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The 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 program, and 'potential radiculopathy' fast tracked to usual in-person care. Primary outcomes include the feasibility of delivering Rapid Stratified Telehealth (i.e. acceptability assessed through interviews with clinicians and patients, intervention fidelity, appointment duration, App and online pain education program usage) and evaluating Rapid Stratified Telehealth in a future trial (i.e. recruitment rates, consent rates, loss 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. 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.

Trial registration: ANZCTR Request ID 382291.

Key words: low back pain; stratified care; telehealth; sciatica; randomised controlled trial; pilot; feasibility.

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 pre-specified 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

1. 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 (e.g. 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 severe LBP are effectively managed using less resources (e.g. telehealth: healthcare delivered via technologies like Apps, websites and telephones) and those with more complex presentations are matched to treatments 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=1,573)[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. Most previous stratified care studies have not considered the mode of care delivery, although some that do are underway (e.g. stratified care integrated with telehealth for with neck and/or shoulder complaints[7]). Combining stratified care with telehealth for patients could free up clinic-based appointments for those who need it more and reduce waiting times.

A telephone assessment and treatment service for patients with LBP and other musculoskeletal conditions was tested in a large UK RCT (n=2,249).[8] 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 to 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[9] and holds promise for improving access to effective, affordable care for LBP in Australia.

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. There is currently no strategy for stratifying care based on the complexity of a patient's condition (e.g. 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.

The primary aim of this feasibility and pilot RCT is to determine the feasibility of:

i) delivering stratified care integrated with eHealth ('Rapid Stratified Telehealth') for patients with low back pain referred to a hospital outpatient clinic; and

ii) 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 adverse events 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 to usual care, be cost-effective and safe.

2. Methods and analysis

2.1. 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 prospectively registered at the Australian and New Zealand Clinical trial registry and reported in accordance with the CONSORT extension for randomised pilot and feasibility trials.[10] The nested qualitative study of clinician and patient acceptability of Rapid Stratified Telehealth will be reported according to the COREQ (Consolidated Criteria for Reporting Qualitative Research).[11] This protocol has been reported according to SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) (Supplementary File 1).[12]

2.2. Participants and recruitment

Sixty participants will be recruited from the LBP Clinic (hospital outpatient clinic where rheumatologists refer select patients to physiotherapy) at Royal Prince Alfred Hospital, Sydney, Australia, over a 6-month period (expected September 2021 to February 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[13].

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 (i.e. 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 (e.g. cancer, fracture, infection, inflammatory arthritis, cauda equina syndrome)
- are pregnant

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 (Supplementary 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).

2.3. 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, language spoken at home, employment status, educational level, previous history of sick leave due to LBP, the Keele STarT MSK tool,[14] and clinical outcomes (Supplementary File 2). The Keele STarT MSK tool[14] 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.

2.4. 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), will be used as a stratification variable. The allocation schedule will be concealed from potential participants and from all 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.

2.4.1. 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[14]), as well as the presence of potential radiculopathy (score of 3 or more on a clinician-developed screening questionnaire administered via telephone; Supplementary File 3). The presence of potential radiculopathy was used for subgrouping as per the telephone assessment and treatment UK

trial[8, 15] and based on the preference of clinicians working in the LBP Clinic. Table 1 describes the intervention.

2.4.2. 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 re-join the waiting list in the position they would have likely been had they not participated.

2.5. 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 according to their treatment subgroup (as assessed by treatment recording forms; Supplementary File 4)
- Mean or median appointment times for each stratified group (treatment stage) and whether this changes over time
- Percentage of participants in the Rapid Stratified Telehealth group (medium- and high-risk) who are comfortable using the App-based exercise program (i.e. do not need print-outs of the exercises; Supplementary File 4)
- Percentage of participants in Rapid Stratified Telehealth group (high-risk) who complete all modules of the online pain education program (Supplementary File 4)

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

- Number of participants recruited per week
- 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,[16] we will implement the following:

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

Secondary outcomes include treatment waiting time (i.e. 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 adverse events. 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 post-randomisation (Supplementary File 5). Adverse events data will be collected at 2 weeks, 6 weeks and 6 months post-randomisation (Supplementary File 6). 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:

1. Physical function using the Roland Morris Disability Questionnaire (RMDQ). 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 RMDQ has demonstrated good validity, reliability and sensitivity for detecting changes in physical function over time in people with LBP.[17]

2. Pain measured using a 0–10 Numerical Pain Rating Scale (NPRS). 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 NPRS is a valid and reliable tool for measuring acute and chronic pain.[18]

4. Quality of life using the PROMIS-29 Profile v2.0. 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.[19]

5. 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 (e.g. GP, physiotherapy, imaging), or community health or other services (e.g. 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 adverse events (AEs) and serious adverse events (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 (e.g. 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 (Supplementary File 6). The Principal Investigator will be responsible for reporting SAEs to the Ethics committee.

2.6. Semi-structured interviews and focus groups

2.6.1. Participants and recruitment

To explore the acceptability of Rapid Stratified Telehealth, we will conduct semi-structured 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 (Supplementary File 7). 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.

2.6.2. Data collection

Interviews and focus groups will be conducted via telephone or videoconference (e.g. 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 minutes and be audio-recorded and transcribed verbatim for analysis. Focus groups will last about 1 hour, include a maximum of 8 participants and be audio-recorded 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 multi-site 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 Supplementary File 8.

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.

2.7. Statistical analysis

2.7.1. 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 program) and feasibility outcomes for evaluating Rapid Stratified Telehealth in a future multi-centre randomised controlled trial (recruitment rates, consent rates, percentage loss to follow up, and percentage missing data). These data will be summarised using descriptive statistics (means and standard deviations, median and interquartile ranges 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, multi-site trial. Meeting the following criteria would justify proceeding to a full trial:

i) Acceptable to clinicians and patients (according to qualitative interviews)

ii) Percentage of participants in the intervention who are only provided care according to their treatment subgroup >75%

iii) Percentage of participants in the Rapid Stratified Telehealth group (medium- and high-risk) who are comfortable using the PhysiTrack App >75%

iv) Percentage of participants in Rapid Stratified Telehealth group (high-risk) who complete all modules of the self-directed online pain education program >75%

v) Recruitment rate of three of more participants per week over 6 months

vi) Consent rate of 50% or more over 6 months (similar to a UK trial[8])

vii) Loss to follow up <25% at 6 months

viii) Missing data in questionnaires <15%

2.7.2. Secondary outcomes

Waiting times, number of consultations patients receive, intervention and healthcare costs, clinical outcomes, healthcare use and adverse events will be compared between Rapid Stratified Telehealth and usual care using descriptive statistics (means and standard deviations, median and interquartile ranges and counts and percentages, as appropriate) in STATA version 16.0. No statistical inference testing will be performed as this is a feasibility study.[20] Data on waiting time and physical function will inform the sample size calculation for the future trial.

2.7.3. Interview data

All interview data will be analysed using thematic analysis; a method for identifying, analysing and reporting patterns within data.[21] 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.[21] Any disagreements in categorising concepts into themes and sub-themes will be discussed and resolved. The mapping of themes and sub-themes will be iterative as new data emerges. Interviews will stop once no new themes are identified (data saturation).

2.8. 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 (e.g. recruitment), study materials (e.g. 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 (e.g. 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 program and online pain education program. 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 program or access the online pain education program, 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.

3. Ethics and dissemination

3.1. 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.

3.2. Data management

All information collected for this trial will be de-identified 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 de-identified. All source documents and trial documentation will be kept in a secure location by the investigators for 15 years.

3.3. 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.

3.4. 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.

4. Conclusion

Rapid Stratified Telehealth could change the way care for LBP, and more broadly musculoskeletal pain, is delivered in Australia and globally. This new way of freeing up hospital resources for those most in need and giving more Australians access to care in their own home, may ensure the two million Australians with LBP but without private health insurance[2, 22] have faster access to appropriate healthcare. Faster access to care may allow patients to recover faster, return to work and their usual activities sooner, and avoid worse symptoms that require more costly, ongoing treatment. Translation of positive findings from a large multi-site trial not only has the potential to improve the lives of the 570 million people that suffer from LBP worldwide[1] but could allow some of the health resources currently spent on the management of low back pain per year (eg. $88 billion in the United States[23]; $5 billion in Australia[22]) to be redirected to other areas of need within healthcare.

Authors' contributions

All authors critically revised the manuscript for important intellectual content and approved the final manuscript. Please find below a detailed description of the role of each author:

- Joshua R Zadro: conception and design, drafting and revision of the manuscript, and final approval of the version to be published
- Christopher Needs: conception and design, drafting and revision of the manuscript, and final approval of the version to be published
- Nadine Foster: conception and design, drafting and revision of the manuscript, and final approval of the version to be published
- David Martens: conception and design, drafting and revision of the manuscript, and final approval of the version to be published
- Danielle M Coombs: conception and design, drafting and revision of the manuscript, and final approval of the version to be published
- Gustavo C Machado: conception and design, drafting and revision of the manuscript, and final approval of the version to be published
- Cameron Adams: conception and design, drafting and revision of the manuscript, and final approval of the version to be published
- Christopher S Han: conception and design, drafting and revision of the manuscript, and final approval of the version to be published
- Christopher G Maher: conception and design, drafting and revision of the manuscript, and final approval of the version to be published

The Corresponding Author (JZ) attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted. We would also like to acknowledge the contribution of four consumer advisors whose valuable input helped us refine the protocol for this trial.

Competing interests: All authors declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work; no other relationships or activities that could appear to have influenced the submitted work.

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Table 1. Rapid Stratified Telehealth and usual care protocol

Treatment group and sub-group	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; Supplementary 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 low back pain 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 (e.g. advice to exercise, modify activities, lose weight, or take simple pain medications if needed), and may include an exercise program delivered via an App (PhysiTrack). PhysiTrack has over 5,000 physiotherapy exercises and over 1,000 specific to low back pain. The physiotherapist will tailor the exercise program 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 (e.g. advice to exercise, modify activities, lose weight, or take simple pain medications if needed), and may provide interventions to address psychological barriers to recovery (e.g. pacing, graded exposure), and an App-based exercise program (PhysiTrack; as described for participants at medium risk of persistent pain). The physiotherapist will direct participants to complete an online self-directed pain education program developed by the Agency for Clinical Innovation. The program (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 minutes); 2) Getting help from your healthcare team (5:56 minutes); 3) Pain and physical activity (12:43 minutes); 4) Pain: Lifestyle and nutrition (8:41 minutes); 5) Pain

	and role of medications (9:57 minutes); 6) Pain and thoughts (10:27 minutes); 6) Pain and sleep (11:08 minutes). Participants will be encouraged to go through the program at their own pace and bring any questions to their next consultation. Participants in this sub-group 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 Supplementary 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 (e.g. 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 (e.g. 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 (e.g. 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 (e.g. not improving, dissatisfaction with care). 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	
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 (e.g. 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 (e.g. 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.

Figure legends

Figure 1. Trial flow diagram

Supplementary files

Supplementary File 1. Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist.

Supplementary File 2. Information pack.

Supplementary File 3. Telephone assessment for Rapid Stratified Telehealth group.

Supplementary File 4. Treatment recording form.

Supplementary File 5. Follow up assessment at 6 weeks and 6 months.

Supplementary File 6. Assessment of adverse events.

Supplementary File 7. Participant Information Statement and Consent Forms for qualitative interviews for patients and clinicians.

Supplementary File 8. Interview guide.

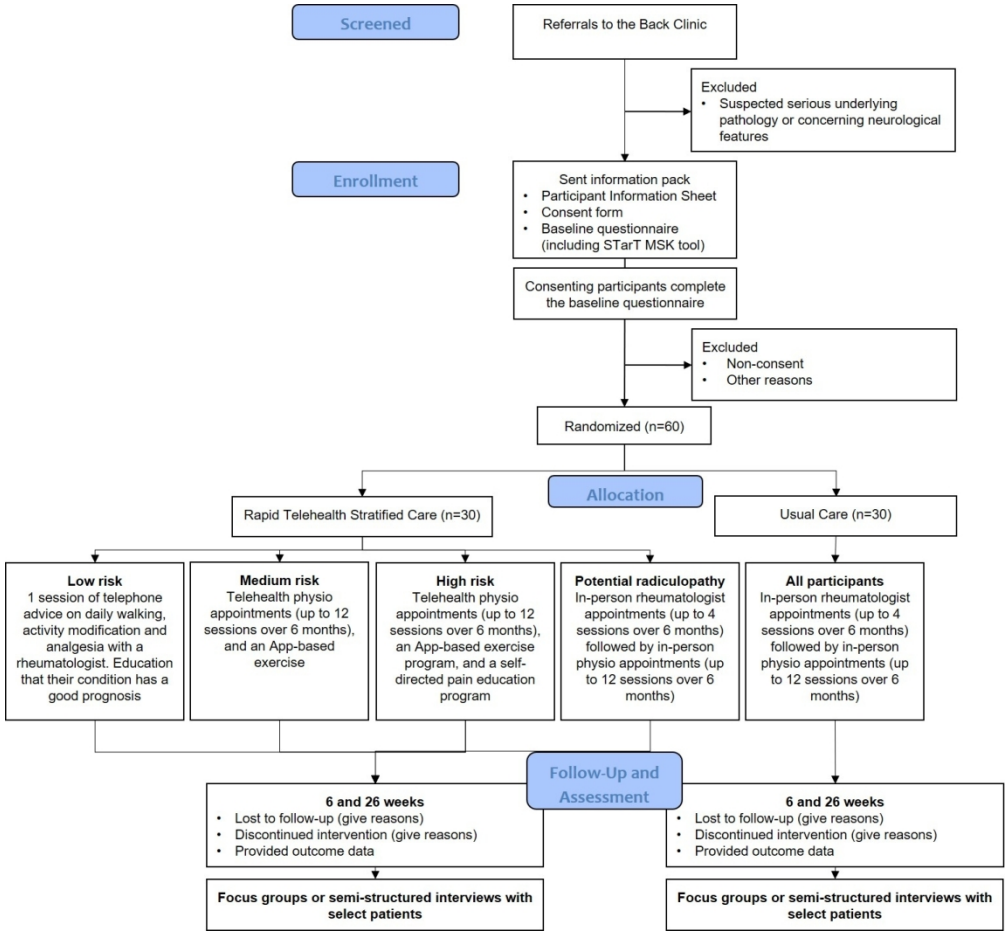

Figure 1. Trial flow diagram

258x239mm (150 x 150 DPI)

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	ItemNo	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)	N/A
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)	N/A
	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)	N/A
	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	N/A
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	N/A
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	N/A
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	N/A

*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.

Supplementary File 2. Information pack

THE UNIVERSITY OF SYDNEY

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Rapid Stratified Telehealth: a feasibility trial comparing two care pathways for people referred to the Back Clinic

PARTICIPANT INFORMATION STATEMENT

1. What is this study about?

You are invited to take part in a research study that will explore a new care pathway for people with back pain and/or leg pain radiating from the back. This Participant Information Statement tells you about the study. Knowing what is involved will help you decide if you want to take part. Please read this sheet carefully and ask questions about anything that you don't understand or want to know more about.

Participation in this research study is voluntary.

By giving your consent to take part in this study you are telling us that you:

- ✓ Understand what you have read
- ✓ Agree to take part in the research study as outlined below
- ✓ Agree to the use of your personal information as described

This Participant Information Statement is yours to keep.

Currently, when you are referred to see a Rheumatologist or Physiotherapist at Royal Prince Alfred Hospital's 'Back Pain Clinic', you are placed on a waiting list. Unfortunately, waiting times for treatment are currently 3 months or longer. This is referred to 'usual care', which is the care you would normally receive when referred to the "Back Pain Clinic'. Our project involves testing a new pathway using telephone and virtual appointments, and an App-based exercise program. This new pathway is based on 'stratified care'. This involves matching the type and amount of care you

receive based on your risk of persisting pain and presence of other symptoms (like leg pain). We want to see whether the new pathway helps people receive treatment sooner and recover sooner.

To find out which pathway is best, we will offer half of people the current pathway and half the new pathway. We will monitor the two groups for 6 months and compare what happens between the groups. To ensure the groups are as similar to each other as possible, the group that you will be placed into is by chance. **There is a 50% chance you will be managed according to the new pathway, and a 50% chance you will be managed according to the current pathway.** To make the results of our study fair, we will not tell you which pathway you have been allocated to.

If you decide you would not like to participate in the research study, you will be managed according to the current pathway. However, your decision whether to participate will not affect your current or future relationship with the researchers or anyone else at the University of Sydney or Royal Prince Alfred Hospital. It also won't affect your position on the waiting list or the quality of care you receive.

2. Who is running the study?

This study is funded by the Agency for Clinical Innovation (ACI) New South Wales and the National Health Medical Research Council. Neither funder will benefit commercially from this study. The manufacturers of PhysiTrack, the mobile App you may be provided during the study, do not have any commercial, financial or business interests in this study.

The people conducting this study are:

- Dr Joshua Zadro, NHMRC Postdoctoral Researcher, Institute for Musculoskeletal Health University of Sydney and Sydney Local Health District
- Dr Chris Needs, Staff Specialist Rheumatologist, Royal Prince Alfred Hospital, Sydney Local District Health
- Prof Christopher Maher, Director, Institute for Musculoskeletal Health, University of Sydney and Sydney Local Health District
- Dr David Martens, Rheumatologist Advanced Trainee, Royal Prince Alfred Hospital, Sydney Local District Health
- Ms Danielle Coombs, Physiotherapist, Institute for Musculoskeletal Health University of Sydney and Sydney Local Health District
- Dr Gustavo Machado, NHMRC Postdoctoral Researcher, Institute for Musculoskeletal Health University of Sydney and Sydney Local Health District
- Mrs Charlotte McLennan, Network Manager, Institute for Musculoskeletal Health University of Sydney and Sydney Local Health District
- Dr Cameron Adams, Rheumatologist Advanced Trainee, Royal Prince Alfred Hospital, Sydney Local District Health
- Prof Nadine Foster, Director, Surgical, Treatment and Rehabilitation Service (STARS) Research and Education Alliance, The University of Queensland and Metro North Hospital and Health Service

3. Who can take part in the study?

A person will be allowed to participate in this study if he or she:

- is referred to the 'Back Pain Clinic' at Royal Prince Alfred Hospital
- has low back pain and/or leg pain radiating from the back

- is 18 years or over and able to provide informed consent

4. What does the study involve?

If you agree to participate in our study, we will send you a survey asking questions about you and your low back pain. We kindly ask you to complete these questionnaires and return them back to us via mail (return-paid envelope provided), email, or SMS. After this, you will be randomly allocated (i.e. by chance) to be managed using the new pathway or current pathway. We will send you another questionnaire at 6 weeks and 6 months after joining the study to see how your low back pain has changed. This questionnaire will contain similar questions to the first one you will complete. If you desire any more information at any point of the study, relevant contact details will be provided.

After 6 months, we may contact you to participate in a group interview (with up to 8 other participants) or one-on-one interview if you prefer. This interview may be conducted via telephone or videoconference (e.g., Zoom) or in person at the Institute for Musculoskeletal Health, Level 10 King George V Building, Royal Prince Alfred Hospital. The interview will explore your opinions on the care you received. You will be sent more information about this interview before you agree to participate.

5. How much of my time will the study take?

If you decide to participate, your treatment time is unlikely to be different than if you did not participate and joined the current waiting list. However, by participating in the study, we will ask you to complete one survey when you enter the study, and another at 6 weeks and 6 months. Each survey will take between 10-15 minutes. You may also be asked to participate in a 1-hour group interview or 30 minutes one-on-one interview, but participation is voluntary.

6. Do I have to be in the study? Can I withdraw from the study once I've started?

Participation in this study is entirely voluntary. You are not obliged to participate. If you do participate, you can withdraw at any time without having to give any reason and without any penalty. Whatever your decision, it will not affect your relationship with the Hospital, Local Health District and The University of Sydney, or the standard of care you receive now or in the future.

7. Are there any risks or costs associated with being in the study?

Aside from giving up your time to complete three 5-10 minutes surveys (plus a possible 30-60 minutes for an interview if you're interested), we do not expect that there will be any risks or costs associated with taking part in this study.

8. Are there any benefits associated with being in the study?

If you are allocated to receive the new care pathway, you may benefit from having faster access to Physiotherapy and Rheumatology care. You may also improve faster because you are seen sooner. If you are allocated to receive the current care pathway, you receive the same treatment as if you had not taken part in the study.

By participating you will be contributing to important research that helps us understand whether our new pathway is potentially beneficial for people with low back pain and worth investigating in a large future study. The results will help us develop better ways to improve the quality of care provided to patients.

9. What will happen to information about me that is collected during the study?

All data collected will be entered electronically and stored on a research database named REDCap (Research Electronic Data Capture). This is a secure, web-based, non-commercial, data management tool designed for research purposes, hosted, and backed up on the Sydney Local Health District servers on a daily basis. No personnel other than the researchers will have access to the research documents. The data will be analysed by the researchers at the Royal Prince Alfred Hospital. All data for use in journal publications and presentations will be de-identified. The files will be retained for 15 years from the day the study is completed. Once this retention expires, the files will be disposed of using the Royal Prince Alfred Hospital confidential waste disposal service. The data may be used for future research purposes; however, Human Research Ethics Committee (HREC) approval will be sought prior to any future use of the data. It will not be shared with local or international collaborators.

10. Will I be told the results of the study?

You have a right to receive feedback about the overall results of this study. You can tell us that you wish to receive feedback by ticking a box and leaving your email when you complete the consent form. This feedback will be in the form of a one-page lay summary of the results. You will receive this feedback after the study is finished.

11. What do I do next?

When you have read this information, please store it in a safe place. If you understand what you have read and would like to participant, please sign and return the consent form.

If you would like to know more about the study at any stage and ask questions, please feel free to contact Mr Christopher Han (research assistant) at Christopher.han@sydney.edu.au or (02) 8627 7423.

12. What if I have a complaint or any concerns about the study?

This study has been approved by the Ethics Review Committee (RPAH Zone) of the Sydney Local Health District.

If you have any complaints or concerns about any aspect of this study, you should call our research team who will do their best to address any issues. If your concerns are not able to be addressed, you can contact the Executive Officer of the Ethics Review Committee on 02 9515 6766 and quote protocol number X21-0221.

This information sheet is for you to keep.

THE UNIVERSITY OF SYDNEY

School of Public Health
Faculty of Medicine and Health

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Rapid Stratified Telehealth: a feasibility trial comparing two care pathways for people referred to the Back Clinic

PARTICIPANT CONSENT FORM

I,_____ *[full name]*

Of_____ *[address]*

have read and understood the Participant Information Sheet on the abovenamed research study and have discussed the study with _____ [investigator responsible for conducting informed consent].

- I have been made aware of the procedures involved in the study, including any known or expected inconvenience, risk, discomfort or potential side effect and of their implications as far as they are currently known by the researchers.

- I understand that my de-identified data may be used for future research and I agree to this.

- I would like to receive a copy of the study results when they become available. My email address is: _____

- I understand that, during the course of this study, my medical records may be accessed by Sydney Local Health District by regulatory authorities or by the Ethics Committee approving the research in order to verify results and determine that the study is being carried out correctly.

- I understand that the SLHD software license for REDCap (Research Electronic Data Capture) will be used to manage the collection and storage of my research data.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I freely choose to participate in this study and understand that I can withdraw at any time.
- I consent to the future use of any data I provide for research purposes. I understand that before the researchers can use any data I provide; they must seek additional ethics approval. YES/ NO
- I consent for other research collaborators to use any data I provide for future research purposes. I understand that before they can use my data, they must seek additional ethics approval. YES/NO
- I also understand that the research study is strictly confidential.
- I hereby agree to participate in this research study.
- I consent to the storage and use of my information collected from me for use, as described in the relevant section of the Participant Information Sheet, for:
  -This specific research project
  -Other research that is closely related to this research project
  -Any future research

Participant Name:_____

Participant Signature:_____

Date:_____

Name of Person conducting informed consent:_____

Signature of Person conducting informed consent: _____

Date:_____

Name of witness to consent form:_____

Signature of witness to informed consent: _____

BASELINE QUESTIONNAIRE

Section 1: Information about you

We want to learn about you, your background, and features of your low back pain.

Gender: **(please tick one only)**	o Male o Female
Date of birth:	____ / _____ / _____ dd / mm / yyyy
Duration of low back pain or leg pain radiating from the back (whichever is the primary issue): **(please tick one only)**	o Less than 12 weeks o Longer than 12 weeks
Language spoken at home other than English	_____
What is your indigenous status? (please tick one only)	o Aboriginal o Torres Strait Islander o Both Aboriginal and Torres Strait Islander o Neither Aboriginal nor Torres Strait Islander
Employment Status: **(please tick one only)**	o Not currently employed o Currently employed o Student o Unpaid carer
Education: What option best describes your highest level of education? (please tick one only)	o Primary school or less o High school (not completed) o High school (completed) o TAFE/Trade o University- undergraduate degree/s (completed) o University- postgraduate degree/s e.g. Masters, PhD (completed) o Other (please specify) _____

Have you previously taken sick leave due to your low back pain or leg pain radiating from the back? (please tick one only)	o Yes o No

Section 2: Information about your back pain and/or leg pain radiating from the back

The Keele STarT MSK Tool © *Self-report version*

For questions 1-9, think about just the last two weeks:

Pain intensity

1) On average, how intense was your low back pain or leg pain radiating from the back (whichever was worse) [where 0 is "no pain" and 10 is "pain as bad as it could be"]?

0	1	2	3	4	5	6	7	8	9	10
□	□	□	□	□	□	□	□	□	□	□

Please cross one box for each question below

	No	Yes
2) Do you often feel unsure about how to manage your pain condition?	□	□
3) Over the last two weeks, have you been bothered a lot by your pain?	□	□
4) Have you only been able to walk short distances because of your pain?	□	□
5) Have you had troublesome joint or muscle pain in more than one part of your body?	□	□
6) Do you think your condition will last a long time?	□	□
7) Do you have other important health problems?	□	□
8) Has pain made you feel down or depressed in the last two weeks?	□	□

9) Do you feel it is unsafe for a person with a condition like yours to be physically active?	□	□
10) Have you had your current pain problem for 6 months or more?	□	□

PROMIS–29 Profile v2.0

Please respond to each question or statement by marking one box per row.

	Physical Function	**Without any difficulty**	**With a little difficulty**	**With some difficulty**	**With much difficulty**	**Unable to do**
1	Are you able to do chores such as vacuuming or yard work?	☐	☐	☐	☐	☐
2	Are you able to go up and down stairs at a normal pace?	☐	☐	☐	☐	☐
3	Are you able to go for a walk of at least 15 minutes?	☐	☐	☐	☐	☐
4	Are you able to run errands and shop?	☐	☐	☐	☐	☐
	Anxiety **In the past 7 days…**	**Never**	**Rarely**	**Sometimes**	**Often**	**Always**
5	I felt fearful	☐	☐	☐	☐	☐
6	I found it hard to focus on anything other than my anxiety	☐	☐	☐	☐	☐
7	My worries overwhelmed me	☐	☐	☐	☐	☐
8	I felt uneasy	☐	☐	☐	☐	☐
	Depression **In the past 7 days...**	**Never**	**Rarely**	**Sometimes**	**Often**	**Always**
9	I felt worthless	☐	☐	☐	☐	☐
10	I felt helpless	☐	☐	☐	☐	☐
11	I felt depressed	☐	☐	☐	☐	☐
12	I felt hopeless	☐	☐	☐	☐	☐
	Fatigue **During the past 7 days…**	**Not at all**	**A little bit**	**Somewhat**	**Quite a bit**	**Very much**
13	I feel fatigued	☐	☐	☐	☐	☐
14	I have trouble starting things because I am tired	☐	☐	☐	☐	☐

Fatigue

	In the past 7 days…	Not at all	A little bit	Somewhat	Quite a bit	Very much
15	How run-down did you feel on average? ...	☐	☐	☐	☐	☐
16	How fatigued were you on average?	☐	☐	☐	☐	☐

Sleep Disturbance

	In the past 7 days…	Very poor	Poor	Fair	Good	Very good
17	My sleep quality was.....	☐	☐	☐	☐	☐

	In the past 7 days…	Not at all	A little bit	Somewhat	Quite a bit	Very much
18	My sleep was refreshing.....	☐	☐	☐	☐	☐
19	I had a problem with my sleep	☐	☐	☐	☐	☐
20	I had difficulty falling asleep	☐	☐	☐	☐	☐

Ability to Participate in Social Roles and Activities

		Never	Rarely	Sometimes	Usually	Always
21	I have trouble doing all of my regular leisure activities with others.....	☐	☐	☐	☐	☐
22	I have trouble doing all of the family activities that I want to do	☐	☐	☐	☐	☐
23	I have trouble doing all of my usual work (include work at home)	☐	☐	☐	☐	☐
24	I have trouble doing all of the activities with friends that I want to do	☐	☐	☐	☐	☐

Pain Interference

	In the past 7 days…	Not at all	A little bit	Somewhat	Quite a bit	Very much
25	How much did pain interfere with your day to day activities?.....	☐	☐	☐	☐	☐
26	How much did pain interfere with work around the home?	☐	☐	☐	☐	☐
27	How much did pain interfere with your ability to participate in social activities? .	☐	☐	☐	☐	☐
28	How much did pain interfere with your household chores?	☐	☐	☐	☐	☐

Pain Intensity

In the past 7 days…

29	How would you rate your pain on average?.....	☐ 0 No pain	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10 Worst imaginable pain

Roland-Morris Low Back Pain and Disability Questionnaire (RMQ)

Instructions

Please read instructions: When your back hurts, you may find it difficult to do some of the things you normally do. Mark only the sentences that describe you today.

- ☐ I stay at home most of the time because of my back.
- ☐ I change position frequently to try to get my back comfortable.
- ☐ I walk more slowly than usual because of my back.
- ☐ Because of my back, I am not doing any jobs that I usually do around the house.
- ☐ Because of my back, I use a handrail to get upstairs.
- ☐ Because of my back, I lie down to rest more often.
- ☐ Because of my back, I have to hold on to something to get out of an easy chair.
- ☐ Because of my back, I try to get other people to do things for me.
- ☐ I get dressed more slowly than usual because of my back.
- ☐ I only stand up for short periods of time because of my back.
- ☐ Because of my back, I try not to bend or kneel down.
- ☐ I find it difficult to get out of a chair because of my back.
- ☐ My back is painful almost all of the time.
- ☐ I find it difficult to turn over in bed because of my back.
- ☐ My appetite is not very good because of my back.
- ☐ I have trouble putting on my socks (or stockings) because of the pain in my back.
- ☐ I can only walk short distances because of my back pain.
- ☐ I sleep less well because of my back.
- ☐ Because of my back pain, I get dressed with the help of someone else.
- ☐ I sit down for most of the day because of my back.
- ☐ I avoid heavy jobs around the house because of my back.
- ☐ Because of back pain, I am more irritable and bad tempered with people than usual.
- ☐ Because of my back, I go upstairs more slowly than usual.
- ☐ I stay in bed most of the time because of my back.

Use of healthcare for your back pain and/or leg pain radiating from the back

Have you used any healthcare services (e.g. GP, physiotherapy, x-rays, hospital admission), or community health or other services (e.g. meals on wheels) for your of low back pain and/or leg pain radiating from the back since this episode of pain started?

- ☐ Yes, please specify the service_____
- ☐ No

Are any services ongoing?

- ☐ Yes, please specify the service_____
- ☐ No

Are you currently taking any prescription or over the counter medication for your low back pain and/or leg pain radiating from the back?

- ☐ Yes, please name the medication (please use the full brand name) and provide details on the dose (e.g. how much do you take per day)

  _____
- ☐ No

Supplementary File 3. Telephone assessment for the Rapid Stratified Telehealth group

Subjective history

Current History				
Past Medical History				
Medications				
Social History				
Previous Imaging				
Red Flag screening (tick as many that are relevant)				
□ History of significant trauma	□ History of Cancer	□ Recent bacterial infection	□ Fever	□ IV drug use
□ Immune suppression	□ Recent unexplained weight loss	□ Severe pain when supine/at night	□ Saddle anaesthesia	□ Bladder or bowel dysfunction
□ Neurological deficit in limb	□ Osteoporosis	□ Long term corticosteroid use	□ Early morning back pain and stiffness	

Potential radiculopathy questionnaire

Symptoms	Score
Duration of pain	
Greater than 6 months	**1**
Less than 6 months	**0**
Pain into one leg	
Above the knee	**0**
Below the knee	**1**
Weakness in the legs	**1**
Paraesthesia in the legs	
Above the knee	**0**
Below the knee	**1**
Cough, sneeze exacerbations	**1**
Temperatures, fevers, and weight loss	Exclude from trial and refer for urgent medical care
Symptoms of cauda equina syndrome	Exclude from trial and refer for urgent medical care

Scoring criteria

- **3 or more** = potential radiculopathy (fast tracked to face-to-face care)

Supplementary File 4. Treatment recording form

Participant ID

_____

Date of appointment

_____

Appointment number

_____

Treatment sub-group at baseline

_____

Please indicate what care the participant received during this appointment

Treatment sub-group	**Treatment protocol summary**	**Tick box if participant received this care**
Patients at low risk of persistent pain (Keele STarT MSK score 0-4) AND no potential radiculopathy	Telephone appointment with Advanced Rheumatology Trainee	
	• Advice on daily walking	☐
	• Advice on activity modification	☐
	• Advice to take simple pain medications	☐
	• Education that their condition has a good prognosis	☐
	• Other advice (Please specify) _____	☐
Patients at medium risk of persistent pain (Keele STarT MSK score 5-8) AND no potential radiculopathy	Virtual physiotherapy appointment	
	• Advice and education to support self-management	☐
	• Advice to exercise	☐
	• Advice to modify activities	☐
	• Advice to lose weight	☐
	• Advice to take simple pain medications	☐
	• App-based exercise program	☐
	• **Tick if participant needed to print out the exercise program**	☐

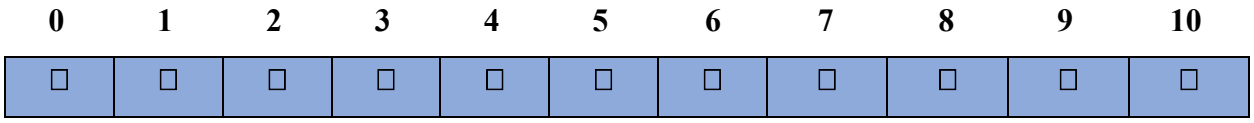
	• Other intervention (Please specify) _____	☐
Patients at high risk of persistent pain (Keele STarT MSK score 9-12) AND no potential radiculopathy	Virtual physiotherapy appointment	
	• Advice and education to support self-management	☐
	• Advice to exercise	☐
	• Advice to modify activities	☐
	• Advice to lose weight	☐
	• Advice to take simple pain medications	☐
	• Interventions to address psychological barriers to recovery (e.g. pacing, graded exposure)	☐
	• App-based exercise program	☐
	• **Tick if participant needed to print out the exercise program**	☐
	• Instructed to complete online pain education modules	☐
	• **Tick if participant has completed all online pain education modules**	☐
	• Referral to psychologist	☐
	• Other intervention (Please specify) _____	☐
Patients with potential radiculopathy	In person rheumatologist appointment	
	• Take patients' medical history (including past history)	☐
	• Conduct a physical examination (including a neurological examination)	☐
	• Review any previously undertaken investigations (e.g. imaging, pathology tests)	☐

	• Formulate a management plan	☐
	• Monitor progress	☐
	In person physiotherapist appointment	
	• Advice and education to support self-management	☐
	• Advice to exercise	☐
	• Advice to modify activities	☐
	• Advice to lose weight	☐
	• Advice to take simple pain medications	☐
	• Exercise program	☐
	• Graded activity	☐
	• Spinal manipulative therapy	☐
	• Interventions to address psychological barriers to recovery (e.g. pacing, graded exposure)	☐
	• Referral to psychologist	☐
	• Other intervention (Please specify) _____	☐

Supplementary File 5. Follow up assessment at 6 weeks and 6 months

Pain intensity

1) On average in the last two weeks, how intense was your low back pain or leg pain radiating from your back (choose whichever was worse) [where 0 is “no pain” and 10 is “pain as bad as it could be”]?



PROMIS–29 Profile v2.0

Please respond to each question or statement by marking one box per row.

	Physical Function	**Without any difficulty**	**With a little difficulty**	**With some difficulty**	**With much difficulty**	**Unable to do**
1	Are you able to do chores such as vacuuming or yard work?	☐	☐	☐	☐	☐
2	Are you able to go up and down stairs at a normal pace?	☐	☐	☐	☐	☐
3	Are you able to go for a walk of at least 15 minutes?	☐	☐	☐	☐	☐
4	Are you able to run errands and shop?	☐	☐	☐	☐	☐
	Anxiety **In the past 7 days…**	**Never**	**Rarely**	**Sometimes**	**Often**	**Always**
5	I felt fearful	☐	☐	☐	☐	☐
6	I found it hard to focus on anything other than my anxiety	☐	☐	☐	☐	☐
7	My worries overwhelmed me	☐	☐	☐	☐	☐
8	I felt uneasy	☐	☐	☐	☐	☐
	Depression **In the past 7 days...**	**Never**	**Rarely**	**Sometimes**	**Often**	**Always**
9	I felt worthless	☐	☐	☐	☐	☐
10	I felt helpless	☐	☐	☐	☐	☐
11	I felt depressed	☐	☐	☐	☐	☐
12	I felt hopeless	☐	☐	☐	☐	☐
	Fatigue **During the past 7 days…**	**Not at all**	**A little bit**	**Somewhat**	**Quite a bit**	**Very much**
13	I feel fatigued	☐	☐	☐	☐	☐
14	I have trouble starting things because I am tired	☐	☐	☐	☐	☐

Fatigue

	In the past 7 days…	Not at all	A little bit	Somewhat	Quite a bit	Very much
15	How run-down did you feel on average? ...	☐	☐	☐	☐	☐
16	How fatigued were you on average?	☐	☐	☐	☐	☐

Sleep Disturbance

	In the past 7 days…	Very poor	Poor	Fair	Good	Very good
17	My sleep quality was.....	☐	☐	☐	☐	☐

	In the past 7 days…	Not at all	A little bit	Somewhat	Quite a bit	Very much
18	My sleep was refreshing.....	☐	☐	☐	☐	☐
19	I had a problem with my sleep	☐	☐	☐	☐	☐
20	I had difficulty falling asleep	☐	☐	☐	☐	☐

Ability to Participate in Social Roles and Activities

		Never	Rarely	Sometimes	Usually	Always
21	I have trouble doing all of my regular leisure activities with others.....	☐	☐	☐	☐	☐
22	I have trouble doing all of the family activities that I want to do	☐	☐	☐	☐	☐
23	I have trouble doing all of my usual work (include work at home)	☐	☐	☐	☐	☐
24	I have trouble doing all of the activities with friends that I want to do	☐	☐	☐	☐	☐

Pain Interference

	In the past 7 days…	Not at all	A little bit	Somewhat	Quite a bit	Very much
25	How much did pain interfere with your day to day activities?.....	☐	☐	☐	☐	☐
26	How much did pain interfere with work around the home?	☐	☐	☐	☐	☐
27	How much did pain interfere with your ability to participate in social activities? .	☐	☐	☐	☐	☐
28	How much did pain interfere with your household chores?	☐	☐	☐	☐	☐

Pain Intensity

In the past 7 days…

29	How would you rate your pain on average?.....	☐ 0 No pain	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10 Worst imaginable pain

Roland-Morris Low Back Pain and Disability Questionnaire (RMQ)

Instructions

Please read instructions: When your back hurts, you may find it difficult to do some of the things you normally do. Mark only the sentences that describe you today.

- ☐ I stay at home most of the time because of my back.
- ☐ I change position frequently to try to get my back comfortable.
- ☐ I walk more slowly than usual because of my back.
- ☐ Because of my back, I am not doing any jobs that I usually do around the house.
- ☐ Because of my back, I use a handrail to get upstairs.
- ☐ Because of my back, I lie down to rest more often.
- ☐ Because of my back, I have to hold on to something to get out of an easy chair.
- ☐ Because of my back, I try to get other people to do things for me.
- ☐ I get dressed more slowly than usual because of my back.
- ☐ I only stand up for short periods of time because of my back.
- ☐ Because of my back, I try not to bend or kneel down.
- ☐ I find it difficult to get out of a chair because of my back.
- ☐ My back is painful almost all of the time.
- ☐ I find it difficult to turn over in bed because of my back.
- ☐ My appetite is not very good because of my back.
- ☐ I have trouble putting on my socks (or stockings) because of the pain in my back.
- ☐ I can only walk short distances because of my back pain.
- ☐ I sleep less well because of my back.
- ☐ Because of my back pain, I get dressed with the help of someone else.
- ☐ I sit down for most of the day because of my back.
- ☐ I avoid heavy jobs around the house because of my back.
- ☐ Because of back pain, I am more irritable and bad tempered with people than usual.
- ☐ Because of my back, I go upstairs more slowly than usual.
- ☐ I stay in bed most of the time because of my back.

Satisfaction with care

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?

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	1	2	3	4	5	6	7	8	9	10
Worst care possible										Best care possible

Use of healthcare for your back pain and/or leg pain radiating from the back

Have you used any healthcare services (e.g. GP, physiotherapy, x-rays, hospital admission), or community health or other services (e.g. meals on wheels) for your low back pain and/or leg pain radiating from the back since the start of this study?

☐ Yes, please specify the service_____
☐ No

Are any services ongoing?

☐ Yes, please specify the service_____
☐ No

Are you currently taking any prescription or over the counter medication for your low back pain and/or leg pain radiating from the back?

☐ Yes, please name the medication (please use the full brand name) and provide details on the dose (e.g. how much do you take per day)

_____

☐ No

Supplementary file 6. Assessment of adverse events

Any adverse events (self-reported by participants at 2 weeks, 6 weeks and 6 months)

Have you had a new medical condition or an exacerbation of an existing condition since beginning the study, e.g. dizziness, increased pain? If yes, can you please describe this?

Adverse event patient data (collected by clinicians)

Type of event	
Start and stop dates	
Action taken	
Causality of the event in relation to treatment provided in this trial (score as: extremely unlikely, unlikely, unsure, likely, or extremely likely)	

Serious adverse events (collected by clinicians)

SERIOUS ADVERSE EVENT REPORT					
Study Site:					
Date of report:		**□ Initial report □ Follow up report F/up No.:_____**			
A. PATIENT DETAILS					
Subject number:		**Patient initials:**	|__|__|__|	**Date of birth:**	|__|__|-|__|__|-|__|__|__|__|
Sex: □ Male □ Female		**Height:**	|__|__|__| **cm**	**Weight:**	|__|__|__| **kg**
B. SERIOUS ADVERSE EVENT DETAILS					
Serious Adverse Event: ***(Diagnosis where available)***				**Start date:**	|__|__|-|__|__|-|__|__|__|__|

Event Narrative ***(include relevant symptoms, lab tests performed as required and any other action taken):***	
C. SEVERITY OF EVENT	
□ Mild **□ Moderate** **□ Severe** **□ Unknown**	
D. SERIOUSNESS CRITERIA ***(select all that***	**E. OUTCOME OF THE EVENT** ***(select one only):***
□ Fatal (results in death)	**□ Fatal; date of death** |__|__|-|__|__|-|__|__|__|__|
□ Life-threatening	**□ Ongoing/ Not resolved**
□ Requires Hospitalisation or Prolongs Hospitalisation ***(if ticked, complete section H)***	**□ Resolved; date** |__|__|-|__|__|-|__|__|__|__|
□ Results in Persistent or Significant Disability/Incapacity	**□ Resolved with sequelae; Sequelae: -** _____
□ Causes a Congenital Abnormality/Birth Defect	**□ Unknown**
□ Medically Important/Significant event	
E. CAUSALITY	
In the investigator's opinion was the adverse event related to study treatment?	***In the medical monitor's opinion was the adverse event related to study treatment?***
□ Not related	**□ Not related**
□ Unlikely related	**□ Unlikely related**
□ Possibly Related	**□ Possibly Related**
□ Probably Related	**□ Probably Related**
□ Definitely Related	**□ Definitely Related**
□ Not applicable (SAE occurring outside the 6-week treatment window)	
F. EXPECTEDNESS	

In the <u>medical monitor's</u> opinion was the adverse event unexpected? **□ Yes** **□ No**

G. ACTION TAKEN WITH STUDY TREATMENT DUE TO EVENT

□ None

□ Temporarily stopped ***Date stopped:*** |__|__| / |__|__| / |__|__|__|__| ***Date restarted*:** |__|__| / |__|__| / |__|__|__|__|

□ Permanently discontinued ***Date stopped*:** |__|__| / |__|__| / |__|__|__|__|

□ Dose changed ***Dose changed to*:** _____

□ Unknown

H. HOSPITALISATION INFORMATION ***(where applicable):***

N/A **□**

Date of Admission: |__|__| / |__|__| / |__|__|__|__| **Date of Discharge:** |__|__| / |__|__| / |__|__|__|__|

Procedure: - **Date of Procedure:** |__|__| / |__|__| / |__|__|__|__|

_____

Procedure: **Date of Procedure:** |__|__| / |__|__| / |__|__|__|__|

_____

I. CONCOMITANT MEDICATION: ***List all patient medications at time of event. Do not list medications***

Medication name	Dose	Route	Frequency	Start date	Stop date or Ongoing
					□ Ongoing
					□ Ongoing
					□ Ongoing
					□ Ongoing

J. PATIENT MEDICAL HISTORY: ***List all previous patient medical history.***

Reporter name: ……....		**Date sent to medical monitor:** …….....
Reviewed by the medical monitor:		
Date of receipt:	**Name:**	**Signature:** ……..

Supplementary File 7. Participant Information Statement and Consent Forms for qualitative interviews with patients and clinicians

THE UNIVERSITY OF SYDNEY

ABN 15 211 513 464

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Faculty of Medicine and Health

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Rapid Stratified Telehealth for people referred to the Back Clinic: interview study for patients

PARTICIPANT INFORMATION STATEMENT

1. What is this study about?

You are invited to take part in a research study that will explore people's opinion on the care they received as part of the study you recently participated in comparing two care pathways for people with back pain and/or leg pain radiating from the back. This Participant Information Statement tells you about the study. Knowing what is involved will help you decide if you want to take part. Please read this sheet carefully and ask questions about anything that you don't understand or want to know more about.

Participation in this research study is voluntary.

By giving your consent to take part in this study you are telling us that you:

- ✓ Understand what you have read
- ✓ Agree to take part in the research study as outlined below
- ✓ Agree to the use of your personal information as described

This Participant Information Statement is yours to keep.

Your decision whether to participate will not affect your current or future relationship with the researchers or anyone else at the University of Sydney or Royal Prince Alfred Hospital. It also won't affect the quality of care you receive.

2. Who is running the study?

This study is funded by the Agency for Clinical Innovation (ACI) New South Wales and the National Health Medical Research Council. Neither funder will benefit commercially from this

study. The manufacturers of PhysiTrack, the mobile App you may be provided during the study, do not have any commercial, financial or business interests in this study.

The people conducting this study are:

- Dr Joshua Zadro, NHMRC Postdoctoral Researcher, Institute for Musculoskeletal Health University of Sydney and Sydney Local Health District
- Dr Chris Needs, Staff Specialist Rheumatologist, Royal Prince Alfred Hospital, Sydney Local District Health
- Prof Christopher Maher, Director, Institute for Musculoskeletal Health, University of Sydney and Sydney Local Health District
- Dr David Martens, Rheumatologist Advanced Trainee, Royal Prince Alfred Hospital, Sydney Local District Health
- Ms Danielle Coombs, Physiotherapist, Institute for Musculoskeletal Health University of Sydney and Sydney Local Health District
- Dr Gustavo Machado, NHMRC Postdoctoral Researcher, Institute for Musculoskeletal Health University of Sydney and Sydney Local Health District
- Mrs Charlotte McLennan, Network Manager, Institute for Musculoskeletal Health University of Sydney and Sydney Local Health District
- Dr Cameron Adams, Rheumatologist Advanced Trainee, Royal Prince Alfred Hospital, Sydney Local District Health
- Prof Nadine Foster, Director, Surgical, Treatment and Rehabilitation Service (STARS) Research and Education Alliance, The University of Queensland and Metro North Hospital and Health Service

3. Who can take part in the study?

A person will be allowed to participate in this study if he or she participated in our study comparing two care pathways for people with back pain and/or leg pain radiating from the back and completed the 6 month follow up.

4. What does the study involve?

If you agree to participate in our study, we will arrange a time for you to participate in a group interview (with up to 8 other participants who took part in the study) or a one-on-one interview if you prefer. This interview may be conducted via telephone or videoconference (e.g. Zoom) or in person at the Institute for Musculoskeletal Health, Level 10 King George V Building, Royal Prince Alfred Hospital. The interview will explore your opinion on the care you received as part of the study comparing two care pathways for people with back pain.

5. How much of my time will the study take?

If you decide to participate, you will need to participate in a 1 hour group interview or 30 minute one-on-one interview. If you would like the interview to be face-to-face, there may be travel time to get to the Institute for Musculoskeletal Health.

6. Do I have to be in the study? Can I withdraw from the study once I've started?

Participation in this study is entirely voluntary. You are not obliged to participate. If you do participate, you can withdraw at any time without having to give any reason and without any

penalty. Whatever your decision, it will not affect your relationship with the Hospital, Local Health District and The University of Sydney, or the standard of care you receive now or in the future.

7. Are there any risks or costs associated with being in the study?

Aside from giving up your time to participate in an interview, we do not expect that there will be any risks or costs associated with taking part in this study.

8. Are there any benefits associated with being in the study?

By participating, you will be contributing to important research that helps us understand whether the new care pathway we are testing is acceptable to patients with back pain. The results may help us refine the care pathway before testing it in large research study.

9. What will happen to information about me that is collected during the study?

By providing your consent, you are agreeing to us collecting personal information about you for the purposes of this research study. Your information will only be used for the purposes outlined in this Participant Information Statement, unless you consent otherwise.

Your information will be stored and analysed securely on a research database within the Institute for Musculoskeletal Health, Sydney Local Health District, and your identity/information will be kept strictly confidential, except as required by law. Study findings may be published, but you will not be individually identifiable in these publications.

We will keep the information we collect for this study, and we may use it in future project. By providing your consent you are allowing us to use your information in future projects, however all identifying data will remain strictly confidential. We don't know at this stage what these other projects may involve. We will seek ethical approval before using the information in these future projects.

If you are allocated to the new pathway, you may be provided with an exercise program delivered via a mobile App (PhysiTrack). No data will be collected through the PhysiTrack App and therefore no data will be sent to the developer. The App will simply be used to show you which exercises to do. PhysiTrack is also not a medical device hence does not require TGA approval. PhysiTrack is simply an App that allows physiotherapists to put together an exercise program to allow you to receive written and video instructions on how to perform the exercises correctly. PhysioTrack is essentially a substitute for drawing an exercise program on a piece of paper. The exercises in PhysiTrack include a range of exercises physiotherapists have been prescribing for patients over many years.

As with any home-exercise program prescribed by a physiotherapist, you are free to stop exercising or using the PhysiTrack app at any time if you experience an increase in your symptoms or are not comfortable performing an exercise.

10. Will I be told the results of the study?

You have a right to receive feedback about the overall results of this study. You can tell us that you wish to receive feedback by ticking a box and leaving your email when you complete the questionnaires. This feedback will be in the form of a one-page lay summary of the results. You will receive this feedback after the study is finished.

11. What do I do next?

When you have read this information, please store it in a safe place. If you understand what you have read and would like to participant, please sign and return the consent form.

If you would like to know more about the study at any stage and ask questions, please feel free to contact Mr Christopher Han (research assistant) at Christopher.han@sydney.edu.au or (02) 8627 7423.

12. What if I have a complaint or any concerns about the study?

This study has been approved by the Ethics Review Committee (RPAH Zone) of the Sydney Local Health District.

If you have any complaints or concerns about any aspect of this study, you should call our research team who will do their best to address any issues. If your concerns are not able to be addressed, you can contact the Executive Officer of the Ethics Review Committee on 02 9515 6766 and quote protocol number X21-0221.

This information sheet is for you to keep.

THE UNIVERSITY OF SYDNEY

ABN 15 211 513 464

School of Public Health
Faculty of Medicine and Health

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Research Fellow

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Rapid Stratified Telehealth for people referred to the Back Clinic: interview study for patients

PARTICIPANT CONSENT FORM

I,_____ *[full name]*

Of_____ *[address]*

have read and understood the Participant Information Sheet on the abovenamed research study

and have discussed the study with _____
[investigator responsible for conducting informed consent].

- I have been made aware of the procedures involved in the study, including any known or expected inconvenience, risk, discomfort or potential side effect and of their implications as far as they are currently known by the researchers.

- I understand that the interview discussion will be audio-recorded and will then be transcribed and be kept in a manner in which I cannot be identified for analysis and I agree to this.

- I understand that my de-identified data may be used for future research and I agree to this.

- I would like to receive a copy of the study results when they become available. My email address is: _____
- I understand that, during the course of this study, my medical records may be accessed by Sydney Local Health District by regulatory authorities or by the Ethics Committee approving the research in order to verify results and determine that the study is being carried out correctly.
- I understand that the SLHD software license for REDCap (Research Electronic Data Capture) will be used to manage the collection and storage of my research data.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I freely choose to participate in this study and understand that I can withdraw at any time.
- I consent to the future use of any data / samples I provide for research purposes. I understand that before they can use any data I provide, they must seek additional ethics approval. YES/ NO
- I consent for other research collaborators to use any data / samples I provide for future research purposes. I understand that before they can use my data, they must seek additional ethics approval. YES/NO
- I also understand that the research study is strictly confidential.
- I hereby agree to participate in this research study.
- I consent to the storage and use of my information collected from me for use, as described in the relevant section of the Participant Information Sheet, for:
  - -This specific research project
  - -Other research that is closely related to this research project
  - -Any future research

Participant Name:_____

Participant Signature:_____

Date:_____

Name of Person conducting informed consent:_____

Signature of Person conducting informed consent: _____

Date:_____

THE UNIVERSITY OF SYDNEY

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Faculty of Medicine and Health

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Rapid Stratified Telehealth for people referred to the Back Clinic: interview study for clinicians

PARTICIPANT INFORMATION STATEMENT

1. What is this study about?

You are invited to take part in a research study that will explore clinicians' opinion on the care they provided as part of the study you recently participated in comparing two care pathways for people with back pain and/or leg pain radiating from the back. This Participant Information Statement tells you about the study. Knowing what is involved will help you decide if you want to take part. Please read this sheet carefully and ask questions about anything that you don't understand or want to know more about.

Participation in this research study is voluntary.

By giving your consent to take part in this study you are telling us that you:

- ✓ Understand what you have read
- ✓ Agree to take part in the research study as outlined below
- ✓ Agree to the use of your personal information as described

This Participant Information Statement is yours to keep.

Your decision whether to participate will not affect your current or future relationship with the researchers or anyone else at the University of Sydney or Royal Prince Alfred Hospital.

2. Who is running the study?

The people conducting this study are:

- Dr Joshua Zadro, NHMRC Postdoctoral Researcher, Institute for Musculoskeletal Health University of Sydney and Sydney Local Health District
- Dr Chris Needs, Staff Specialist Rheumatologist, Royal Prince Alfred Hospital, Sydney Local District Health
- Prof Christopher Maher, Director, Institute for Musculoskeletal Health, University of Sydney and Sydney Local Health District

- Dr David Martens, Rheumatologist Advanced Trainee, Royal Prince Alfred Hospital, Sydney Local District Health
- Ms Danielle Coombs, Physiotherapist, Institute for Musculoskeletal Health University of Sydney and Sydney Local Health District
- Dr Gustavo Machado, NHMRC Postdoctoral Researcher, Institute for Musculoskeletal Health University of Sydney and Sydney Local Health District
- Mrs Charlotte McLennan, Network Manager, Institute for Musculoskeletal Health University of Sydney and Sydney Local Health District
- Dr Cameron Adams, Rheumatologist Advanced Trainee, Royal Prince Alfred Hospital, Sydney Local District Health
- Prof Nadine Foster, Director, Surgical, Treatment and Rehabilitation Service (STARS) Research and Education Alliance, The University of Queensland and Metro North Hospital and Health Service

This study is funded by the Agency for Clinical Innovation (ACI) New South Wales and the National Health Medical Research Council. Neither funder will benefit commercially from this study.

3. Who can take part in the study?

A person will be allowed to participate in this study if he or she is a physiotherapist or rheumatologist who provided care as part of our study comparing two care pathways for people with back pain and/or leg pain radiating from the back.

4. What does the study involve?

If you agree to participate in our study, we will arrange a time for you to participate in a one-on-one interview with a member of the research team. This interview may be conducted via telephone or videoconference (e.g. Zoom) or in person at the Institute for Musculoskeletal Health, Level 10 King George V Building, Royal Prince Alfred Hospital. The interview will explore your opinion on the care you provided as part of the study comparing two care pathways for people with back pain and/or leg pain radiating from the back.

5. How much of my time will the study take?

If you decide to participate, you will need to participate in a 30 minute one-on-one interview. If you would like the interview to be face-to-face, there may be travel time to get to the Institute for Musculoskeletal Health.

6. Do I have to be in the study? Can I withdraw from the study once I've started?

Participation in this study is entirely voluntary. You are not obliged to participate. If you do participate, you can withdraw at any time without having to give any reason and without any penalty. Whatever your decision, it will not affect your relationship with the Hospital, Local Health District and The University of Sydney.

7. Are there any risks or costs associated with being in the study?

Aside from giving up your time to participate in an interview, we do not expect that there will be any risks or costs associated with taking part in this study.

8. Are there any benefits associated with being in the study?

By participating, you will be contributing to important research that helps us understand whether the new care pathway we are testing is acceptable to patients with back pain and/or leg pain radiating from the back and clinicians providing care to these patients. The results may help us refine the care pathway before testing it in large research study.

9. What will happen to information about me that is collected during the study?

By providing your consent, you are agreeing to us collecting personal information about you for the purposes of this research study. Your information will only be used for the purposes outlined in this Participant Information Statement, unless you consent otherwise.

Your information will be stored and analysed securely on a research database within the Institute for Musculoskeletal Health, Sydney Local Health District, and your identity/information will be kept strictly confidential, except as required by law. Study findings may be published, but you will not be individually identifiable in these publications.

We will keep the information we collect for this study, and we may use it in future project. By providing your consent you are allowing us to use your information in future projects, however all identifying data will remain strictly confidential. We don't know at this stage what these other projects may involve. We will seek ethical approval before using the information in these future projects.

10. Will I be told the results of the study?

You have a right to receive feedback about the overall results of this study. You can tell us that you wish to receive feedback by ticking a box and leaving your email when you complete the questionnaires. This feedback will be in the form of a one-page lay summary of the results. You will receive this feedback after the study is finished.

11. What do I do next?

When you have read this information, please store it in a safe place. If you understand what you have read and would like to participant, please sign and return the consent form.

If you would like to know more about the study at any stage and ask questions, please feel free to contact Mr Christopher Han (research assistant) at Christopher.han@sydney.edu.au or (02) 8627 7423.

12. What if I have a complaint or any concerns about the study?

This study has been approved by the Ethics Review Committee (RPAH Zone) of the Sydney Local Health District.

If you have any complaints or concerns about any aspect of this study, you should call our research team who will do their best to address any issues. If your concerns are not able to be addressed, you can contact the Executive Officer of the Ethics Review Committee on 02 9515 6766 and quote protocol number **xxxx**.

This information sheet is for you to keep.

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Rapid Stratified Telehealth for people referred to the Back Clinic: interview study for clinicians

PARTICIPANT CONSENT FORM

I,_____ *[full name]*

Of_____ *[address]*

have read and understood the Participant Information Sheet on the abovenamed research study

and have discussed the study with _____
[investigator responsible for conducting informed consent].

- I have been made aware of the procedures involved in the study, including any known or expected inconvenience, risk, discomfort or potential side effect and of their implications as far as they are currently known by the researchers.

- I understand that the interview discussion will be audio-recorded and will then be transcribed and be kept in a manner in which I cannot be identified for analysis and I agree to this.

- I understand that my de-identified data may be used for future research and I agree to this.

- I would like to receive a copy of the study results when they become available. My email address is: _____
- I understand that, during the course of this study, my medical records may be accessed by Sydney Local Health District by regulatory authorities or by the Ethics Committee approving the research in order to verify results and determine that the study is being carried out correctly.
- I understand that the SLHD software license for REDCap (Research Electronic Data Capture) will be used to manage the collection and storage of my research data.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I freely choose to participate in this study and understand that I can withdraw at any time.
- I consent to the future use of any data / samples I provide for research purposes. I understand that before they can use any data I provide, they must seek additional ethics approval. YES/ NO
- I consent for other research collaborators to use any data / samples I provide for future research purposes. I understand that before they can use my data, they must seek additional ethics approval. YES/NO
- I also understand that the research study is strictly confidential.
- I hereby agree to participate in this research study.
- I consent to the storage and use of my information collected from me for use, as described in the relevant section of the Participant Information Sheet, for:
  - -This specific research project
  - -Other research that is closely related to this research project
  - -Any future research

Participant Name:_____

Participant Signature:_____

Date:_____

Name of Person conducting informed consent:_____

Signature of Person conducting informed consent: _____

Date:_____

Supplementary File 8. Interview guide

INTERVIEW GUIDE FOR PATIENTS

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

Introduction

Hi, my name is [name]. Thank you for taking part in this interview. Researchers and health professionals at The University of Sydney and Royal Prince Alfred Hospital want to find out whether a new treatment pathway using telephone and virtual appointments, and App-based exercise programs, helps people receive treatment sooner and get better sooner.

We would like to ask you questions about the treatment you received in the Back Clinic. If at any time you would like to stop the interview, please let us know and we will stop. You can change your mind about talking to me at any time before or during the interview and stop the interview at any time. You can choose not to answer a question.

Are you happy to continue? [If no, thank them for their time and end the interview; if yes, continue].

Thank you [name] for agreeing to take part. We will use your feedback and the feedback of others to write a summary of what people have told us. There will be absolutely no identification of any real names or identification of where you live or which hospitals or health professionals you have seen.

Are you happy for me to record the interview? Do you have any questions before we start?

CONTEXT: TO UNDERSTAND WHAT WORKED, WHAT DIDN'T WORK, AND WHY/ WHY NOT FOR THE TWO METHODS OF SERVICE DELIVERY.

I am interested in exploring your experiences with the care you received in greater detail. Please feel free to be honest about what it was like for you.

All participants

1. Please tell me about your experiences overall of [face-to-face care, virtual consultation, App, pain education program, telephone consultation].

Prompts:

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

2. How convenient was your treatment?

Prompts:

- How convenient was it for you to receive [face-to-face care, virtual consultation, App, pain education program, telephone consultation]?
- How do you feel about not having to attend the hospital for treatment (for low-, medium-, and high-risk participants)?

- How do you feel about having to attend the hospital for treatment (for participants with potential radiculopathy and the usual care group)?

Low-risk participants

3. Next, I'd like to get your views about the virtual/telephone call you received (or why you did not receive it).

Prompts:

- How did you find the call? What was helpful? What wasn't?
- Do you feel as though you got any benefit from the phone call?
- What kinds of things did you talk about with the rheumatologist?
- Would you recommend this method of delivering for others? What kinds of people would this approach suit? Who wouldn't it suit?
- What else would you liked to have received as part of your treatment during the trial?

Medium- and high risk participants

4. Next, I'd like to get your views about the virtual consultation(s) you received (or why you did not receive them).

Prompts:

- How did you find the consultation(s)? What was helpful? What wasn't?
- Do you feel as though you got any benefit from the virtual consultation(s)?
- Do you feel the benefit was similar to what you would have got with face-to-face appointment(s)?
- Would you recommend this method of delivering treatment for others? What kinds of people would this approach suit? Who wouldn't it suit?
- What else would you liked to have received as part of your treatment during the trial?
- Can you comment on the frequency of your appointments?

5. Next, I want to discuss the PhysiTrack App.

- Did you ever use the App?
- If no, why was that?
- If yes, how easy was it to use the App? Did it get easier over time?
- Did you need help to use it? If yes, explore.
- What do you think about the physio using the App to monitor your compliance with the rehabilitation exercises? Why do you say that?
- How long did you use the App?
- How long did you do the rehabilitation exercises? Why or why not?

6. Next, I want to discuss the self-directed pain education program.

- Did you access the program?
- If no, why was that?
- If yes, how easy was it to navigate? Did it get easier over time?
- Did you need help to access it? If yes, explore.
- How did you find the information in the program?
- Did you watch all the videos? Explore

Participants with potential radiculopathy (and people in the usual-care group)

7. Next, I'd like to get your views about the face-to-face appointments you received (or why you did not receive them).

Prompts:

- How did you find the appointment(s)? What was helpful? What wasn't?
- Can you tell me about the process of scheduling appointments? What was the availability of your rheumatologist and physiotherapist?
- Did you always have the same person?
- What is it about seeing a rheumatologist or physiotherapist in person that you like or don't like?
- How convenient was it for you to travel to and attend a face-to-face appointment(s) at the hospital?
- Can you comment on the frequency of your appointments? Is that what you expected? Why or why not?
- Do you feel as though you got any benefit from the appointment(s)?
- Would you recommend this method of delivering treatment for others? What kinds of people would this approach suit? Who wouldn't it suit?
- Do you feel you could have a got a similar benefit from a telephone or virtual consultation(s)?
- What else would you liked to have received as part of your treatment during the trial?

8. Is there anything else you would like to say that we have not talked about in this interview?

Thank you so much for your time.

INTERVIEW GUIDE FOR CLINICIANS

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

Hi, my name is [name and background]. Thank you for taking part in this interview. Researchers and health professionals at The University of Sydney and Royal Prince Alfred Hospital want to find out whether a new treatment pathway using telephone and virtual appointments, and App-based exercise programs, helps people receive treatment sooner and get better sooner. We also want to see if the new treatment pathway is acceptable to clinicians.

We would like to ask you questions about the treatment you provided in the Back Clinic as part of the trial. You can change your mind about talking to me at any time before or during the interview and stop the interview at any time.

Are you happy to continue? [If no, thank them for their time and end interview; if yes continue.]

Thank you [name] for agreeing to take part. We will use your feedback and the feedback of others to write a summary of what people have told us. There will be absolutely no identification of any real names or identification of your professional details.

Are you happy for me to record the interview? Do you have any questions before we start?

CONTEXT: TO UNDERSTAND WHAT WORKED, WHAT DIDN'T WORK, AND WHY/ WHY NOT FOR THE TWO METHODS OF SERVICE DELIVERY

1. Let's first talk about the way your service normally operates.

Prompt:

- How often would you typically see patients? Do you have a waiting list? How long is that waiting list usually?

2. Please tell me about your overall experiences coordinating the Rapid Stratified Telehealth trial.

Prompts:

- What pleased you about the trial?
- What surprised you?
- What were your concerns?
- What would you do differently?

3. How did the clinicians and patients involved in the trial respond to being involved?

4. Please tell us about the recruitment process for the trial.

Prompts:

- How did you manage the logistics of recruitment?
- Was there any difficulty in recruiting participants? If so, please describe.

CONTEXT: TO UNDERSTAND THE PERCEIVED BARRIERS/ FACILITATORS FOR EVALUATING IN A LARGE, MULTI-SITE TRIAL

5. On the basis of your experience in the trial, how easy do you think it will be to introduce delivering this model of care in other outpatient musculoskeletal settings?

6. Has the COVID-19 crisis changed your or your colleagues' attitudes towards delivering rehabilitation remotely?

7. Looking back on the approach used to deliver treatment using eHealth in the trial – are there any aspects of the intervention that could have been delivered differently?

Prompts:

- Could participants at high-risk of persistent pain be better managed with face-to-face appointments?
- Could participants with potential radiculopathy be managed equally effectively with virtual appointments?

8. What is the potential for eHealth-based stratified care to provide more patients with treatment sooner? How important is it to cut down waiting lists?

9. Thinking about what you have learnt from your experiences in the trial – what are the pros and cons of using eHealth-based stratified care, from patients' perspectives?

Prompts:

- What are the main advantages for patients compared to usual practice?

- How acceptable is eHealth-based stratified care likely to be to those accessing treatment for low back pain in a public hospital? Why or why not?
- What kinds of patients do you think are most suitable for being managed or monitored using eHealth?

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

Prompts:

- How compatible/ acceptable will eHealth-based stratified care be to hospital physios and rheumatologists?
- What are the main advantages for clinicians in delivering care via eHealth, compared to usual practice? What are the main disadvantages?

11. What has to be in place for eHealth-based stratified care to be viable to deliver in the hospital setting?

Prompts:

- What are some things that will make this hard/ easy?
- Could this model of care be rolled out in your hospital right now?
- What are some of the barriers?
- What are some of the facilitators?
- Where will the main resistance come from?

12. What kinds of benefits would you anticipate that introducing eHealth-based stratified care would have for patients; physiotherapists; rheumatologists; for hospitals? (Ask about health, service access, cost savings for the hospital).

13. If eHealth-based stratified care was found to be beneficial in a large trial, would you want to provide this intervention in the future? Why, or why not?

14. Is there anything else you would like to say that we have not talked about in this interview?

Thank you so much for your time.

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	ItemNo	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)	N/A
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)	N/A
	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)	N/A
	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	N/A
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	N/A
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	N/A
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	N/A

*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.

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The 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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The 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 program, and 'potential radiculopathy' fast tracked to usual in-person care. Primary outcomes include the feasibility of delivering Rapid Stratified Telehealth (i.e. acceptability assessed through interviews with clinicians and patients, intervention fidelity, appointment duration, App useability, and online pain education program usage) and evaluating Rapid Stratified Telehealth in a future trial (i.e. recruitment rates, consent rates, loss 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. 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.

Trial registration: ANZCTR Trial Registration: ACTRN12621001104842.

Key words: low back pain; stratified care; telehealth; sciatica; randomised controlled trial; pilot; feasibility.

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 pre-specified 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

1. 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 (e.g. 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 (e.g. 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=1,573)[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 (e.g. STarT Back) are recommended in some Australian LBP guidelines and models of care (e.g. NSW Agency for Clinical Innovation[7]; Australian Commission on Safety and Quality in Health Care[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 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 (e.g. 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 to 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=2,249)[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 to 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 3-12 months). There is currently no strategy for stratifying care based on the complexity of a patient's condition in this clinic (e.g. 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:

i) delivering stratified care integrated with eHealth ('Rapid Stratified Telehealth') for patients with low back pain referred to a hospital outpatient clinic; and

ii) 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 adverse events 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 to usual care, be cost-effective and safe.

2. Methods and analysis

2.1. Study design

We will conduct a single-blind, single-site, two-arm, parallel feasibility and pilot RCT with nested qualitative interviews. The trial has been prospectively registered at the Australian and New Zealand Clinical trial registry (ACTRN12621001104842) and will be reported in accordance with the CONSORT 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 COREQ (Consolidated Criteria for Reporting Qualitative Research).[18] This protocol has been reported according to SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) (Supplementary File 1).[19]

2.2. 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 physiotherapy-related interventions to physiotherapy) at Royal Prince Alfred Hospital, Sydney, Australia, over a 6-month period (expected September 2021 to February 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]

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 (i.e. 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 (e.g. cancer, fracture, infection, inflammatory arthritis, cauda equina syndrome)
- referral strongly suggestive of concerning neurological features (e.g., progressive radiculopathy)
- are pregnant

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 (Supplementary 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).

2.3. 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 (Supplementary 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 (e.g. 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).

2.4. 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.

2.4.1. 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; Supplementary 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.

2.4.2. 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 re-join the waiting list in the position they would have likely been had they not participated.

2.5. 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 subgroup ('treatment fidelity' as assessed by treatment recording forms developed for this trial; Supplementary 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 to 100 score. Score above 70 indicates above average usability (as assessed by System Useability Scale, Supplementary File 5)[23, 24]
- Percentage of participants in Rapid Stratified Telehealth group (high-risk) who complete all modules of the online pain education program (Supplementary File 4)

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

- Number of participants recruited per week
- 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
- Pre-notifications and reminders via SMS or email

Secondary outcomes include treatment waiting time (i.e. 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 adverse events. 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 post-randomisation (Supplementary File 6). Adverse events data will be collected at 2 weeks, 6 weeks and 6 months post-randomisation (Supplementary 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:

1. Physical function using the Roland Morris Disability Questionnaire (RMDQ). 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 RMDQ has demonstrated good validity, reliability and sensitivity for detecting changes in physical function over time in people with LBP.[26]

2. Pain measured using a 0–10 Numerical Pain Rating Scale (NPRS). 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 NPRS is a valid and reliable tool for measuring acute and chronic pain.[27]

3. Quality of life using the PROMIS-29 Profile v2.0. 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]

4. 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 (e.g. GP, physiotherapy, imaging), or community health or other services

(e.g. 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 adverse events (AEs) and serious adverse events (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 (e.g. 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 (Supplementary File 7). The Principal Investigator will be responsible for reporting SAEs to the Ethics committee.

2.6. Semi-structured interviews and focus groups

2.6.1. Participants and recruitment

To explore the acceptability of Rapid Stratified Telehealth, we will conduct semi-structured 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 (Supplementary 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.

2.6.2. Data collection

Interviews and focus groups will be conducted via telephone or videoconference (e.g. 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 minutes and be audio-recorded and transcribed verbatim for analysis. Focus groups will last about 1 hour, include a maximum of 8 participants and be audio-recorded 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 multi-site 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 Supplementary 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.

2.7. Statistical analysis

2.7.1. 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 program) and feasibility outcomes for evaluating Rapid Stratified Telehealth in a future multi-centre randomised controlled trial (recruitment rates, consent rates, percentage loss to follow up, and percentage missing data). These data will be summarised using descriptive statistics (means and standard deviations, median and interquartile ranges 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, multi-site trial. Meeting the following criteria would justify proceeding to a full trial:

i) Acceptable to clinicians and patients (according to qualitative interviews)

ii) Percentage of participants in the intervention who are only provided care according to their treatment subgroup >75%

iii) 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

iv) Percentage of participants in Rapid Stratified Telehealth group (high-risk) who complete all modules of the self-directed online pain education program >75%

v) Recruitment rate of three or more participants per week over 6 months

vi) Consent rate of 50% or more over 6 months (similar to a UK trial[15])

vii) Loss to follow up <25% at 6 months

viii) Missing data in questionnaires <15%

2.7.2. Secondary outcomes

Waiting times, number of consultations patients receive, intervention and healthcare costs, clinical outcomes, healthcare use and adverse events will be compared between Rapid Stratified Telehealth and usual care using descriptive statistics (means and standard deviations, median and interquartile ranges and counts and percentages, as appropriate) in STATA version 16.0. No statistical inference testing will be performed as this is a feasibility study.[29] Between-group mean differences and post-intervention standard deviations 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.

2.7.3. 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 sub-themes will be discussed and resolved. The mapping of themes and sub-themes will be iterative as new data emerges. Interviews will stop once no new themes are identified (data saturation).

2.8. 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 (e.g. recruitment), study materials (e.g. 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 (e.g. 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 program and online pain education program. 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 program or access the online pain education program, 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.

3. Ethics and dissemination

3.1. 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.

3.2. Data management

All information collected for this trial will be de-identified 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 de-identified. All source documents and trial documentation will be kept in a secure location by the investigators for 15 years.

3.3. 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.

3.4. 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.

Authors' contributions

All authors critically revised the manuscript for important intellectual content and approved the final manuscript. Please find below a detailed description of the role of each author:

- Joshua R Zadro: conception and design, drafting and revision of the manuscript, and final approval of the version to be published
- Christopher Needs: conception and design, drafting and revision of the manuscript, and final approval of the version to be published
- Nadine Foster: conception and design, drafting and revision of the manuscript, and final approval of the version to be published
- David Martens: conception and design, drafting and revision of the manuscript, and final approval of the version to be published
- Danielle M Coombs: conception and design, drafting and revision of the manuscript, and final approval of the version to be published
- Gustavo C Machado: conception and design, drafting and revision of the manuscript, and final approval of the version to be published
- Cameron Adams: conception and design, drafting and revision of the manuscript, and final approval of the version to be published
- Christopher S Han: conception and design, drafting and revision of the manuscript, and final approval of the version to be published
- Christopher G Maher: conception and design, drafting and revision of the manuscript, and final approval of the version to be published

The Corresponding Author (JZ) attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted. We would also like to acknowledge the contribution of four consumer advisors whose valuable input helped us refine the protocol for this trial.

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Data availability statement: Individual participant data (IPD) for this trial will be available following publication of this study. This includes baseline and post-intervention data. Data will be available to anyone upon reasonable request and with ethics approval (if applicable).

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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; Supplementary 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 low back pain 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 (e.g. advice to exercise, modify activities, lose weight, or take simple pain medications if needed), and may include an exercise program delivered via an App (PhysiTrack). PhysiTrack has over 5,000 physiotherapy exercises and over 1,000 specific to low back pain. The physiotherapist will tailor the exercise program 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 (e.g. advice to exercise, modify activities, lose weight, or take simple pain medications if needed), and may provide interventions to address psychological barriers to recovery (e.g. pacing, graded exposure), and an App-based exercise program (PhysiTrack; as described for participants at medium risk of persistent pain). The physiotherapist will direct participants to complete an online self-directed pain education program developed by the Agency for Clinical Innovation. The program (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 minutes); 2) Getting help from your healthcare team (5:56 minutes); 3) Pain and physical activity (12:43 minutes); 4) Pain: Lifestyle and nutrition (8:41 minutes); 5) Pain

	and role of medications (9:57 minutes); 6) Pain and thoughts (10:27 minutes); 6) Pain and sleep (11:08 minutes). Participants will be encouraged to go through the program 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 Supplementary 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 (e.g. 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 (e.g. 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 (e.g. 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 (e.g. 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	
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 (e.g. 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 (e.g. 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.

Figure legends

Figure 1. Trial flow diagram

Supplementary files

Supplementary File 1. Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist.

Supplementary File 2. Information pack.

Supplementary File 3. Telephone assessment for Rapid Stratified Telehealth group.

Supplementary File 4. Treatment recording form.

Supplementary File 5. System Useability Scale.

Supplementary File 6. Follow up assessment at 6 weeks and 6 months.

Supplementary File 7. Assessment of adverse events.

Supplementary File 8. Participant Information Statement and Consent Forms for qualitative interviews for patients and clinicians.

Supplementary File 9. Interview guide.

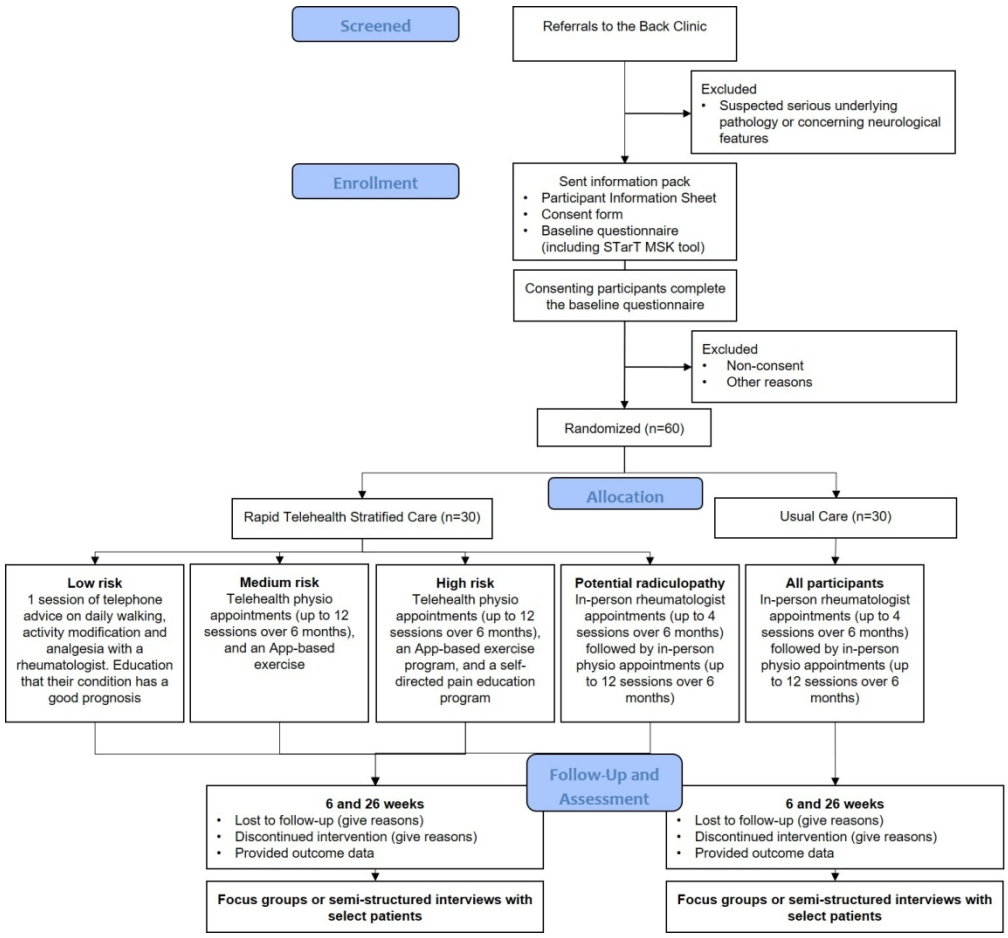

Figure 1. Trial flow diagram

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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	ItemNo	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)	N/A
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)	N/A
	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)	N/A
	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	N/A
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	N/A
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	N/A
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	N/A

*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.

Supplementary File 2. Information pack

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Rapid Stratified Telehealth: a feasibility trial comparing two care pathways for people referred to the Back Clinic

PARTICIPANT INFORMATION STATEMENT

1. What is this study about?

You are invited to take part in a research study that will explore a new care pathway for people with back pain and/or leg pain radiating from the back. This Participant Information Statement tells you about the study. Knowing what is involved will help you decide if you want to take part. Please read this sheet carefully and ask questions about anything that you don't understand or want to know more about.

Participation in this research study is voluntary.

By giving your consent to take part in this study you are telling us that you:

- ✓ Understand what you have read
- ✓ Agree to take part in the research study as outlined below
- ✓ Agree to the use of your personal information as described

This Participant Information Statement is yours to keep.

Currently, when you are referred to see a Rheumatologist or Physiotherapist at Royal Prince Alfred Hospital's 'Back Pain Clinic', you are placed on a waiting list. Unfortunately, waiting times for treatment are currently 3 months or longer. This is referred to 'usual care', which is the care you would normally receive when referred to the "Back Pain Clinic'. Our project involves testing a new pathway using telephone and virtual appointments, and an App-based exercise program. This new pathway is based on 'stratified care'. This involves matching the type and amount of care you

receive based on your risk of persisting pain and presence of other symptoms (like leg pain). We want to see whether the new pathway helps people receive treatment sooner and recover sooner.

To find out which pathway is best, we will offer half of people the current pathway and half the new pathway. We will monitor the two groups for 6 months and compare what happens between the groups. To ensure the groups are as similar to each other as possible, the group that you will be placed into is by chance. **There is a 50% chance you will be managed according to the new pathway, and a 50% chance you will be managed according to the current pathway.** To make the results of our study fair, we will not tell you which pathway you have been allocated to.

If you decide you would not like to participate in the research study, you will be managed according to the current pathway. However, your decision whether to participate will not affect your current or future relationship with the researchers or anyone else at the University of Sydney or Royal Prince Alfred Hospital. It also won't affect your position on the waiting list or the quality of care you receive.

2. Who is running the study?

This study is funded by the Agency for Clinical Innovation (ACI) New South Wales and the National Health Medical Research Council. Neither funder will benefit commercially from this study. The manufacturers of PhysiTrack, the mobile App you may be provided during the study, do not have any commercial, financial or business interests in this study.

The people conducting this study are:

- Dr Joshua Zadro, NHMRC Postdoctoral Researcher, Institute for Musculoskeletal Health University of Sydney and Sydney Local Health District
- Dr Chris Needs, Staff Specialist Rheumatologist, Royal Prince Alfred Hospital, Sydney Local District Health
- Prof Christopher Maher, Director, Institute for Musculoskeletal Health, University of Sydney and Sydney Local Health District
- Dr David Martens, Rheumatologist Advanced Trainee, Royal Prince Alfred Hospital, Sydney Local District Health
- Ms Danielle Coombs, Physiotherapist, Institute for Musculoskeletal Health University of Sydney and Sydney Local Health District
- Dr Gustavo Machado, NHMRC Postdoctoral Researcher, Institute for Musculoskeletal Health University of Sydney and Sydney Local Health District
- Mrs Charlotte McLennan, Network Manager, Institute for Musculoskeletal Health University of Sydney and Sydney Local Health District
- Dr Cameron Adams, Rheumatologist Advanced Trainee, Royal Prince Alfred Hospital, Sydney Local District Health
- Prof Nadine Foster, Director, Surgical, Treatment and Rehabilitation Service (STARS) Research and Education Alliance, The University of Queensland and Metro North Hospital and Health Service
- Mr Christopher Han, Physiotherapist Research Assistant, Institute for Musculoskeletal Health, University of Sydney and Sydney Local Health District

3. Who can take part in the study?

A person will be allowed to participate in this study if he or she:

- is referred to the 'Back Pain Clinic' at Royal Prince Alfred Hospital
- has low back pain and/or leg pain radiating from the back
- is 18 years or over and able to provide informed consent

4. What does the study involve?

If you agree to participate in our study, we will send you a survey asking questions about you and your low back pain. We kindly ask you to complete these questionnaires and return them back to us via mail (return-paid envelope provided), email, or SMS. After this, you will be randomly allocated (i.e. by chance) to be managed using the new pathway or current pathway. We will send you another questionnaire at 6 weeks and 6 months after joining the study to see how your low back pain has changed. This questionnaire will contain similar questions to the first one you will complete. If you desire any more information at any point of the study, relevant contact details will be provided.

After 6 months, we may contact you to participate in a group interview (with up to 8 other participants) or one-on-one interview if you prefer. This interview may be conducted via telephone or videoconference (e.g., Zoom) or in person at the Institute for Musculoskeletal Health, Level 10 King George V Building, Royal Prince Alfred Hospital. The interview will explore your opinions on the care you received. You will be sent more information about this interview before you agree to participate.

5. How much of my time will the study take?

If you decide to participate, your treatment time is unlikely to be different than if you did not participate and joined the current waiting list. However, by participating in the study, we will ask you to complete one survey when you enter the study, and another at 6 weeks and 6 months. Each survey will take between 10-15 minutes. You may also be asked to participate in a 1-hour group interview or 30 minutes one-on-one interview, but participation is voluntary.

6. Do I have to be in the study? Can I withdraw from the study once I've started?

Participation in this study is entirely voluntary. You are not obliged to participate. If you do participate, you can withdraw at any time without having to give any reason and without any penalty. Whatever your decision, it will not affect your relationship with the Hospital, Local Health District and The University of Sydney, or the standard of care you receive now or in the future.

7. Are there any risks or costs associated with being in the study?

Aside from giving up your time to complete three 5-10 minutes surveys (plus a possible 30-60 minutes for an interview if you're interested), we do not expect that there will be any risks or costs associated with taking part in this study.

8. Are there any benefits associated with being in the study?

If you are allocated to receive the new care pathway, you may benefit from having faster access to Physiotherapy and Rheumatology care. You may also improve faster because you are seen sooner. If you are allocated to receive the current care pathway, you receive the same treatment as if you had not taken part in the study.

By participating you will be contributing to important research that helps us understand whether our new pathway is potentially beneficial for people with low back pain and worth investigating

in a large future study. The results will help us develop better ways to improve the quality of care provided to patients.

9. What will happen to information about me that is collected during the study?

All data collected will be entered electronically and stored on a research database named REDCap (Research Electronic Data Capture). This is a secure, web-based, non-commercial, data management tool designed for research purposes, hosted, and backed up on the Sydney Local Health District servers on a daily basis. No personnel other than the researchers will have access to the research documents. The data will be analysed by the researchers at the Royal Prince Alfred Hospital. All data for use in journal publications and presentations will be de-identified. The files will be retained for 15 years from the day the study is completed. Once this retention expires, the files will be disposed of using the Royal Prince Alfred Hospital confidential waste disposal service. The data may be used for future research purposes; however, Human Research Ethics Committee (HREC) approval will be sought prior to any future use of the data. It will not be shared with local or international collaborators.

10. Will I be told the results of the study?

You have a right to receive feedback about the overall results of this study. You can tell us that you wish to receive feedback by ticking a box and leaving your email when you complete the consent form. This feedback will be in the form of a one-page lay summary of the results. You will receive this feedback after the study is finished.

11. What do I do next?

When you have read this information, please store it in a safe place. If you understand what you have read and would like to participant, please sign and return the consent form.

If you would like to know more about the study at any stage and ask questions, please feel free to contact Mr Christopher Han (research assistant) at Christopher.han@sydney.edu.au or (02) 8627 7423.

12. What if I have a complaint or any concerns about the study?

This study has been approved by the Ethics Review Committee (RPAH Zone) of the Sydney Local Health District.

If you have any complaints or concerns about any aspect of this study, you should call our research team who will do their best to address any issues. If your concerns are not able to be addressed, you can contact the Executive Officer of the Ethics Review Committee on 02 9515 6766 and quote protocol number X21-0221.

This information sheet is for you to keep.

THE UNIVERSITY OF SYDNEY

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Rapid Stratified Telehealth: a feasibility trial comparing two care pathways for people referred to the Back Clinic

PARTICIPANT CONSENT FORM

I,_____ *[full name]*

Of_____ *[address]*

have read and understood the Participant Information Sheet on the abovenamed research study and have discussed the study with _____ [investigator responsible for conducting informed consent].

- I have been made aware of the procedures involved in the study, including any known or expected inconvenience, risk, discomfort or potential side effect and of their implications as far as they are currently known by the researchers.

- I understand that my de-identified data may be used for future research and I agree to this.

- I would like to receive a copy of the study results when they become available. My email address is: _____
- I understand that, during the course of this study, my medical records may be accessed by Sydney Local Health District by regulatory authorities or by the Ethics Committee approving the research in order to verify results and determine that the study is being carried out correctly.
- I understand that the SLHD software license for REDCap (Research Electronic Data Capture) will be used to manage the collection and storage of my research data.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I freely choose to participate in this study and understand that I can withdraw at any time.
- I consent to the future use of any data I provide for research purposes. I understand that before the researchers can use any data I provide; they must seek additional ethics approval. YES/ NO
- I consent for other research collaborators to use any data I provide for future research purposes. I understand that before they can use my data, they must seek additional ethics approval. YES/NO
- I also understand that the research study is strictly confidential.
- I hereby agree to participate in this research study.
- I consent to the storage and use of my information collected from me for use, as described in the relevant section of the Participant Information Sheet, for:
  - -This specific research project
  - -Other research that is closely related to this research project
  - -Any future research

Participant Name:_____

Participant Signature:_____

Date:_____

Name of Person conducting informed consent:_____

Signature of Person conducting informed consent: _____

Date:_____

___

Name of witness to consent form:_____

Signature of witness to informed consent: _____

BASELINE QUESTIONNAIRE

Section 1: Information about you

We want to learn about you, your background, and features of your low back pain.

Gender: **(please tick one only)**	o Male o Female
Date of birth:	____ / _____ / _____ dd / mm / yyyy
Duration of low back pain or leg pain radiating from the back (whichever is the primary issue): **(please tick one only)**	o Less than 12 weeks o Longer than 12 weeks
Do you have pain that starts from your back and goes below your knee?	o Yes o No
Language spoken at home other than English	_____
What is your indigenous status? (please tick one only)	o Aboriginal o Torres Strait Islander o Both Aboriginal and Torres Strait Islander o Neither Aboriginal nor Torres Strait Islander
Employment Status: **(please tick one only)**	o Not currently employed o Currently employed o Student o Unpaid carer
Education: What option best describes your highest level of education? (please tick one only)	o Primary school or less o High school (not completed) o High school (completed) o TAFE/Trade o University- undergraduate degree/s (completed) o University- postgraduate degree/s e.g. Masters, PhD (completed)

	o Other (please specify) _____
Have you previously taken sick leave due to your low back pain or leg pain radiating from the back? (please tick one only)	o Yes o No

Section 2: Information about your back pain and/or leg pain radiating from the back

The Keele STarT MSK Tool © *Self-report version*

For questions 1-9, think about just the last two weeks:

Pain intensity

1) On average, how intense was your low back pain or leg pain radiating from the back (whichever was worse) [where 0 is "no pain" and 10 is "pain as bad as it could be"]?

0	1	2	3	4	5	6	7	8	9	10
□	□	□	□	□	□	□	□	□	□	□

Please cross one box for each question below

	No	Yes
2) Do you often feel unsure about how to manage your pain condition?	□	□
3) Over the last two weeks, have you been bothered a lot by your pain?	□	□
4) Have you only been able to walk short distances because of your pain?	□	□
5) Have you had troublesome joint or muscle pain in more than one part of your body?	□	□
6) Do you think your condition will last a long time?	□	□
7) Do you have other important health problems?	□	□

8) Has pain made you feel down or depressed in the last two weeks?	□	□
9) Do you feel it is unsafe for a person with a condition like yours to be physically active?	□	□
10) Have you had your current pain problem for 6 months or more?	□	□

PROMIS–29 Profile v2.0

Please respond to each question or statement by marking one box per row.

	Physical Function	**Without any difficulty**	**With a little difficulty**	**With some difficulty**	**With much difficulty**	**Unable to do**
1	Are you able to do chores such as vacuuming or yard work?	☐	☐	☐	☐	☐
2	Are you able to go up and down stairs at a normal pace?	☐	☐	☐	☐	☐
3	Are you able to go for a walk of at least 15 minutes?	☐	☐	☐	☐	☐
4	Are you able to run errands and shop?	☐	☐	☐	☐	☐
	Anxiety **In the past 7 days…**	**Never**	**Rarely**	**Sometimes**	**Often**	**Always**
5	I felt fearful	☐	☐	☐	☐	☐
6	I found it hard to focus on anything other than my anxiety	☐	☐	☐	☐	☐
7	My worries overwhelmed me	☐	☐	☐	☐	☐
8	I felt uneasy	☐	☐	☐	☐	☐
	Depression **In the past 7 days...**	**Never**	**Rarely**	**Sometimes**	**Often**	**Always**
9	I felt worthless	☐	☐	☐	☐	☐
10	I felt helpless	☐	☐	☐	☐	☐
11	I felt depressed	☐	☐	☐	☐	☐
12	I felt hopeless	☐	☐	☐	☐	☐
	Fatigue **During the past 7 days…**	**Not at all**	**A little bit**	**Somewhat**	**Quite a bit**	**Very much**
13	I feel fatigued	☐	☐	☐	☐	☐
14	I have trouble starting things because I am tired	☐	☐	☐	☐	☐

Fatigue

	In the past 7 days…	Not at all	A little bit	Somewhat	Quite a bit	Very much
15	How run-down did you feel on average? ...	☐	☐	☐	☐	☐
16	How fatigued were you on average?	☐	☐	☐	☐	☐

Sleep Disturbance

	In the past 7 days…	Very poor	Poor	Fair	Good	Very good
17	My sleep quality was.....	☐	☐	☐	☐	☐

	In the past 7 days…	Not at all	A little bit	Somewhat	Quite a bit	Very much
18	My sleep was refreshing.....	☐	☐	☐	☐	☐
19	I had a problem with my sleep	☐	☐	☐	☐	☐
20	I had difficulty falling asleep	☐	☐	☐	☐	☐

Ability to Participate in Social Roles and Activities

		Never	Rarely	Sometimes	Usually	Always
21	I have trouble doing all of my regular leisure activities with others.....	☐	☐	☐	☐	☐
22	I have trouble doing all of the family activities that I want to do	☐	☐	☐	☐	☐
23	I have trouble doing all of my usual work (include work at home)	☐	☐	☐	☐	☐
24	I have trouble doing all of the activities with friends that I want to do	☐	☐	☐	☐	☐

Pain Interference

	In the past 7 days…	Not at all	A little bit	Somewhat	Quite a bit	Very much
25	How much did pain interfere with your day to day activities?.....	☐	☐	☐	☐	☐
26	How much did pain interfere with work around the home?	☐	☐	☐	☐	☐
27	How much did pain interfere with your ability to participate in social activities? .	☐	☐	☐	☐	☐
28	How much did pain interfere with your household chores?	☐	☐	☐	☐	☐

Pain Intensity

In the past 7 days…

29	How would you rate your pain on average?.....	☐ 0 No pain	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10 Worst imaginable pain

Roland-Morris Low Back Pain and Disability Questionnaire (RMQ)

Instructions

Please read instructions: When your back hurts, you may find it difficult to do some of the things you normally do. Mark only the sentences that describe you today.

- ☐ I stay at home most of the time because of my back.
- ☐ I change position frequently to try to get my back comfortable.
- ☐ I walk more slowly than usual because of my back.
- ☐ Because of my back, I am not doing any jobs that I usually do around the house.
- ☐ Because of my back, I use a handrail to get upstairs.
- ☐ Because of my back, I lie down to rest more often.
- ☐ Because of my back, I have to hold on to something to get out of an easy chair.
- ☐ Because of my back, I try to get other people to do things for me.
- ☐ I get dressed more slowly than usual because of my back.
- ☐ I only stand up for short periods of time because of my back.
- ☐ Because of my back, I try not to bend or kneel down.
- ☐ I find it difficult to get out of a chair because of my back.
- ☐ My back is painful almost all of the time.
- ☐ I find it difficult to turn over in bed because of my back.
- ☐ My appetite is not very good because of my back.
- ☐ I have trouble putting on my socks (or stockings) because of the pain in my back.
- ☐ I can only walk short distances because of my back pain.
- ☐ I sleep less well because of my back.
- ☐ Because of my back pain, I get dressed with the help of someone else.
- ☐ I sit down for most of the day because of my back.
- ☐ I avoid heavy jobs around the house because of my back.
- ☐ Because of back pain, I am more irritable and bad tempered with people than usual.
- ☐ Because of my back, I go upstairs more slowly than usual.
- ☐ I stay in bed most of the time because of my back.

Use of healthcare for your back pain and/or leg pain radiating from the back

Have you used any healthcare services (e.g. GP, physiotherapy, x-rays, hospital admission), or community health or other services (e.g. meals on wheels) for your of low back pain and/or leg pain radiating from the back since this episode of pain started?

- ☐ Yes, please specify the service_____
- ☐ No

Are any services ongoing?

- ☐ Yes, please specify the service_____
- ☐ No

Are you currently taking any prescription or over the counter medication for your low back pain and/or leg pain radiating from the back?

- ☐ Yes, please name the medication (please use the full brand name) and provide details on the dose (e.g. how much do you take per day)

  _____
- ☐ No

Supplementary File 3. Telephone assessment for the Rapid Stratified Telehealth group

Subjective history

Current History				
Past Medical History				
Medications				
Social History				
Previous Imaging				
Red Flag screening (tick as many that are relevant)				
□ History of significant trauma	□ History of Cancer	□ Recent bacterial infection	□ Fever	□ IV drug use
□ Immune suppression	□ Recent unexplained weight loss	□ Severe pain when supine/at night	□ Saddle anaesthesia	□ Bladder or bowel dysfunction
□ Neurological deficit in limb	□ Osteoporosis	□ Long term corticosteroid use	□ Early morning back pain and stiffness	

Potential radiculopathy questionnaire

Symptoms	Score
Duration of pain	
Greater than 6 months	**1**
Less than 6 months	**0**
Pain into one leg	
Above the knee	**0**
Below the knee	**1**
Weakness in the legs	**1**
Paraesthesia in the legs	
Above the knee	**0**
Below the knee	**1**
Cough, sneeze exacerbations	**1**
Temperatures, fevers, and weight loss	Exclude from trial and refer for urgent medical care
Symptoms of cauda equina syndrome	Exclude from trial and refer for urgent medical care

Scoring criteria

- **3 or more** = potential radiculopathy (fast tracked to face-to-face care)

Supplementary File 4. Treatment recording form

Participant ID

_____

Date of appointment

_____

Appointment number

_____

Treatment sub-group at baseline

_____

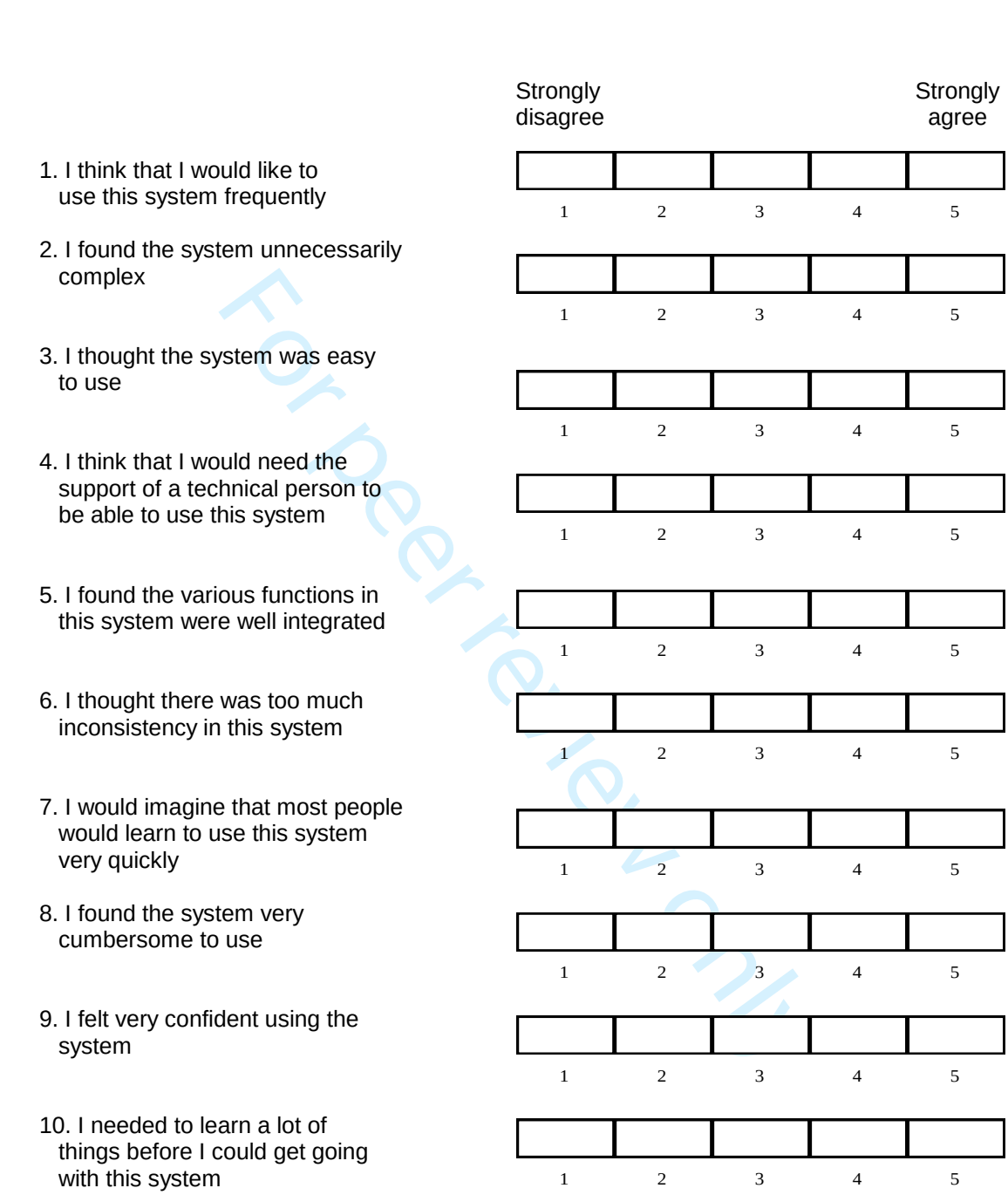
Please indicate what care the participant received during this appointment

Treatment sub-group	**Treatment protocol summary**	**Tick box if participant received this care**
Patients at low risk of persistent pain (Keele STarT MSK score 0-4) AND no potential radiculopathy	Telephone appointment with Advanced Rheumatology Trainee	
	• Advice on daily walking	☐
	• Advice on activity modification	☐
	• Advice to take simple pain medications	☐
	• Education that their condition has a good prognosis	☐
	• Other advice (Please specify) _____	☐
Patients at medium risk of persistent pain (Keele STarT MSK score 5-8) AND no potential radiculopathy	Virtual physiotherapy appointment	
	• Advice and education to support self-management	☐
	• Advice to exercise	☐
	• Advice to modify activities	☐
	• Advice to lose weight	☐
	• Advice to take simple pain medications	☐
	• App-based exercise program	☐
	• **Tick if participant needed to print out the exercise program**	☐

	• Other intervention (Please specify) _____	☐
Patients at high risk of persistent pain (Keele STarT MSK score 9-12) AND no potential radiculopathy	Virtual physiotherapy appointment	
	• Advice and education to support self-management	☐
	• Advice to exercise	☐
	• Advice to modify activities	☐
	• Advice to lose weight	☐
	• Advice to take simple pain medications	☐
	• Interventions to address psychological barriers to recovery (e.g. pacing, graded exposure)	☐
	• App-based exercise program	☐
	• **Tick if participant needed to print out the exercise program**	☐
	• Instructed to complete online pain education modules	☐
	• **Tick if participant has completed all online pain education modules**	☐
	• Referral to psychologist	☐
	• Other intervention (Please specify) _____	☐
Patients with potential radiculopathy	In person rheumatologist appointment	
	• Take patients' medical history (including past history)	☐
	• Conduct a physical examination (including a neurological examination)	☐
	• Review any previously undertaken investigations (e.g. imaging, pathology tests)	☐

	• Formulate a management plan	☐
	• Monitor progress	☐
	In person physiotherapist appointment	
	• Advice and education to support self-management	☐
	• Advice to exercise	☐
	• Advice to modify activities	☐
	• Advice to lose weight	☐
	• Advice to take simple pain medications	☐
	• Exercise program	☐
	• Graded activity	☐
	• Spinal manipulative therapy	☐
	• Interventions to address psychological barriers to recovery (e.g. pacing, graded exposure)	☐
	• Referral to psychologist	☐
	• Other intervention (Please specify) _____	☐

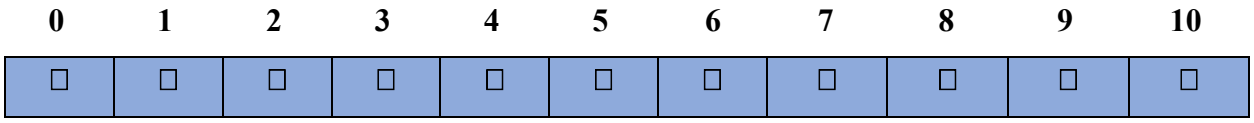
Supplementary File 5. System Usability Scale



Supplementary File 6. Follow up assessment at 6 weeks and 6 months

Pain intensity

1) On average in the last two weeks, how intense was your low back pain or leg pain radiating from your back (choose whichever was worse) [where 0 is “no pain” and 10 is “pain as bad as it could be”]?



PROMIS–29 Profile v2.0

Please respond to each question or statement by marking one box per row.

	Physical Function	**Without any difficulty**	**With a little difficulty**	**With some difficulty**	**With much difficulty**	**Unable to do**
1	Are you able to do chores such as vacuuming or yard work?	☐	☐	☐	☐	☐
2	Are you able to go up and down stairs at a normal pace?	☐	☐	☐	☐	☐
3	Are you able to go for a walk of at least 15 minutes?	☐	☐	☐	☐	☐
4	Are you able to run errands and shop?	☐	☐	☐	☐	☐
	Anxiety **In the past 7 days…**	**Never**	**Rarely**	**Sometimes**	**Often**	**Always**
5	I felt fearful	☐	☐	☐	☐	☐
6	I found it hard to focus on anything other than my anxiety	☐	☐	☐	☐	☐
7	My worries overwhelmed me	☐	☐	☐	☐	☐
8	I felt uneasy	☐	☐	☐	☐	☐
	Depression **In the past 7 days...**	**Never**	**Rarely**	**Sometimes**	**Often**	**Always**
9	I felt worthless	☐	☐	☐	☐	☐
10	I felt helpless	☐	☐	☐	☐	☐
11	I felt depressed	☐	☐	☐	☐	☐
12	I felt hopeless	☐	☐	☐	☐	☐
	Fatigue **During the past 7 days…**	**Not at all**	**A little bit**	**Somewhat**	**Quite a bit**	**Very much**
13	I feel fatigued	☐	☐	☐	☐	☐
14	I have trouble starting things because I am tired	☐	☐	☐	☐	☐

Fatigue

	In the past 7 days…	Not at all	A little bit	Somewhat	Quite a bit	Very much
15	How run-down did you feel on average? ...	☐	☐	☐	☐	☐
16	How fatigued were you on average?	☐	☐	☐	☐	☐

Sleep Disturbance

	In the past 7 days…	Very poor	Poor	Fair	Good	Very good
17	My sleep quality was.....	☐	☐	☐	☐	☐

	In the past 7 days…	Not at all	A little bit	Somewhat	Quite a bit	Very much
18	My sleep was refreshing.....	☐	☐	☐	☐	☐
19	I had a problem with my sleep	☐	☐	☐	☐	☐
20	I had difficulty falling asleep	☐	☐	☐	☐	☐

Ability to Participate in Social Roles and Activities

		Never	Rarely	Sometimes	Usually	Always
21	I have trouble doing all of my regular leisure activities with others.....	☐	☐	☐	☐	☐
22	I have trouble doing all of the family activities that I want to do	☐	☐	☐	☐	☐
23	I have trouble doing all of my usual work (include work at home)	☐	☐	☐	☐	☐
24	I have trouble doing all of the activities with friends that I want to do	☐	☐	☐	☐	☐

Pain Interference

	In the past 7 days…	Not at all	A little bit	Somewhat	Quite a bit	Very much
25	How much did pain interfere with your day to day activities?.....	☐	☐	☐	☐	☐
26	How much did pain interfere with work around the home?	☐	☐	☐	☐	☐
27	How much did pain interfere with your ability to participate in social activities? .	☐	☐	☐	☐	☐
28	How much did pain interfere with your household chores?	☐	☐	☐	☐	☐

Pain Intensity

In the past 7 days…

29	How would you rate your pain on average?.....	☐ 0 No pain	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10 Worst imaginable pain

Roland-Morris Low Back Pain and Disability Questionnaire (RMQ)

Instructions

Please read instructions: When your back hurts, you may find it difficult to do some of the things you normally do. Mark only the sentences that describe you today.

- ☐ I stay at home most of the time because of my back.
- ☐ I change position frequently to try to get my back comfortable.
- ☐ I walk more slowly than usual because of my back.
- ☐ Because of my back, I am not doing any jobs that I usually do around the house.
- ☐ Because of my back, I use a handrail to get upstairs.
- ☐ Because of my back, I lie down to rest more often.
- ☐ Because of my back, I have to hold on to something to get out of an easy chair.
- ☐ Because of my back, I try to get other people to do things for me.
- ☐ I get dressed more slowly than usual because of my back.
- ☐ I only stand up for short periods of time because of my back.
- ☐ Because of my back, I try not to bend or kneel down.
- ☐ I find it difficult to get out of a chair because of my back.
- ☐ My back is painful almost all of the time.
- ☐ I find it difficult to turn over in bed because of my back.
- ☐ My appetite is not very good because of my back.
- ☐ I have trouble putting on my socks (or stockings) because of the pain in my back.
- ☐ I can only walk short distances because of my back pain.
- ☐ I sleep less well because of my back.
- ☐ Because of my back pain, I get dressed with the help of someone else.
- ☐ I sit down for most of the day because of my back.
- ☐ I avoid heavy jobs around the house because of my back.
- ☐ Because of back pain, I am more irritable and bad tempered with people than usual.
- ☐ Because of my back, I go upstairs more slowly than usual.
- ☐ I stay in bed most of the time because of my back.

Satisfaction with care

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?

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	1	2	3	4	5	6	7	8	9	10
Worst care possible										Best care possible

Use of healthcare for your back pain and/or leg pain radiating from the back

Have you used any healthcare services (e.g. GP, physiotherapy, x-rays, hospital admission), or community health or other services (e.g. meals on wheels) for your low back pain and/or leg pain radiating from the back since the start of this study?

☐ Yes, please specify the service_____
☐ No

Are any services ongoing?

☐ Yes, please specify the service_____
☐ No

Are you currently taking any prescription or over the counter medication for your low back pain and/or leg pain radiating from the back?

☐ Yes, please name the medication (please use the full brand name) and provide details on the dose (e.g. how much do you take per day)

_____

☐ No

Supplementary file 7. Assessment of adverse events

Any adverse events (self-reported by participants at 2 weeks, 6 weeks and 6 months)

Have you had a new medical condition or an exacerbation of an existing condition since beginning the study, e.g. dizziness, increased pain? If yes, can you please describe this?

Adverse event patient data (collected by clinicians)

Type of event	
Start and stop dates	
Action taken	
Causality of the event in relation to treatment provided in this trial (score as: extremely unlikely, unlikely, unsure, likely, or extremely likely)	

Serious adverse events (collected by clinicians)

SERIOUS ADVERSE EVENT REPORT

Study Site:					
Date of report:		**□ Initial report □ Follow up report F/up No.:_____**			
A. PATIENT DETAILS					
Subject number:		**Patient initials:**	|__|__|__|	**Date of birth:**	|__|__|-|__|__|-|__|__|__|__|
Sex: □ Male □ Female		**Height:**	|__|__|__| **cm**	**Weight:**	|__|__|__| **kg**
B. SERIOUS ADVERSE EVENT DETAILS					
Serious Adverse Event: ***(Diagnosis where available)***				**Start date:**	|__|__|-|__|__|-|__|__|__|__|

Event Narrative ***(include relevant symptoms, lab tests performed as required and any other action taken):***	
C. SEVERITY OF EVENT	
□ Mild **□ Moderate** **□ Severe** **□ Unknown**	
D. SERIOUSNESS CRITERIA ***(select all that***	**E. OUTCOME OF THE EVENT** ***(select one only):***
□ Fatal (results in death)	**□ Fatal; date of death** |__|__|-|__|__|-|__|__|__|__|
□ Life-threatening	**□ Ongoing/ Not resolved**
□ Requires Hospitalisation or Prolongs Hospitalisation ***(if ticked, complete section H)***	**□ Resolved; date** |__|__|-|__|__|-|__|__|__|__|
□ Results in Persistent or Significant Disability/Incapacity	**□ Resolved with sequelae; Sequelae: -** _____
□ Causes a Congenital Abnormality/Birth Defect	**□ Unknown**
□ Medically Important/Significant event	
E. CAUSALITY	
In the investigator's opinion was the adverse event related to study treatment?	***In the medical monitor's opinion was the adverse event related to study treatment?***
□ Not related	**□ Not related**
□ Unlikely related	**□ Unlikely related**
□ Possibly Related	**□ Possibly Related**
□ Probably Related	**□ Probably Related**
□ Definitely Related	**□ Definitely Related**
□ Not applicable (SAE occurring outside the 6-week treatment window)	
F. EXPECTEDNESS	

In the medical monitor's opinion was the adverse event unexpected? **□ Yes** **□ No**

G. ACTION TAKEN WITH STUDY TREATMENT DUE TO EVENT

□ None

□ Temporarily stopped ***Date stopped:*** |__|__| / |__|__| / |__|__|__|__| ***Date restarted*:** |__|__| / |__|__| / |__|__|__|__|

□ Permanently discontinued ***Date stopped*:** |__|__| / |__|__| / |__|__|__|__|

□ Dose changed ***Dose changed to*:** _____

□ Unknown

H. HOSPITALISATION INFORMATION ***(where applicable):***

N/A **□**

Date of Admission: |__|__| / |__|__| / |__|__|__|__| **Date of Discharge:** |__|__| / |__|__| / |__|__|__|__|

Procedure: - **Date of Procedure:** |__|__| / |__|__| / |__|__|__|__|

_____

Procedure: **Date of Procedure:** |__|__| / |__|__| / |__|__|__|__|

_____

I. CONCOMITANT MEDICATION: ***List all patient medications at time of event. Do not list medications***

Medication name	Dose	Route	Frequency	Start date	Stop date or Ongoing
					□ Ongoing
					□ Ongoing
					□ Ongoing
					□ Ongoing

J. PATIENT MEDICAL HISTORY: ***List all previous patient medical history.***

Reporter name: ……....		**Date sent to medical monitor:** ……...
Reviewed by the medical monitor:		
Date of receipt:	**Name:**	**Signature:** ……..

Supplementary File 8. Participant Information Statement and Consent Forms for qualitative interviews with patients and clinicians

THE UNIVERSITY OF SYDNEY

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Faculty of Medicine and Health

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Rapid Stratified Telehealth for people referred to the Back Clinic: interview study for patients

PARTICIPANT INFORMATION STATEMENT

1. What is this study about?

You are invited to take part in a research study that will explore people's opinion on the care they received as part of the study you recently participated in comparing two care pathways for people with back pain and/or leg pain radiating from the back. This Participant Information Statement tells you about the study. Knowing what is involved will help you decide if you want to take part. Please read this sheet carefully and ask questions about anything that you don't understand or want to know more about.

Participation in this research study is voluntary.

By giving your consent to take part in this study you are telling us that you:

- ✓ Understand what you have read
- ✓ Agree to take part in the research study as outlined below
- ✓ Agree to the use of your personal information as described

This Participant Information Statement is yours to keep.

Your decision whether to participate will not affect your current or future relationship with the researchers or anyone else at the University of Sydney or Royal Prince Alfred Hospital. It also won't affect the quality of care you receive.

2. Who is running the study?

This study is funded by the Agency for Clinical Innovation (ACI) New South Wales and the National Health Medical Research Council. Neither funder will benefit commercially from this study. The manufacturers of PhysiTrack, the mobile App you may be provided during the study, do not have any commercial, financial or business interests in this study.

The people conducting this study are:

- Dr Joshua Zadro, NHMRC Postdoctoral Researcher, Institute for Musculoskeletal Health University of Sydney and Sydney Local Health District
- Dr Chris Needs, Staff Specialist Rheumatologist, Royal Prince Alfred Hospital, Sydney Local District Health
- Prof Christopher Maher, Director, Institute for Musculoskeletal Health, University of Sydney and Sydney Local Health District
- Dr David Martens, Rheumatologist Advanced Trainee, Royal Prince Alfred Hospital, Sydney Local District Health
- Ms Danielle Coombs, Physiotherapist, Institute for Musculoskeletal Health University of Sydney and Sydney Local Health District
- Dr Gustavo Machado, NHMRC Postdoctoral Researcher, Institute for Musculoskeletal Health University of Sydney and Sydney Local Health District
- Mrs Charlotte McLennan, Network Manager, Institute for Musculoskeletal Health University of Sydney and Sydney Local Health District
- Dr Cameron Adams, Rheumatologist Advanced Trainee, Royal Prince Alfred Hospital, Sydney Local District Health
- Prof Nadine Foster, Director, Surgical, Treatment and Rehabilitation Service (STARS) Research and Education Alliance, The University of Queensland and Metro North Hospital and Health Service
- Mr Christopher Han, Physiotherapist Research Assistant, Institute for Musculoskeletal Health, University of Sydney and Sydney Local Health District

3. Who can take part in the study?

A person will be allowed to participate in this study if he or she participated in our study comparing two care pathways for people with back pain and/or leg pain radiating from the back and completed the 6 month follow up.

4. What does the study involve?

If you agree to participate in our study, we will arrange a time for you to participate in a group interview (with up to 8 other participants who took part in the study) or a one-on-one interview if you prefer. This interview may be conducted via telephone or videoconference (e.g. Zoom) or in person at the Institute for Musculoskeletal Health, Level 10 King George V Building, Royal Prince Alfred Hospital. The interview will explore your opinion on the care you received as part of the study comparing two care pathways for people with back pain.

5. How much of my time will the study take?

If you decide to participate, you will need to participate in a 1 hour group interview or 30 minute one-on-one interview. If you would like the interview to be face-to-face, there may be travel time to get to the Institute for Musculoskeletal Health.

6. Do I have to be in the study? Can I withdraw from the study once I've started?

Participation in this study is entirely voluntary. You are not obliged to participate. If you do participate, you can withdraw at any time without having to give any reason and without any penalty. Whatever your decision, it will not affect your relationship with the Hospital, Local Health District and The University of Sydney, or the standard of care you receive now or in the future.

7. Are there any risks or costs associated with being in the study?

Aside from giving up your time to participate in an interview, we do not expect that there will be any risks or costs associated with taking part in this study.

8. Are there any benefits associated with being in the study?

By participating, you will be contributing to important research that helps us understand whether the new care pathway we are testing is acceptable to patients with back pain. The results may help us refine the care pathway before testing it in large research study.

9. What will happen to information about me that is collected during the study?

By providing your consent, you are agreeing to us collecting personal information about you for the purposes of this research study. Your information will only be used for the purposes outlined in this Participant Information Statement, unless you consent otherwise.

Your information will be stored and analysed securely on a research database within the Institute for Musculoskeletal Health, Sydney Local Health District, and your identity/information will be kept strictly confidential, except as required by law. Study findings may be published, but you will not be individually identifiable in these publications.

We will keep the information we collect for this study, and we may use it in future project. By providing your consent you are allowing us to use your information in future projects, however all identifying data will remain strictly confidential. We don't know at this stage what these other projects may involve. We will seek ethical approval before using the information in these future projects.

If you are allocated to the new pathway, you may be provided with an exercise program delivered via a mobile App (PhysiTrack). No data will be collected through the PhysiTrack App and therefore no data will be sent to the developer. The App will simply be used to show you which exercises to do. PhysiTrack is also not a medical device hence does not require TGA approval. PhysiTrack is simply an App that allows physiotherapists to put together an exercise program to allow you to receive written and video instructions on how to perform the exercises correctly. PhysioTrack is essentially a substitute for drawing an exercise program on a piece of paper. The exercises in PhysiTrack include a range of exercises physiotherapists have been prescribing for patients over many years.

As with any home-exercise program prescribed by a physiotherapist, you are free to stop exercising or using the PhysiTrack app at any time if you experience an increase in your symptoms or are not comfortable performing an exercise.

10. Will I be told the results of the study?

You have a right to receive feedback about the overall results of this study. You can tell us that you wish to receive feedback by ticking a box and leaving your email when you complete the

questionnaires. This feedback will be in the form of a one-page lay summary of the results. You will receive this feedback after the study is finished.

11. What do I do next?

When you have read this information, please store it in a safe place. If you understand what you have read and would like to participant, please sign and return the consent form.

If you would like to know more about the study at any stage and ask questions, please feel free to contact Mr Christopher Han (research assistant) at Christopher.han@sydney.edu.au or (02) 8627 7423.

12. What if I have a complaint or any concerns about the study?

This study has been approved by the Ethics Review Committee (RPAH Zone) of the Sydney Local Health District.

If you have any complaints or concerns about any aspect of this study, you should call our research team who will do their best to address any issues. If your concerns are not able to be addressed, you can contact the Executive Officer of the Ethics Review Committee on 02 9515 6766 and quote protocol number X21-0221.

This information sheet is for you to keep.

THE UNIVERSITY OF SYDNEY

ABN 15 211 513 464

School of Public Health
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Rapid Stratified Telehealth for people referred to the Back Clinic: interview study for patients

PARTICIPANT CONSENT FORM

I,_____ *[full name]*

Of_____ *[address]*

have read and understood the Participant Information Sheet on the abovenamed research study

and have discussed the study with _____
[investigator responsible for conducting informed consent].

- I have been made aware of the procedures involved in the study, including any known or expected inconvenience, risk, discomfort or potential side effect and of their implications as far as they are currently known by the researchers.

- I understand that the interview discussion will be audio-recorded and will then be transcribed and be kept in a manner in which I cannot be identified for analysis and I agree to this.

- I understand that my de-identified data may be used for future research and I agree to this.

- I would like to receive a copy of the study results when they become available. My email address is: _____
- I understand that, during the course of this study, my medical records may be accessed by Sydney Local Health District by regulatory authorities or by the Ethics Committee approving the research in order to verify results and determine that the study is being carried out correctly.
- I understand that the SLHD software license for REDCap (Research Electronic Data Capture) will be used to manage the collection and storage of my research data.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I freely choose to participate in this study and understand that I can withdraw at any time.
- I consent to the future use of any data / samples I provide for research purposes. I understand that before they can use any data I provide, they must seek additional ethics approval. YES/ NO
- I consent for other research collaborators to use any data / samples I provide for future research purposes. I understand that before they can use my data, they must seek additional ethics approval. YES/NO
- I also understand that the research study is strictly confidential.
- I hereby agree to participate in this research study.
- I consent to the storage and use of my information collected from me for use, as described in the relevant section of the Participant Information Sheet, for:
  -This specific research project
  -Other research that is closely related to this research project
  -Any future research

Participant Name:_____

Participant Signature:_____

Date:_____

Name of Person conducting informed consent:_____

Signature of Person conducting informed consent: _____

Date:_____

THE UNIVERSITY OF SYDNEY

ABN 15 211 513 464

School of Public Health
Faculty of Medicine and Health

Dr Joshua Zadro
Chief Investigator
Research Fellow

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Rapid Stratified Telehealth for people referred to the Back Clinic: interview study for clinicians

PARTICIPANT INFORMATION STATEMENT

1. What is this study about?

You are invited to take part in a research study that will explore clinicians' opinion on the care they provided as part of the study you recently participated in comparing two care pathways for people with back pain and/or leg pain radiating from the back. This Participant Information Statement tells you about the study. Knowing what is involved will help you decide if you want to take part. Please read this sheet carefully and ask questions about anything that you don't understand or want to know more about.

Participation in this research study is voluntary.

By giving your consent to take part in this study you are telling us that you:

- ✓ Understand what you have read
- ✓ Agree to take part in the research study as outlined below
- ✓ Agree to the use of your personal information as described

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- Mr Christopher Han, Physiotherapist Research Assistant, Institute for Musculoskeletal Health, University of Sydney and Sydney Local Health District

This study is funded by the Agency for Clinical Innovation (ACI) New South Wales and the National Health Medical Research Council. Neither funder will benefit commercially from this study.

3. Who can take part in the study?

A person will be allowed to participate in this study if he or she is a physiotherapist or rheumatologist who provided care as part of our study comparing two care pathways for people with back pain and/or leg pain radiating from the back.

4. What does the study involve?

If you agree to participate in our study, we will arrange a time for you to participate in a one-on-one interview with a member of the research team. This interview may be conducted via telephone or videoconference (e.g. Zoom) or in person at the Institute for Musculoskeletal Health, Level 10 King George V Building, Royal Prince Alfred Hospital. The interview will explore your opinion on the care you provided as part of the study comparing two care pathways for people with back pain and/or leg pain radiating from the back.

5. How much of my time will the study take?

If you decide to participate, you will need to participate in a 30 minute one-on-one interview. If you would like the interview to be face-to-face, there may be travel time to get to the Institute for Musculoskeletal Health.

6. Do I have to be in the study? Can I withdraw from the study once I've started?

Participation in this study is entirely voluntary. You are not obliged to participate. If you do participate, you can withdraw at any time without having to give any reason and without any penalty. Whatever your decision, it will not affect your relationship with the Hospital, Local Health District and The University of Sydney.

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Aside from giving up your time to participate in an interview, we do not expect that there will be any risks or costs associated with taking part in this study.

8. Are there any benefits associated with being in the study?

By participating, you will be contributing to important research that helps us understand whether the new care pathway we are testing is acceptable to patients with back pain and/or leg pain radiating from the back and clinicians providing care to these patients. The results may help us refine the care pathway before testing it in large research study.

9. What will happen to information about me that is collected during the study?

By providing your consent, you are agreeing to us collecting personal information about you for the purposes of this research study. Your information will only be used for the purposes outlined in this Participant Information Statement, unless you consent otherwise.

Your information will be stored and analysed securely on a research database within the Institute for Musculoskeletal Health, Sydney Local Health District, and your identity/information will be kept strictly confidential, except as required by law. Study findings may be published, but you will not be individually identifiable in these publications.

We will keep the information we collect for this study, and we may use it in future project. By providing your consent you are allowing us to use your information in future projects, however all identifying data will remain strictly confidential. We don't know at this stage what these other projects may involve. We will seek ethical approval before using the information in these future projects.

10. Will I be told the results of the study?

You have a right to receive feedback about the overall results of this study. You can tell us that you wish to receive feedback by ticking a box and leaving your email when you complete the questionnaires. This feedback will be in the form of a one-page lay summary of the results. You will receive this feedback after the study is finished.

11. What do I do next?

When you have read this information, please store it in a safe place. If you understand what you have read and would like to participant, please sign and return the consent form.

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If you have any complaints or concerns about any aspect of this study, you should call our research team who will do their best to address any issues. If your concerns are not able to be addressed, you can contact the Executive Officer of the Ethics Review Committee on 02 9515 6766 and quote protocol number **xxxx**.

This information sheet is for you to keep.

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Rapid Stratified Telehealth for people referred to the Back Clinic: interview study for clinicians

PARTICIPANT CONSENT FORM

I,_____ *[full name]*

Of_____ *[address]*

have read and understood the Participant Information Sheet on the abovenamed research study

and have discussed the study with _____
[investigator responsible for conducting informed consent].

- I have been made aware of the procedures involved in the study, including any known or expected inconvenience, risk, discomfort or potential side effect and of their implications as far as they are currently known by the researchers.

- I understand that the interview discussion will be audio-recorded and will then be transcribed and be kept in a manner in which I cannot be identified for analysis and I agree to this.

- I understand that my de-identified data may be used for future research and I agree to this.

- I would like to receive a copy of the study results when they become available. My email address is: _____
- I understand that, during the course of this study, my medical records may be accessed by Sydney Local Health District by regulatory authorities or by the Ethics Committee approving the research in order to verify results and determine that the study is being carried out correctly.
- I understand that the SLHD software license for REDCap (Research Electronic Data Capture) will be used to manage the collection and storage of my research data.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I freely choose to participate in this study and understand that I can withdraw at any time.
- I consent to the future use of any data / samples I provide for research purposes. I understand that before they can use any data I provide, they must seek additional ethics approval. YES/ NO
- I consent for other research collaborators to use any data / samples I provide for future research purposes. I understand that before they can use my data, they must seek additional ethics approval. YES/NO
- I also understand that the research study is strictly confidential.
- I hereby agree to participate in this research study.
- I consent to the storage and use of my information collected from me for use, as described in the relevant section of the Participant Information Sheet, for:
  - -This specific research project
  - -Other research that is closely related to this research project
  - -Any future research

Participant Name:_____

Participant Signature:_____

Date:_____

Name of Person conducting informed consent:_____

Signature of Person conducting informed consent: _____

Date:_____

Supplementary File 9. Interview guide

INTERVIEW GUIDE FOR PATIENTS

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

Introduction

Hi, my name is [name]. Thank you for taking part in this interview. Researchers and health professionals at The University of Sydney and Royal Prince Alfred Hospital want to find out whether a new treatment pathway using telephone and virtual appointments, and App-based exercise programs, helps people receive treatment sooner and get better sooner.

We would like to ask you questions about the treatment you received in the Back Clinic. If at any time you would like to stop the interview, please let us know and we will stop. You can change your mind about talking to me at any time before or during the interview and stop the interview at any time. You can choose not to answer a question.

Are you happy to continue? [If no, thank them for their time and end the interview; if yes, continue].

Thank you [name] for agreeing to take part. We will use your feedback and the feedback of others to write a summary of what people have told us. There will be absolutely no identification of any real names or identification of where you live or which hospitals or health professionals you have seen.

Are you happy for me to record the interview? Do you have any questions before we start?

CONTEXT: TO UNDERSTAND WHAT WORKED, WHAT DIDN'T WORK, AND WHY/ WHY NOT FOR THE TWO METHODS OF SERVICE DELIVERY.

I am interested in exploring your experiences with the care you received in greater detail. Please feel free to be honest about what it was like for you.

All participants

1. Please tell me about your experiences overall of [face-to-face care, virtual consultation, App, pain education program, telephone consultation].

Prompts:

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

2. How convenient was your treatment?

Prompts:

- How convenient was it for you to receive [face-to-face care, virtual consultation, App, pain education program, telephone consultation]?
- How do you feel about not having to attend the hospital for treatment (for low-, medium-, and high-risk participants)?

- How do you feel about having to attend the hospital for treatment (for participants with potential radiculopathy and the usual care group)?

Low-risk participants

3. Next, I'd like to get your views about the virtual/telephone call you received (or why you did not receive it).

Prompts:

- How did you find the call? What was helpful? What wasn't?
- Do you feel as though you got any benefit from the phone call?
- What kinds of things did you talk about with the rheumatologist?
- Would you recommend this method of delivering for others? What kinds of people would this approach suit? Who wouldn't it suit?
- What else would you liked to have received as part of your treatment during the trial?

Medium- and high risk participants

4. Next, I'd like to get your views about the virtual consultation(s) you received (or why you did not receive them).

Prompts:

- How did you find the consultation(s)? What was helpful? What wasn't?
- Do you feel as though you got any benefit from the virtual consultation(s)?
- Do you feel the benefit was similar to what you would have got with face-to-face appointment(s)?
- Would you recommend this method of delivering treatment for others? What kinds of people would this approach suit? Who wouldn't it suit?
- What else would you liked to have received as part of your treatment during the trial?
- Can you comment on the frequency of your appointments?

5. Next, I want to discuss the PhysiTrack App.

- Did you ever use the App?
- If no, why was that?
- If yes, how easy was it to use the App? Did it get easier over time?
- Did you need help to use it? If yes, explore.
- What do you think about the physio using the App to monitor your compliance with the rehabilitation exercises? Why do you say that?
- How long did you use the App?
- How long did you do the rehabilitation exercises? Why or why not?

6. Next, I want to discuss the self-directed pain education program.

- Did you access the program?
- If no, why was that?
- If yes, how easy was it to navigate? Did it get easier over time?
- Did you need help to access it? If yes, explore.
- How did you find the information in the program?
- Did you watch all the videos? Explore

Participants with potential radiculopathy (and people in the usual-care group)

7. Next, I'd like to get your views about the face-to-face appointments you received (or why you did not receive them).

Prompts:

- How did you find the appointment(s)? What was helpful? What wasn't?
- Can you tell me about the process of scheduling appointments? What was the availability of your rheumatologist and physiotherapist?
- Did you always have the same person?
- What is it about seeing a rheumatologist or physiotherapist in person that you like or don't like?
- How convenient was it for you to travel to and attend a face-to-face appointment(s) at the hospital?
- Can you comment on the frequency of your appointments? Is that what you expected? Why or why not?
- Do you feel as though you got any benefit from the appointment(s)?
- Would you recommend this method of delivering treatment for others? What kinds of people would this approach suit? Who wouldn't it suit?
- Do you feel you could have a got a similar benefit from a telephone or virtual consultation(s)?
- What else would you liked to have received as part of your treatment during the trial?

8. Is there anything else you would like to say that we have not talked about in this interview?

Thank you so much for your time.

INTERVIEW GUIDE FOR CLINICIANS

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

Hi, my name is [name and background]. Thank you for taking part in this interview. Researchers and health professionals at The University of Sydney and Royal Prince Alfred Hospital want to find out whether a new treatment pathway using telephone and virtual appointments, and App-based exercise programs, helps people receive treatment sooner and get better sooner. We also want to see if the new treatment pathway is acceptable to clinicians.

We would like to ask you questions about the treatment you provided in the Back Clinic as part of the trial. You can change your mind about talking to me at any time before or during the interview and stop the interview at any time.

Are you happy to continue? [If no, thank them for their time and end interview; if yes continue.]

Thank you [name] for agreeing to take part. We will use your feedback and the feedback of others to write a summary of what people have told us. There will be absolutely no identification of any real names or identification of your professional details.

Are you happy for me to record the interview? Do you have any questions before we start?

CONTEXT: TO UNDERSTAND WHAT WORKED, WHAT DIDN'T WORK, AND WHY/ WHY NOT FOR THE TWO METHODS OF SERVICE DELIVERY

1. Let's first talk about the way your service normally operates.

Prompt:

- How often would you typically see patients? Do you have a waiting list? How long is that waiting list usually?

2. Please tell me about your overall experiences coordinating the Rapid Stratified Telehealth trial.

Prompts:

- What pleased you about the trial?
- What surprised you?
- What were your concerns?
- What would you do differently?

3. How did the clinicians and patients involved in the trial respond to being involved?

4. Please tell us about the recruitment process for the trial.

Prompts:

- How did you manage the logistics of recruitment?
- Was there any difficulty in recruiting participants? If so, please describe.

CONTEXT: TO UNDERSTAND THE PERCEIVED BARRIERS/ FACILITATORS FOR EVALUATING IN A LARGE, MULTI-SITE TRIAL

5. On the basis of your experience in the trial, how easy do you think it will be to introduce delivering this model of care in other outpatient musculoskeletal settings?

6. Has the COVID-19 crisis changed your or your colleagues' attitudes towards delivering rehabilitation remotely?

7. Looking back on the approach used to deliver treatment using eHealth in the trial – are there any aspects of the intervention that could have been delivered differently?

Prompts:

- Could participants at high-risk of persistent pain be better managed with face-to-face appointments?
- Could participants with potential radiculopathy be managed equally effectively with virtual appointments?

8. What is the potential for eHealth-based stratified care to provide more patients with treatment sooner? How important is it to cut down waiting lists?

9. Thinking about what you have learnt from your experiences in the trial – what are the pros and cons of using eHealth-based stratified care, from patients' perspectives?

Prompts:

- What are the main advantages for patients compared to usual practice?

- How acceptable is eHealth-based stratified care likely to be to those accessing treatment for low back pain in a public hospital? Why or why not?
- What kinds of patients do you think are most suitable for being managed or monitored using eHealth?

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

Prompts:

- How compatible/ acceptable will eHealth-based stratified care be to hospital physios and rheumatologists?
- What are the main advantages for clinicians in delivering care via eHealth, compared to usual practice? What are the main disadvantages?

11. What has to be in place for eHealth-based stratified care to be viable to deliver in the hospital setting?

Prompts:

- What are some things that will make this hard/ easy?
- Could this model of care be rolled out in your hospital right now?
- What are some of the barriers?
- What are some of the facilitators?
- Where will the main resistance come from?

12. What kinds of benefits would you anticipate that introducing eHealth-based stratified care would have for patients; physiotherapists; rheumatologists; for hospitals? (Ask about health, service access, cost savings for the hospital).

13. If eHealth-based stratified care was found to be beneficial in a large trial, would you want to provide this intervention in the future? Why, or why not?

14. Is there anything else you would like to say that we have not talked about in this interview?

Thank you so much for your time.

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

Section/item	ItemNo	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)	N/A
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)	N/A
	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)	N/A
	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	N/A
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	N/A
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	N/A
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	N/A

*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.