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

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ABSTRACT

Introduction Long waiting time is an important barrier to accessing recommended care for low back pain (LBP) in Australia's public health system. This study describes the protocol for a randomised controlled trial (RCT) that aims to establish the feasibility of delivering and evaluating stratified care integrated with telehealth ('Rapid Stratified Telehealth'), which aims to reduce waiting times for LBP.

Methods and analysis We will conduct a single-centre feasibility and pilot RCT with nested qualitative interviews. Sixty participants with LBP newly referred to a hospital outpatient clinic will be randomised to receive Rapid Stratified Telehealth or usual care. Rapid Stratified Telehealth involves matching the mode and type of care to participants' risk of persistent disabling pain (using the Keele STarT MSK Tool) and presence of potential radiculopathy. 'Low risk' patients are matched to one session of advice over the telephone, 'medium risk' to telehealth physiotherapy plus App-based exercises, 'high risk' to telehealth physiotherapy, App-based exercises, and an online pain education programme, and 'potential radiculopathy' fast tracked to usual in-person care. Primary outcomes include the feasibility of delivering Rapid Stratified Telehealth (ie, acceptability assessed through interviews with clinicians and patients, intervention fidelity, appointment duration, App useability and online pain education programme usage) and evaluating Rapid Stratified Telehealth in a future trial (ie, recruitment rates, consent rates, lost to follow-up and missing data). Secondary outcomes include waiting times, number of appointments, intervention and healthcare costs, clinical outcomes (pain, function, quality of life, satisfaction), healthcare use and adverse events (AEs). Quantitative analyses will be descriptive and inform a future adequately-powered RCT. Interview data will be analysed using thematic analysis.

Ethics and dissemination This study has received approval from the Ethics Review Committee (RPAH Zone: X21-0221). Results will be published in peer-reviewed journals and presented at conferences.

Strengths and limitations of this study

- This will be the first study to investigate the feasibility of delivering and evaluating a novel intervention integrating stratified care with telehealth ('Rapid Stratified Telehealth') to reduce waiting times for people with low back pain and ensure more efficient use of health resources.
- Feasibility will be established using mixed-methods and prespecified feasibility targets.
- Feasibility will be established in a hospital outpatient clinic, facilitating delivery and evaluation of Rapid Stratified Telehealth in similar clinics.
- The use of a feasibility and pilot study design means the findings cannot be used to make conclusions about the effectiveness of Rapid Stratified Telehealth for reducing waiting times and improving clinical outcomes in people with low back pain.
- Given the nature of the intervention, it will not be possible to blind those delivering or receiving the intervention.

Trial registration number ACTRN12621001104842.

INTRODUCTION

Low back pain (LBP) is the leading cause of disability in Australia and globally.[1] Long waiting times is an important barrier to accessing recommended care for LBP in the public health system (eg, advice to stay active, exercise), especially since 55% Australians do not have private health insurance.[2] Long waiting times can delay recovery for some patients and lead to the development of chronic and disabling symptoms that become difficult to manage and require more intensive, costly treatment.[3] One potential strategy

to reduce waiting times is to stratify care so patients with less complex LBP are effectively managed using less resources (eg, telehealth: healthcare delivered via technologies like Apps, websites and telephones) and those with more complex presentations are matched to care that better meet their needs more quickly.

Stratified care involves subgrouping and matching patients to treatments.[4] One particular stratified care approach—risk-based stratified care—was shown to be both clinically and cost-effective for LBP in primary care in a large UK randomised controlled trial (RCT; n=1573)[5] and feasible to implement in primary care.[6] This trial used the STarT Back tool and three matched treatments for patients at low, medium and high risk of persistent disabling pain.[5] Patients at low risk of persistent pain were provided reassurance and simple self-management strategies, as their symptoms would likely resolve without further treatment. Patients at medium and high risk were offered more intensive treatment that aimed to address potential physical or psychological barriers to recovery.

Risk stratification tools (eg, STarT Back) are recommended in some Australian LBP guidelines and models of care (eg, NSW Agency for Clinical Innovation[7]; Australian Commission on Safety and Quality in Healthcare[8]), but to the best of our knowledge, there are no national data summarising the use of stratified care (comprising both the use of such tools and matched treatments) for LBP in Australia. Given that around three in four general practitioners (GPs) and physiotherapists are aware of LBP guidelines,[9] it is likely many are aware of or are using some components of risk stratification for their patients with LBP.

Most previous stratified care studies have not considered the mode of care delivery, although some that do are underway (eg, stratified care integrated with telehealth for people with neck and/or shoulder complaints[10]). Telehealth provides similar improvements in pain and function for people with musculoskeletal conditions (including LBP) compared with in-person care[11 12] and appears to be cost-effective in some settings[13] (although most trials of telehealth have not evaluated cost-effectiveness[14]). Combining stratified care with telehealth could free up clinic-based appointments for patients who need these more, reduce waiting times and improve time to intervention.

A telephone assessment and treatment service for patients with LBP and other musculoskeletal conditions was tested in a large UK RCT (n=2249)[15] and holds promise for improving access to effective, affordable care for LBP in Australia. Physiotherapists assessed patients via telephone supported by a computerised system, to help them diagnose the musculoskeletal problem and determine whether the patient could be managed with advice, information and exercise via telephone appointments and postal information, or whether the patient needed assessment and treatment in person. This approach provided similar improvements in physical health compared with usual clinic-based care, while reducing waiting times by 27 days and the number of clinic appointments by 40%. This model of care was acceptable to patients and clinicians in the UK.[16]

The LBP Clinic at Royal Prince Alfred Hospital (Sydney, Australia) provides a suitable context to examine the feasibility of delivering and evaluating stratified care integrated with telehealth in Australia's public health system. This clinic is staffed by physiotherapists and rheumatologists and receives referrals from Primary Care and the Emergency Department. Due to limited capacity for new appointment slots, patients referred from primary care experience substantial waiting times for appointments (estimated between 3 and 12 months). There is currently no strategy for stratifying care based on the complexity of a patient's condition in this clinic (eg, risk of persistent pain, potential radiculopathy). Currently, using the referral information provided, all patients are triaged for potential red flags while the rest are given the next available in-person appointment. We expect there will be a greater need to focus on increasing the acceptability of stratified care (vs telehealth) given this clinic already implemented telehealth appointments in response to COVID-19.

The primary aim of this feasibility and pilot RCT is to determine the feasibility of: (1) delivering stratified care integrated with eHealth ('Rapid Stratified Telehealth') for patients with LBP referred to a hospital outpatient clinic and (2) a future large RCT to test the effectiveness and cost-effectiveness of this new model of stratified care.

The secondary aims are to describe waiting times, number of appointments, intervention and healthcare costs, clinical outcomes (pain, function, quality of life, satisfaction), healthcare use and AEs in the two arms of the trial (Rapid Stratified Telehealth and usual care). For the future RCT, we hypothesise that Rapid Stratified Telehealth will reduce treatment waiting times (while not compromising clinical outcomes) compared with usual care, be cost-effective and safe.

METHODS AND ANALYSIS

Study design

We will conduct a single-blind, single-site, two-arm, parallel feasibility and pilot RCT with nested qualitative interviews. The trial will be reported in accordance with the Consolidated Standards of Reporting Trials extension for randomised pilot and feasibility trials.[17] The nested qualitative study of clinician and patient acceptability of Rapid Stratified Telehealth will be reported according to the Consolidated Criteria for Reporting Qualitative Research.[18] This protocol has been reported according to Standard Protocol Items: Recommendations for Interventional Trials (online supplemental file 1).[19]

Participants and recruitment

Sixty participants will be recruited from the LBP Clinic (hospital outpatient clinic where rheumatologists typically refer patients who would benefit from exercise and other

Box 1 Inclusion and exclusion criteria.

Inclusion criteria:
- Are 18 years or over.
- Have LBP (non-specific LBP or radicular LBP/sciatica).
- Are a new referral to the LBP Clinic from primary care (ie, have not been on the waiting list prior to enrolment).
- Are willing to participate for up to 6 months and provide follow-up data at 6 weeks and 6 months.

Exclusion criteria:
- Have a suspected serious underlying pathology (eg, cancer, fracture, infection, inflammatory arthritis, cauda equina syndrome).
- Referral strongly suggestive of concerning neurological features (eg, progressive radiculopathy).
- Are pregnant.

physiotherapy-related interventions to physiotherapy) at Royal Prince Alfred Hospital, Sydney, Australia, over a 6-month period (expected February 2022 to July 2022). New referrals will be screened by a rheumatologist according to the inclusion and exclusion criteria (box 1). Our target sample size of 60 is based on a rule of thumb for feasibility studies.[20]

Patients who are potentially eligible will be contacted by the trial physiotherapist to be informed they are on the waiting list. At the end of this routine call, the physiotherapist will mention the study and confirm eligibility. Interested participants will be emailed or posted an information pack including a Participant Information Statement, Participant Consent Form, and baseline questionnaire (online supplemental file 2). Participants will be made aware that participation is voluntary, and they are free to withdraw at any time with no repercussions. Each participant will be asked to provide written consent by signing a consent form or provide consent by 'checking' a box in an online survey through Research Electronic Data Capture (REDCap).

Data collection

Participants will return hard copy baseline questionnaires to the trial physiotherapist via reply paid envelope, or by completing the questionnaire in REDCap via email or SMS. Participants will also have the option to complete the questionnaire over the telephone. The trial physiotherapist will enter data from hard copy questionnaires into REDCap. Data entry will be double checked by an independent researcher for accuracy. The baseline questionnaire will include questions on date of birth, gender, duration of LBP, presence of pain that starts from the back and goes below the knee ('radicular pain'), language spoken at home, employment status, educational level, previous history of sick leave due to LBP, the Keele STarT MSK tool,[21] and clinical outcomes (online supplemental file 2). The Keele STarT MSK tool[21] will be used for risk subgrouping instead of the Keele STarT Back tool[5] because we plan to include patients with LBP and other musculoskeletal conditions in our future trial. Both tools assess the risk of persistent disabling pain and ask questions about similar concepts (eg, activity restrictions, pain in other body parts, recovery expectations). However, STarT Back has a specific psychological subscale; STarT MSK does not. STarT Back only includes modifiable risk factors as items, whereas STarT MSK also asks about duration of pain (a non-modifiable factor).

Interventions and procedures

Eligible participants will be randomised (via 1:1 ratio) into one of two groups (figure 1):

1. Rapid Stratified Telehealth.
2. Usual Care.

The secure random allocation schedule will be computer-generated independently and kept off site. Randomisation will be blocked to ensure equal numbers in both groups. Risk subgroups, as assessed by the Keele STarT MSK tool (low, medium, high risk), and the presence of radicular pain (single item question in the baseline questionnaire), will be used as stratification variables. This will ensure the intervention and control groups have a similar proportion of participants in the four subgroups (table 1). The allocation schedule will be concealed from potential participants and from all on-site staff associated with the trial. The trial physiotherapist will contact the central randomisation unit by telephone or email to be notified of the treatment assignment.

Rapid Stratified Telehealth

The mode and type of care will be matched to the patient's risk of persistent disabling pain, categorised as low, medium or high (using the Keele STarT MSK Tool[21]), as well as the presence of potential (or suspected) radiculopathy (score of 3 or more on a clinician-developed screening questionnaire administered via telephone; online supplemental file 3). The presence of potential radiculopathy was used for subgrouping as per the telephone assessment and treatment UK trial[15 22] and based on the preference of clinicians working in the LBP Clinic. Table 1 describes the intervention.

Usual care

The usual care protocol is in table 1.

Since this is a pragmatic comparison of two real-life models of care, there is no restriction on participants' healthcare use outside the study. Participants who withdraw from the trial will rejoin the waiting list in the position they would have likely been had they not participated.

Outcomes

The primary outcomes are feasibility measures. Feasibility outcomes for 'delivering' Rapid Stratified Telehealth include:

- Clinician and patient acceptability of the intervention (through semi-structured interviews with clinicians and focus groups with patients where possible; see section 2.6).
- Percentage of participants who are only provided care that matches the protocol for their treatment

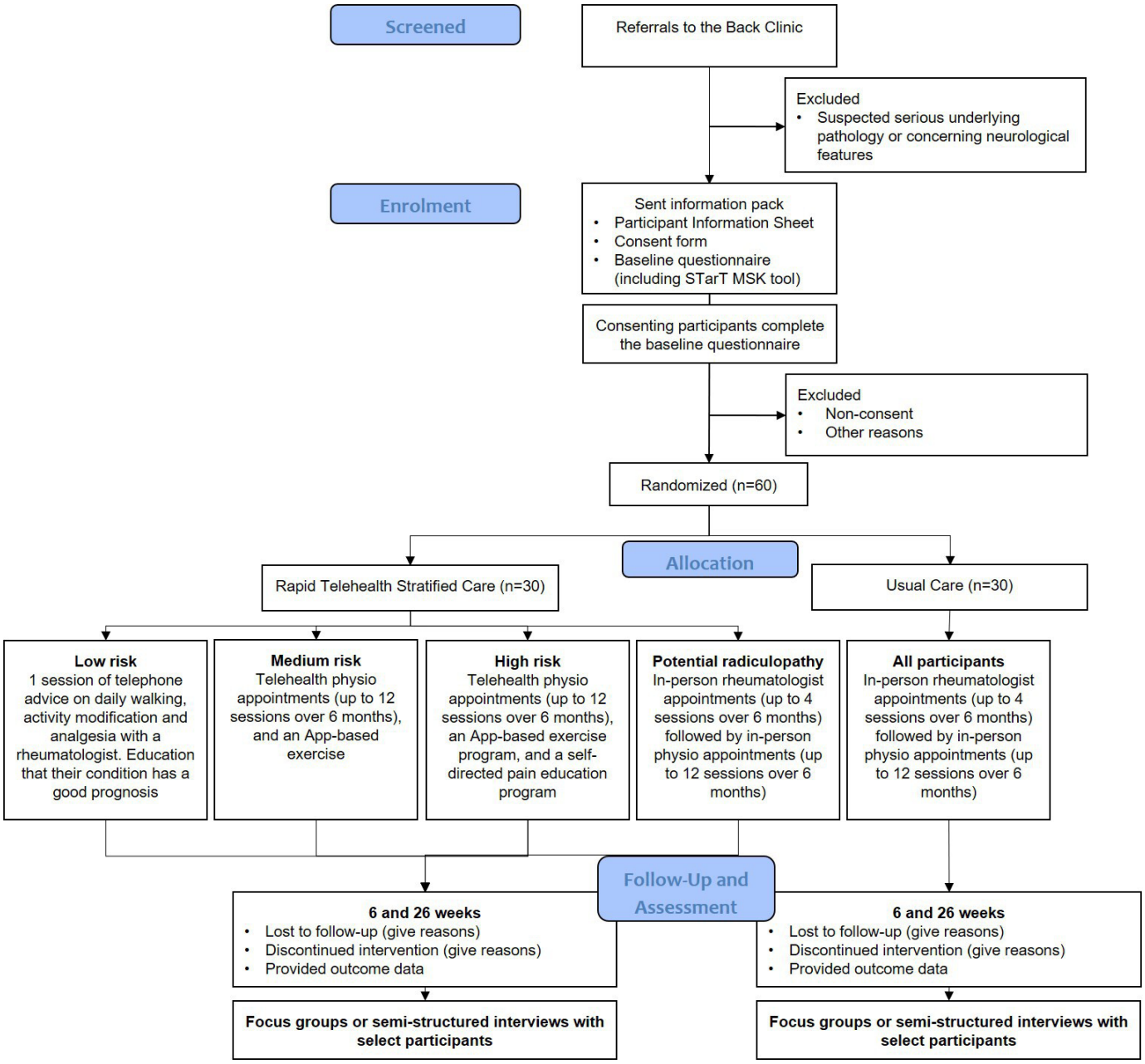

Figure 1 Trial flow diagram.

subgroup ('treatment fidelity' as assessed by treatment recording forms developed for this trial; online supplemental file 4). Clinicians will be instructed to be consistent when reporting treatment choices in the treatment recording forms and clinical notes. Treatment recording forms will be audited throughout the trial. Clinicians will be informed if they are providing care that does not match the protocol for a given subgroup and work with one of the trial investigators to overcome any barriers to implementing the protocol.

- Mean or median appointment times for each stratified group (treatment stage) and whether this changes over time.
- Self-reported useability of the PhysiTrack App provided to participants in the Rapid Virtual Stratified Care group (medium and high risk) assessed using the System Usability Scale (SUS) at 6 months, 0 –100 score. Score above 70 indicates above average usability (as assessed by the SUS, online supplemental file 5).[23 24]
- Percentage of participants in Rapid Stratified Telehealth group (high risk) who complete all modules of the online pain education programme (online supplemental file 4).

Feasibility outcomes for 'evaluating' Rapid Stratified Telehealth in a future multi-centre RCT include:

- Number of participants recruited per week.

Table 1 Rapid Stratified Telehealth and usual care protocol

Treatment group and subgroup	Intervention protocol
Rapid Stratified Telehealth	
Low risk of persistent pain (Keele STarT MSK tool score 0–4)	Participants will receive a telephone call by a Rheumatology Advanced trainee. Participants without suspected serious spinal pathology or potential radiculopathy (score of 3 or more on a clinician-developed screening questionnaire; online supplemental file 3) will be told their condition does not warrant further formal treatment as they have a good prognosis and their pain will likely resolve on its own. They will be encouraged to gradually increase their daily walking (or other activities) as pain permits, temporarily modify their activities to manage their symptoms, take a regular dose of paracetamol if required, and receive written educational material on LBP from the Agency for Clinical Innovation (https://bit.ly/3iGfGrX). Participants will be instructed to call back if their condition does not improve over the next 6 weeks.
Medium risk of persistent pain (Keele STarT MSK tool score 5–8)	Participants will receive a telephone call by a rheumatology advanced trainee. Participants without suspected serious spinal pathology or potential radiculopathy (score of 3 or more on a clinician-developed screening questionnaire) will be offered telehealth physiotherapy. The number of telehealth consultations will be determined by the physiotherapist (maximum of 12 over 6 months). The type of physiotherapy provided will include advice and education to support self-management (eg, advice to exercise, modify activities, lose weight or take simple pain medications if needed), and may include an exercise programme delivered via an App (PhysiTrack). PhysiTrack has over 5000 physiotherapy exercises and over 1000 specific to LBP. The physiotherapist will tailor the exercise programme to participants' activity goals and level of function and be free to select any type and dosage of exercise. Exercise progression will be at the discretion of the treating physiotherapist. The physiotherapist will have the option to print out the exercises if the participant is not comfortable using the app. All physiotherapists in the trial have completed online training modules developed by the Sydney Local Health District and Agency for Clinical Innovation to facilitate the use of the PhysiTrack App.
High risk of persistent pain (Keele STarT MSK tool score 9–12)	Participants will receive a telephone call by a rheumatology advanced trainee. Participants without suspected serious spinal pathology or potential radiculopathy (score of 3 or more on a clinician-developed screening questionnaire) will be offered telehealth physiotherapy. The number of telehealth consultations will be determined by the physiotherapist (maximum of 12 over 6 months). The physiotherapist will provide advice and education to support self-management (eg, advice to exercise, modify activities, lose weight or take simple pain medications if needed), and may provide interventions to address psychological barriers to recovery (eg, pacing, graded exposure), and an App-based exercise programme (PhysiTrack; as described for participants at medium risk of persistent pain). The physiotherapist will direct participants to complete an online self-directed pain education programme developed by the Agency for Clinical Innovation. The programme (Pain Management: For Everyone https://www.aci.health.nsw.gov.au/chronic-pain/for-everyone) is publicly available and includes seven modules: (1) Introduction to pain (6:47 min); (2) Getting help from your healthcare team (5:56 min); (3) Pain and physical activity (12:43 min); (4) Pain: Lifestyle and nutrition (8:41 min); (5) Pain and role of medications (9:57 min); (6) Pain and thoughts (10:27 min); (7) Pain and sleep (11:08 min). Participants will be encouraged to go through the programme at their own pace and bring any questions to their next consultation. Participants in this subgroup can be referred to see a psychologist if the Rheumatology Advanced trainee and physiotherapist agree it would be valuable.
Potential radiculopathy (score of 3 or more on a clinician-developed screening questionnaire; see online supplemental file 3)	Participants will receive a telephone call by a rheumatology advanced trainee. Participants without suspected serious spinal pathology but with potential radiculopathy (score of 3 or more on a clinician-developed screening questionnaire) will be prioritised for a face-to-face consultation with a rheumatologist in the LBP Clinic. The rheumatologist will take participants' medical history (including past history), conduct a physical and neurological examination, review any previously undertaken investigations (eg, imaging, pathology tests), formulate a management plan, and monitor progress. The number of face-to-face consultations will be determined by the rheumatologist (maximum of 4 over 6 months). If necessary, the rheumatologist will refer participants to receive a course of face-to-face physiotherapy. The type of physiotherapy provided will include any advice and education to support self-management (eg, advice to exercise, modify activities, lose weight, or take simple pain medications if needed), and may include a combination of any type and dosage of exercise tailored to patients' activity goals and level of function, graded activity, graded exposure, and spinal manipulative therapy. The treating physiotherapist will ensure that participants at high-risk of persistent pain receive interventions to address psychological barriers to recovery (eg, pacing) and are referred to see a psychologist if necessary. The number of face-to-face physiotherapy consultations will be determined by the physiotherapist (maximum of 12 over 6 months).
All participants	Rheumatology advanced trainees and physiotherapists will be able to overrule the stratified care matched treatment protocol if they feel doing so is clearly needed (eg, not improving, dissatisfaction with care, poor health literacy). Participants can also be referred to a specialised pain clinic if the treating clinicians agree participants are not improving and physiotherapy treatment is no longer beneficial.
Usual care	

Continued

Table 1 Continued

Treatment group and subgroup	Intervention protocol
All participants	Participants will join the waiting list to receive a face-to-face appointment with a rheumatologist in the LBP Clinic. The rheumatologist will take patients' medical history (including past history), conduct a physical and neurological examination, review any previously undertaken investigations (eg, imaging, pathology tests), formulate a management plan, and monitor progress. The number of face-to-face consultations will be determined by the rheumatologist (maximum of 4 over 6 months). If necessary, the rheumatologist will refer patients to receive a course of face-to-face physiotherapy as typically provided in Sydney government hospitals. The type of physiotherapy provided will include any advice and education to support self-management (eg, advice to exercise, modify activities, lose weight, or take simple pain medications if needed), and may include a combination of any type and dosage of exercise tailored to patients' activity goals and level of function, graded activity, graded exposure, and spinal manipulative therapy. The number of face-to-face consultations will be determined by the physiotherapist (maximum of 12 over 6 months). Participants can be referred to a specialised pain clinic or to see a psychologist if the treating clinicians agree it would be valuable.

LBP, low back pain.

- Number of eligible participants per week.
- Percentage of participants who consent to be part of the study from those who were eligible (consent rate).
- Percentage of participants lost to follow-up at 6 weeks and 6 months.
- Percentage of missing data for outcome measures at 6 weeks and 6 months.

Based on a 2021 Cochrane review on strategies to improve retention to RCTs,[25] we will implement the following:

- Paid return postage envelopes.
- Including a pen with posted questionnaires.
- Prenotifications and reminders via SMS or email.

Secondary outcomes include treatment waiting time (ie, time in days from LBP Clinic receiving referral to first treatment; either face to face or telehealth), the number of consultations patients receive, intervention and healthcare costs, clinical outcomes, healthcare use and AEs. Since waiting time is an outcome, we will create separate waiting lists for each group and adjust for time staff spend assessing and treating patients from each list.

We will collect data on the cost of intervention delivery and healthcare use. Costs will be considered from a health system perspective. Intervention costs will be based on clinician time and wage, the cost of PhysiTrack licences and other resources required to deliver the intervention. Costs related to the LBP Clinic will be determined using local costing models in consultation with local management. Healthcare use costs will be estimated from data on healthcare use (see below) and allow for estimates of costs to the healthcare system, outside the LBP Clinic.

Clinical outcomes and healthcare use will be obtained at baseline immediately prior to randomisation, and at 6 weeks and 6 months postrandomisation (online supplemental file 6). AEs data will be collected at 2 weeks, 6 weeks and 6 months postrandomisation (online supplemental file 7). Data will be collected via email, postal mail or telephone (based on participant preference). Data collected by telephone will be performed by a blinded assessor. The success of blinding will be checked at the 6-week and 6-month assessment by asking the assessor if they have become unblinded. If the assessor becomes unblinded at 6 weeks, a new assessor will be used for the 6-month assessment. All personnel responsible for collecting data will be appropriately trained.

Clinical outcomes include:

Physical function using the Roland Morris Disability Questionnaire

Participants will be asked to indicate whether certain activities are impacted by their LBP ('yes' or 'no') forming a total score out of 24. The Roland Morris Disability Questionnaire has demonstrated good validity, reliability and sensitivity for detecting changes in physical function over time in people with LBP.[26]

Pain measured using a 0–10 Numerical Pain Rating Scale

Participants will be 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 Numerical Pain Rating Scale (NPRS) is a valid and reliable tool for measuring acute and chronic pain.[27]

Quality of life using the PROMIS-29 Profile V.2.0

This questionnaire assesses pain intensity, using a 0–10 NPRS (as above), and seven other health domains (physical function, anxiety, depression, fatigue, sleep disturbance, ability to participate in social roles and activities, pain interference) each including multiple items scored on a 5-point Likert Scale. Summary scores for physical and mental health have been shown to be a reliable and valid measure of quality of life in people with chronic conditions.[28]

Patient satisfaction

Participants will be asked to rate their satisfaction with the care they received on an 11-point numerical scale: 'Using any number from 0 to 10, where 0 is the worst care possible and 10 is the best care possible, what number would you use to rate the care you received as part of this study?'

For healthcare use, participants will be asked if they have used or are currently using any healthcare services

(eg, GP, physiotherapy, imaging), or community health or other services (eg, meals on wheels) for their LBP. Participants will also be asked whether they are currently taking any prescription or over the counter medication for their LBP, and to specify the type and dose of their medication.

We will collect data on AEs and serious AEs (SAEs; those which are life threatening, result in hospitalisation, significant disability or incapacity, or death). At 2 weeks, 6 weeks and 6 months, participants will be asked whether they have developed a new medical condition or experienced an exacerbation of an existing condition since beginning the study or last follow-up point (eg, dizziness, increased pain). If the participant answers yes, they will be asked to describe this. When an AE or SAE occurs that is potentially related to the treatments provided in the trial, the trial physiotherapist will record all the relevant information regarding the AE/SAE, including the type of event, the start and stop dates, the action taken and causality of the event (online supplemental file 7). The principal investigator will be responsible for reporting SAEs to the Ethics committee.

Semistructured interviews and focus groups

Participants and recruitment

To explore the acceptability of Rapid Stratified Telehealth, we will conduct semistructured interviews with the physiotherapists and rheumatologists delivering Rapid Stratified Telehealth and focus groups (where possible) with 15 patients who were managed using Rapid Stratified Telehealth. Exact numbers may vary based on saturation of elicited themes. We will purposively sample patients to achieve diversity in age, gender, ethnicity, treatment subgroup and response to the intervention. We will seek participation from patients at the 6-month follow-up and from clinicians after all patients have been recruited.

The trial physiotherapist will email or post clinicians and patients a Participant Information Statement and Participant Consent Form for the qualitative interviews and arrange a time for an intervention or focus group (online supplemental file 8). Clinicians and patients will be made aware that participation is voluntary, and that non-consent to participate or withdrawal from this study will have no repercussions.

Data collection

Interviews and focus groups will be conducted via telephone or videoconference (eg, Zoom) or face-to-face at the Institute for Musculoskeletal Health, Royal Prince Alfred Hospital, depending on clinician and patient preferences. Interviews and focus groups will be conducted by a researcher with experience in conducting qualitative interviews. One-on-one interviews with clinicians will last about 30 min and be audiorecorded and transcribed verbatim for analysis. Focus groups will last about 1 hour, include a maximum of 8 participants and be audiorecorded and transcribed verbatim for analysis. Where patients are unable to participate in a focus group, one-on-one interviews will be offered.

Interviews and focus groups will explore clinician and patient acceptability of Rapid Stratified Telehealth. Specifically, what worked, what didn't work, and the pros and cons of the two models of care from a clinician and patient perspective, and the perceived barriers and facilitators for evaluating Rapid Stratified Telehealth in a multisite trial from a clinician perspective. Throughout the interviews and focus groups, clinicians and patients will be invited to share their perspectives of the Rapid Stratified Telehealth approach and suggest modifications that would increase its appeal and effectiveness for clinicians and patients. The interview guide is in online supplemental file 9.

The researcher facilitating the interviews and focus groups will take notes to highlight key themes that emerge and direct further questioning. This will also enable the facilitator to summarise information back to clinicians and patients at the end of the interview and give them an opportunity to provide further information. Clinicians and patients will have the opportunity to review the transcript of their interviews and focus groups prior to data analysis if they wish.

Statistical analysis

Feasibility outcomes

The main analysis will focus on feasibility (process) outcomes and will investigate feasibility outcomes for delivering Rapid Stratified Telehealth (acceptability, percentage of participants in the intervention who are only provided care according to their treatment subgroup, appointment durations, percentage of participants in the intervention who are comfortable using the App and complete the online pain education programme) and feasibility outcomes for evaluating Rapid Stratified Telehealth in a future multi-centre RCT (recruitment rates, consent rates, percentage lost to follow-up and percentage missing data). These data will be summarised using descriptive statistics (means and SD, median and IQR and counts and percentages, as appropriate).

The research team will review the feasibility outcomes at the completion of the study and make a judgement about whether to proceed to planning an adequately powered, multisite trial. Meeting the following criteria would justify proceeding to a full trial: (1) Acceptable to clinicians and patients (according to qualitative interviews) (2) Percentage of participants in the intervention who are only provided care according to their treatment subgroup >75% (3) Mean or median self-reported useability scores of the PhysiTrack App provided to participants in the Rapid Virtual Stratified Care group (medium and high risk) >70/100 (4) Percentage of participants in Rapid Stratified Telehealth group (high risk) who complete all modules of the self-directed online pain education program >75% (5) Recruitment rate of three or more participants per week over 6 months (6) Consent rate of 50% or more over 6 months (similar to a UK trial[15]) (7) Lost to follow-up <25% at 6 months and (8) Missing data in questionnaires <15%.

Secondary outcomes

Waiting times, number of consultations patients receive, intervention and healthcare costs, clinical outcomes, healthcare use and AEs will be compared between Rapid Stratified Telehealth and usual care using descriptive statistics (means and SD, median and IQRs and counts and percentages, as appropriate) in STATA V.16.0. No statistical inference testing will be performed as this is a feasibility study.[29] Between-group mean differences and postintervention SD for waiting time and physical function and/or the best available evidence from other trials in similar topic areas will inform the sample size calculation for the future trial.

Interview data

All interview data will be analysed using thematic analysis; a method for identifying, analysing and reporting patterns within data.[30] Two researchers will independently familiarise themselves with the interviews (via audio-recordings or transcripts), record initial observations, and identify concepts relevant to the questions asked. The two researchers will develop a framework to organise concepts into broader themes and sub-themes in Excel.[30] Any disagreements in categorising concepts into themes and subthemes will be discussed and resolved. The mapping of themes and subthemes will be iterative as new data emerges. Interviews will stop once no new themes are identified (data saturation).

Patient and public involvement

Physiotherapists working in the LBP Clinic and other members of the research team discussed the protocol with four patients with LBP. Feedback was sought on study processes (eg, recruitment), study materials (eg, participant information sheets, consent forms, questionnaires) and the Rapid Stratified Telehealth intervention. Several changes to the protocol were made based on feedback from consumers.

We initially thought baseline questionnaires (eg, to assess potential radiculopathy) could replace the initial telephone assessment by the rheumatology advanced trainee for participants in the Rapid Stratified Telehealth group. However, consumers expressed that initial contact with a Rheumatology Advanced trainee would reassure patients that their condition was not serious, and that they had not been forgotten while on the waiting list. Consumers provided positive feedback on the App-based exercise programme and online pain education programme. Some consumers thought these tools may help patients access treatment earlier than if they waited for an in-person appointment, reduce the risk of developing persistent symptoms, and eliminate the need for in-person care entirely. Given concerns from consumers that older patients might not be able to use the App-based exercise programme or access the online pain education programme, we have allowed up to 12 telehealth consultations with a physiotherapist over 6 months to facilitate use to these tools, and the option of being scheduled for a face-to-face appointment if patients are not improving or dissatisfied with their care.

Regarding the dissemination of the results of this study, participants will be offered to receive feedback about the overall results of this study when completing the baseline questionnaire. This feedback will be in the form of a one-page lay summary of the results. Individual participant results will be available on request from the principal investigator.

ETHICS AND DISSEMINATION

Ethics approval

This study has been granted ethics approval from the Ethics Review Committee (RPAH Zone: X21-0221). Any protocol deviations will be submitted to the Ethics Review Committee for review.

Data management

All information collected for this trial will be deidentified and kept confidential and secure. All electronically transcribed data will be securely stored on REDCap hosted by Sydney Local Health District and managed by the trial physiotherapist. All hard copy study material will be stored in a locked filing cabinet in the secure office within Royal Prince Alfred Hospital. Access to data will only be granted to members of the study team. Individual names of participants will not be considered in data analysis and they will not be identified in published data. Any data stored for future analysis will be deidentified. All source documents and trial documentation will be kept in a secure location by the investigators for 15 years.

Trial monitoring and quality assurance

Trial monitoring will be done by the trial physiotherapist and overseen by the principal investigator, with frequent contacts by phone and in person to ensure the objectives of the study are being fulfilled. Monitoring will allow the trial physiotherapist to maintain current knowledge of the study through observation, discussion and to ensure compliance to the study protocol.

Dissemination plan

The results of the study will be published in peer-reviewed journals. It is expected that the investigators will author a full report of the quantitative and qualitative findings. Results will likely be presented at national and international conferences. Individual participants will not be identifiable in any publications or presentations.

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