated for the probability of being cost-effective at different thresholds. The robustness of the ICERs will be tested through multiple one-way sensitivity analyses.

Data collection:

Baseline data will be collected on paper case report forms (CRFs) and then entered into an electronic database (REDcap) by the trial physiotherapist. The data at 6 and 26 weeks will be collected in one of four ways. Most participants will be guided while they use an online data collection form or the assessor will take responses from participants over the telephone and enter them into the online data collection form for the participant. If the participant prefers a paper copy to be sent in the mail then the assessor will take responses from the participant over the telephone and enter them into the data base while the participants read the questions from the paper copy. Participants will also be given the option to complete the assessment on paper and return the completed forms via an

included prepaid envelope. The final option of data collection will allow the participant to complete the online assessment independently by receiving a link via email and completing the questions online without any assistance from the assessor. Regardless of the method used to collect the data, the assessor responsible for interacting with the participant and/or collecting the data over the telephone, will be blinded to the treatment. In addition, participants will be reminded at the time of the assessment not to reveal any details regarding their physiotherapy treatments to the assessor. If unblinding occurs, a new blinded assessor will complete the next assessment for that participant. Data for the economic evaluation will be collected over the telephone by an unblinded trial physiotherapist after the 6-week blinded assessment has been completed.

Data storage:

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

Data confidentiality:

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

Trial monitoring:

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

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

Provenance:

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

Trial status:

The first participant was randomised on 19/03/2019, and it is anticipated that the last participant will be recruited at the end of Dec 2021. Recruitment was stopped between March 2020 and December 2020 due to the global COVID-19 pandemic. The most recent version of the protocol is V.1.2 dated November 2019.

Dissemination plan:

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

Acknowledgements and Funding:

The authors acknowledge support from the health professionals, patients and staff at each of the sites. This project has received funding through the Medical Research Future Fund (MRFF) Rapid Applied Research Translation Program grant awarded to Sydney Health Partners. Grant number N/A.

Contributors:

LAH, JG, HW, JC, CM, CS, MJ, MF and AH were responsible for the design of the intervention and the trial. LAH, JG, HW, MF, BL, AH, DT, IS and MJ secured funding. AH is responsible for the economics analysis. TL, JC, HW, AB, JJC, KD and BP are responsible for collecting data. LS, JJC, IS, BP, DW, KD, AB, MT, MJ and HW are responsible for the sites. All authors have read and approved the final manuscript.

Competing Interests:

None Declared.

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APPENDIX:

Table 1: Timeline for the study.

Phase	**Objective**	**Planned Completion Date**
Preparation	Finalise protocol Submit to ethics Finalise CRF Complete Database	From October 2016
Recruitment	Commence Recruitment	April 2019
Dissemination	Publish Protocol	December 2020
Recruitment and data collection	Continue recruitment Collect data from 6 week and 26-week assessments Recruit 100% of participants	April 2019 to Dec 2020 Due to COVID -19 recruitment was stopped in March 2020, and will be resumed in January 2021. Currently n=113. Revised planned completion date: December 2021.
Analysis	Clean and lock data base Complete Analysis Submit papers for publication	From December 2021
Dissemination	Present results at seminars, conferences Disseminate results into policy and practice	From December 2021

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

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

Table 3: Description of the intervention based on the TIDieR checklist.

Checklist Item	**Intervention group**	**Control group**
	Setting: Home	*Setting*: Out patients
Brief Name:	Supported Home Exercise Group	Face-to-Face Group
Why:	Exercise, support and advice are considered core components of management for most musculoskeletal conditions. Exercise can be provided remotely as part of a home exercise program while support and advice can be provided over the telephone.	Pragmatic trial design
What:		
Materials for Therapists	A detailed protocol outlining the trial procedures. Knowledge on accessing and devising and exercise programme using www.physiotherapyexercises.com and creating an App to monitor adherence. Programming text messages using a website. Study phone for follow up phone calls.	A detailed protocol. Providing physiotherapy in a public hospital outpatient setting.
Materials for Participants	Device such as a smart phone or tablet. Access to the internet. Participants are provided with an exercises programme and an App to monitor adherence.	Participants are provided with outpatient usual care.
Who provided	Trial physiotherapist who is a PhD candidate at University of Sydney.	Physiotherapists employed at the study site hospitals.

How	Initial face-to-face session for assessment and exercise prescription.	Face-to-face physiotherapy consisting of usual care.
Where	Initially on site in a study hospital in the outpatient department, then in the participants' home environment.	Onsite at a study hospital in the outpatient department.
When and How much?	One initial session lasting approximately one hour Participants are asked to exercise on their own each day. The trial physiotherapist will call at week 2 and week 4 to monitor adherence and give support and advice.	One initial session lasting approximately one hour. Regular face-to-face physiotherapy sessions of up to one hour per session. The frequency is determined by the treating physiotherapist but can be up to 3 times per week
Tailoring:	Each participant is prescribed an individualised exercise programme following an initial assessment by the trial physiotherapist.	Determined by the outpatient physiotherapist.

Table 4: Visit schedule for Study

	Enrolment	B/L Assessment	Allocation							Week 6 Assessment	HEQs	Week 26 Assessment
	Day -7 to 0	Day 0	Day 0	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 6	Week 6	Week 26
Visit Activity		Clinic								Ph	Ph	Ph
Eligibility	✓											
Informed Consent	✓											
Randomisation allocation			✓									
Face-to-face Physiotherapy				✓	✓	✓	✓	✓	✓		✓	
Supported Home Exercise				✓ (Text)	✓ (Text/ ph)	✓ (Text)	✓ (Text/ ph)	✓ (Text)	✓ (Text)		✓	
ASSESSMENTS												
PSFS		✓								✓		✓
TSK		✓								✓		✓
Pain		✓								✓		✓
PGIC		✓								✓		✓
PSHCSD		✓								✓		✓
EuroQol-5D		✓								✓		✓
LLFDI – function		✓								✓		✓
LLFDI – disability (freq)		✓								✓		✓
LLFDI – disability (capability)		✓								✓		✓
AEs										✓		✓

Abbreviations: *PSFS: Patient specific functional scale. TSK: Tampa Scale for Kinesiophobia. PGIC: Patient Global impression of Change. PSHCSD: Patient Satisfaction with Health Care Service Delivery. LLFDI: Late Life Function and Disability Instrument. AEs: Adverse Events. PH: Phone. B/L: Baseline. HEQs: Health Economics Questions.*