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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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Manuscripts

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3 1 **The feasibility of delivering and evaluating stratified care integrated with telehealth**
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5 2 **(‘Rapid Stratified Telehealth’) for patients with low back pain: protocol for a feasibility**
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7
8 3 **and pilot randomised controlled trial**
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3 18 **ABSTRACT**
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5 19 **Introduction:** Long waiting time is an important barrier to accessing recommended care for
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7
8 20 low back pain (LBP) in Australia's public health system. This study describes the protocol
9
10 21 for a randomised controlled trial (RCT) that aims to establish the feasibility of delivering and
11
12 22 evaluating stratified care integrated with telehealth ('Rapid Stratified Telehealth') which aims
13
14
15 23 to reduce waiting times for LBP.

16
17 24 **Methods and analysis:** We will conduct a single-centre feasibility and pilot RCT with nested
18
19 25 qualitative interviews. Sixty participants with LBP newly referred to a hospital outpatient
20
21 26 clinic will be randomised to receive Rapid Stratified Telehealth or usual care. Rapid Stratified
22
23 27 Telehealth involves matching the mode and type of care to participants' risk of persistent
24
25 28 disabling pain (using the Keele STarT MSK Tool) and presence of potential radiculopathy.
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28 29 'Low risk' patients are matched to one session of advice over the telephone, 'medium risk' to
29
30 30 telehealth physiotherapy plus App-based exercises, 'high risk' to telehealth physiotherapy,
31
32 31 App-based exercises, and an online pain education program, and 'potential radiculopathy'
33
34 32 fast tracked to usual in-person care. Primary outcomes include the feasibility of delivering
35
36 33 Rapid Stratified Telehealth (i.e. acceptability assessed through interviews with clinicians and
37
38 34 patients, intervention fidelity, appointment duration, App and online pain education program
39
40 35 usage) and evaluating Rapid Stratified Telehealth in a future trial (i.e. recruitment rates,
41
42 36 consent rates, loss to follow up, and missing data). Secondary outcomes include waiting
43
44 37 times, number of appointments, intervention and healthcare costs, clinical outcomes (pain,
45
46 38 function, quality of life, satisfaction), healthcare use and adverse events. Quantitative
47
48 39 analyses will be descriptive and inform a future adequately-powered RCT. Interview data
49
50 40 will be analysed using thematic analysis.
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3 41 **Ethics and dissemination:** This study has received approval from the Ethics Review
4
5 42 Committee (RPAH Zone: X21-0221). Results will be published in peer-reviewed journals and
6
7 43 presented at conferences.
8
9

10 44 **Trial registration:** ANZCTR Request ID 382291.
11

12 45 **Key words:** low back pain; stratified care; telehealth; sciatica; randomised controlled trial;
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14 46 pilot; feasibility.
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3 49 **Strengths and limitations of this study**
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- 6 50 - This will be the first study to investigate the feasibility of delivering and evaluating a
7
8 51 novel intervention integrating stratified care with telehealth ('Rapid Stratified
9
10 52 Telehealth') to reduce waiting times for people with low back pain and ensure more
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12
13 53 efficient use of health resources
14
15 54 - Feasibility will be established using mixed-methods and pre-specified feasibility targets
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17 55 - Feasibility will be established in a hospital outpatient clinic, facilitating delivery and
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19
20 56 evaluation of Rapid Stratified Telehealth in similar clinics
21
22 57 - The use of a feasibility and pilot study design means the findings cannot be used to
23
24 58 make conclusions about the effectiveness of Rapid Stratified Telehealth for reducing
25
26 59 waiting times and improving clinical outcomes in people with low back pain
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29 60 - Given the nature of the intervention, it will not be possible to blind those delivering or
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31 61 receiving the intervention
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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.

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3 86 A telephone assessment and treatment service for patients with LBP and other musculoskeletal
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5 87 conditions was tested in a large UK RCT (n=2,249).[8] Physiotherapists assessed patients via
6
7 88 telephone supported by a computerised system, to help them diagnose the musculoskeletal
8
9 89 problem and determine whether the patient could be managed with advice, information and
10
11 90 exercise via telephone appointments and postal information, or whether the patient needed
12
13 91 assessment and treatment in person. This approach provided similar improvements in physical
14
15 92 health compared to usual clinic-based care, while reducing waiting times by 27 days and the
16
17 93 number of clinic appointments by 40%. This model of care was acceptable to patients and
18
19 94 clinicians in the UK[9] and holds promise for improving access to effective, affordable care
20
21 95 for LBP in Australia.

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26
27 96 The LBP Clinic at Royal Prince Alfred Hospital (Sydney, Australia) provides a suitable context
28
29 97 to examine the feasibility of delivering and evaluating stratified care integrated with telehealth
30
31 98 in Australia's public health system. This clinic is staffed by physiotherapists and
32
33 99 rheumatologists and receives referrals from Primary Care and the Emergency Department. Due
34
35 100 to limited capacity for new appointment slots, patients referred from primary care experience
36
37 101 substantial waiting times for appointments. There is currently no strategy for stratifying care
38
39 102 based on the complexity of a patient's condition (e.g. risk of persistent pain, potential
40
41 103 radiculopathy). Currently, using the referral information provided, all patients are triaged for
42
43 104 potential red flags while the rest are given the next available in-person appointment.

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47
48 105 The primary aim of this feasibility and pilot RCT is to determine the feasibility of:

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50 106 i) delivering stratified care integrated with eHealth ('Rapid Stratified Telehealth') for
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52 patients with low back pain referred to a hospital outpatient clinic; and
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54 107 ii) a future large RCT to test the effectiveness and cost-effectiveness of this new model
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56 of stratified care.
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3 110 The secondary aims are to describe waiting times, number of appointments, intervention and
4
5 111 healthcare costs, clinical outcomes (pain, function, quality of life, satisfaction), healthcare use
6
7 112 and adverse events in the two arms of the trial (Rapid Stratified Telehealth and usual care).
8
9
10 113 For the future RCT, we hypothesise that Rapid Stratified Telehealth will reduce treatment
11
12 114 waiting times (while not compromising clinical outcomes) compared to usual care, be cost-
13
14
15 115 effective and safe.

17 116 **2. Methods and analysis**

20 117 **2.1. Study design**

22 118 We will conduct a single-blind, single-site, two-arm, parallel feasibility and pilot RCT with
23
24 119 nested qualitative interviews. The trial will be prospectively registered at the Australian and
25
26
27 120 New Zealand Clinical trial registry and reported in accordance with the CONSORT extension
28
29 121 for randomised pilot and feasibility trials.[10] The nested qualitative study of clinician and
30
31 122 patient acceptability of Rapid Stratified Telehealth will be reported according to the COREQ
32
33 123 (Consolidated Criteria for Reporting Qualitative Research).[11] This protocol has been
34
35
36 124 reported according to SPIRIT (Standard Protocol Items: Recommendations for Interventional
37
38 125 Trials) (Supplementary File 1).[12]

41 126 **2.2. Participants and recruitment**

43 127 Sixty participants will be recruited from the LBP Clinic (hospital outpatient clinic where
44
45 128 rheumatologists refer select patients to physiotherapy) at Royal Prince Alfred Hospital,
46
47 129 Sydney, Australia, over a 6-month period (expected September 2021 to February 2022). New
48
49
50 130 referrals will be screened by a rheumatologist according to the inclusion and exclusion
51
52 131 criteria (Box 1). Our target sample size of 60 is based on a rule of thumb for feasibility
53
54
55 132 studies[13].

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57
58 133

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

134

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

2.3. Data collection

145 Participants will return hard copy baseline questionnaires to the trial physiotherapist via reply
146 paid envelope, or by completing the questionnaire in REDCap via email or SMS. Participants

1
2
3 147 will also have the option to complete the questionnaire over the telephone. The trial
4
5 148 physiotherapist will enter data from hard copy questionnaires into REDCap. Data entry will
6
7
8 149 be double checked by an independent researcher for accuracy. The baseline questionnaire
9
10 150 will include questions on date of birth, gender, duration of LBP, language spoken at home,
11
12 151 employment status, educational level, previous history of sick leave due to LBP, the Keele
13
14 152 STarT MSK tool,[14] and clinical outcomes (Supplementary File 2). The Keele STarT MSK
15
16 153 tool[14] will be used for risk subgrouping instead of the Keele STarT Back tool[5] because
17
18
19 154 we plan to include patients with LBP and other musculoskeletal conditions in our future trial.
20
21

22 155 **2.4. Interventions and procedures**

23
24 156 Eligible participants will be randomised (via 1:1 ratio) into one of two groups (Figure 1):
25

- 26 157 1. Rapid Stratified Telehealth;
- 27 158 2. Usual Care

28
29
30 159 The secure random allocation schedule will be computer-generated independently and kept
31
32 160 off site. Randomisation will be blocked to ensure equal numbers in both groups. Risk
33
34 161 subgroups, as assessed by the Keele STarT MSK tool (low, medium, high risk), will be used
35
36 162 as a stratification variable. The allocation schedule will be concealed from potential
37
38 163 participants and from all staff associated with the trial. The trial physiotherapist will contact
39
40 164 the central randomisation unit by telephone or email to be notified of the treatment
41
42 165 assignment.
43
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48 166 **2.4.1. Rapid Stratified Telehealth**

49
50 167 The mode and type of care will be matched to the patient's risk of persistent disabling pain,
51
52 168 categorised as low, medium or high (using the Keele STarT MSK Tool[14]), as well as the
53
54 169 presence of potential radiculopathy (score of 3 or more on a clinician-developed screening
55
56 170 questionnaire administered via telephone; Supplementary File 3). The presence of potential
57
58 171 radiculopathy was used for subgrouping as per the telephone assessment and treatment UK
59
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1
2
3 172 trial[8, 15] and based on the preference of clinicians working in the LBP Clinic. Table 1
4
5 173 describes the intervention.
6
7

8 174 **2.4.2. Usual care**

9
10 175 The usual care protocol is in Table 1.

11
12
13 176 Since this is a pragmatic comparison of two real-life models of care, there is no restriction on
14
15
16 177 participants' healthcare use outside the study. Participants who withdraw from the trial will
17
18 178 re-join the waiting list in the position they would have likely been had they not participated.
19

20 21 179 **2.5. Outcomes**

22
23 180 The primary outcomes are feasibility measures. Feasibility outcomes for 'delivering' Rapid
24
25
26 181 Stratified Telehealth include:

- 27
28 182 • Clinician and patient acceptability of the intervention (through semi-structured
29
30 183 interviews with clinicians and focus groups with patients where possible; see section
31
32 184 2.6)
- 33
34
35 185 • Percentage of participants who are only provided care according to their treatment
36
37 186 subgroup (as assessed by treatment recording forms; Supplementary File 4)
- 38
39
40 187 • Mean or median appointment times for each stratified group (treatment stage) and
41
42 188 whether this changes over time
- 43
44
45 189 • Percentage of participants in the Rapid Stratified Telehealth group (medium- and
46
47 190 high-risk) who are comfortable using the App-based exercise program (i.e. do not
48
49 191 need print-outs of the exercises; Supplementary File 4)
- 50
51 192 • Percentage of participants in Rapid Stratified Telehealth group (high-risk) who
52
53 193 complete all modules of the online pain education program (Supplementary File 4)

54
55
56 194 Feasibility outcomes for 'evaluating' Rapid Stratified Telehealth in a future multi-centre
57
58
59 195 randomised controlled trial include:
60

- 196 • Number of participants recruited per week
- 197 • Number of eligible participants per week
- 198 • Percentage of participants who consent to be part of the study from those who were
199 eligible (consent rate)
- 200 • Percentage of participants lost to follow-up at 6 weeks and 6 months
- 201 • Percentage of missing data for outcome measures at 6 weeks and 6 months

202 Based on a 2021 Cochrane review on strategies to improve retention to RCTs,[16] we will
203 implement the following:

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

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

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

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2
3 220 Clinical outcomes and healthcare use will be obtained at baseline immediately prior to
4
5 221 randomisation, and at 6 weeks and 6 months post-randomisation (Supplementary File 5).
6
7 222 Adverse events data will be collected at 2 weeks, 6 weeks and 6 months post-randomisation
8
9 223 (Supplementary File 6). Data will be collected via email, postal mail or telephone (based on
10
11 224 participant preference). Data collected by telephone will be performed by a blinded assessor.
12
13 225 The success of blinding will be checked at the 6-week and 6-month assessment by asking the
14
15 226 assessor if they have become unblinded. If the assessor becomes unblinded at 6 weeks, a new
16
17 227 assessor will be used for the 6-month assessment. All personnel responsible for collecting
18
19 228 data will be appropriately trained.

23
24 229 Clinical outcomes include:

25
26
27 230 *1. Physical function* using the Roland Morris Disability Questionnaire (RMDQ). Participants
28
29 231 will be asked to indicate whether certain activities are impacted by their LBP ('yes' or 'no')
30
31 232 forming a total score out of 24. The RMDQ has demonstrated good validity, reliability and
32
33 233 sensitivity for detecting changes in physical function over time in people with LBP.[17]

34
35
36
37 234 *2. Pain measured* using a 0–10 Numerical Pain Rating Scale (NPRS). Participants will be
38
39 235 asked to rate their average pain over the past 24 hours on a 0–10 numerical rating scale
40
41 236 anchored at each end with “no pain” and “worst pain imaginable”. The NPRS is a valid and
42
43 237 reliable tool for measuring acute and chronic pain.[18]

44
45
46
47 238 *4. Quality of life* using the PROMIS-29 Profile v2.0. This questionnaire assesses pain
48
49 239 intensity, using a 0–10 NPRS (as above), and seven other health domains (physical function,
50
51 240 anxiety, depression, fatigue, sleep disturbance, ability to participate in social roles and
52
53 241 activities, pain interference) each including multiple items scored on a 5-point Likert Scale.
54
55 242 Summary scores for physical and mental health have been shown to be a reliable and valid
56
57 243 measure of quality of life in people with chronic conditions.[19]
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3 244 *5. Patient satisfaction.* Participants will be asked to rate their satisfaction with the care they
4
5 245 received on an 11-point numerical scale: “Using any number from 0 to 10, where 0 is the
6
7 246 worst care possible and 10 is the best care possible, what number would you use to rate the
8
9 247 care you received as part of this study?”

10
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12
13 248 For healthcare use, participants will be asked if they have used or are currently using any
14
15 249 healthcare services (e.g. GP, physiotherapy, imaging), or community health or other services
16
17 250 (e.g. meals on wheels) for their LBP. Participants will also be asked whether they are
18
19 251 currently taking any prescription or over the counter medication for their LBP, and to specify
20
21 252 the type and dose of their medication.

22
23
24
25 253 We will collect data on adverse events (AEs) and serious adverse events (SAEs; those which
26
27 254 are life threatening, result in hospitalisation, significant disability or incapacity, or death). At
28
29 255 2 weeks, 6 weeks and 6 months, participants will be asked whether they have developed a
30
31 256 new medical condition or experienced an exacerbation of an existing condition since
32
33 257 beginning the study or last follow-up point (e.g. dizziness, increased pain). If the participant
34
35 258 answers yes, they will be asked to describe this. When an AE or SAE occurs that is
36
37 259 potentially related to the treatments provided in the trial, the trial physiotherapist will record
38
39 260 all the relevant information regarding the AE/SAE, including the type of event, the start and
40
41 261 stop dates, the action taken, and causality of the event (Supplementary File 6). The Principal
42
43 262 Investigator will be responsible for reporting SAEs to the Ethics committee.

263 **2.6. Semi-structured interviews and focus groups**

264 **2.6.1. Participants and recruitment**

265 To explore the acceptability of Rapid Stratified Telehealth, we will conduct semi-structured
266 interviews with the physiotherapists and rheumatologists delivering Rapid Stratified
267 Telehealth and focus groups (where possible) with 15 patients who were managed using

1
2
3 268 Rapid Stratified Telehealth. Exact numbers may vary based on saturation of elicited themes.
4
5 269 We will purposively sample patients to achieve diversity in age, gender, ethnicity, treatment
6
7 270 subgroup, and response to the intervention. We will seek participation from patients at the 6-
8
9 271 month follow-up and from clinicians after all patients have been recruited.
10
11
12

13 272 The trial physiotherapist will email or post clinicians and patients a Participant Information
14
15 273 Statement and Participant Consent Form for the qualitative interviews and arrange a time for
16
17 274 an intervention or focus group (Supplementary File 7). Clinicians and patients will be made
18
19 275 aware that participation is voluntary, and that non-consent to participate or withdrawal from
20
21 276 this study will have no repercussions.
22
23
24

25 277 **2.6.2. Data collection**

26
27 278 Interviews and focus groups will be conducted via telephone or videoconference (e.g. Zoom)
28
29 279 or face-to-face at the Institute for Musculoskeletal Health, Royal Prince Alfred Hospital,
30
31 280 depending on clinician and patient preferences. Interviews and focus groups will be conducted
32
33 281 by a researcher with experience in conducting qualitative interviews. One-on-one interviews
34
35 282 with clinicians will last about 30 minutes and be audio-recorded and transcribed verbatim for
36
37 283 analysis. Focus groups will last about 1 hour, include a maximum of 8 participants and be
38
39 284 audio-recorded and transcribed verbatim for analysis. Where patients are unable to participate
40
41 285 in a focus group, one-on-one interviews will be offered.
42
43
44
45

46 286 Interviews and focus groups will explore clinician and patient acceptability of Rapid Stratified
47
48 287 Telehealth. Specifically, what worked, what didn't work, and the pros and cons of the two
49
50 288 models of care from a clinician and patient perspective, and the perceived barriers and
51
52 289 facilitators for evaluating Rapid Stratified Telehealth in a multi-site trial from a clinician
53
54 290 perspective. Throughout the interviews and focus groups, clinicians and patients will be invited
55
56 291 to share their perspectives of the Rapid Stratified Telehealth approach and suggest
57
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60

292 modifications that would increase its appeal and effectiveness for clinicians and patients. The
293 interview guide is in Supplementary File 8.

294 The researcher facilitating the interviews and focus groups will take notes to highlight key
295 themes that emerge and direct further questioning. This will also enable the facilitator to
296 summarise information back to clinicians and patients at the end of the interview and give them
297 an opportunity to provide further information. Clinicians and patients will have the opportunity
298 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

301 The main analysis will focus on feasibility (process) outcomes and will investigate feasibility
302 outcomes for delivering Rapid Stratified Telehealth (acceptability, percentage of participants
303 in the intervention who are only provided care according to their treatment subgroup,
304 appointment durations, percentage of participants in the intervention who are comfortable
305 using the App and complete the online pain education program) and feasibility outcomes for
306 evaluating Rapid Stratified Telehealth in a future multi-centre randomised controlled trial
307 (recruitment rates, consent rates, percentage loss to follow up, and percentage missing data).
308 These data will be summarised using descriptive statistics (means and standard deviations,
309 median and interquartile ranges and counts and percentages, as appropriate).

310 The research team will review the feasibility outcomes at the completion of the study and
311 make a judgement about whether to proceed to planning an adequately powered, multi-site
312 trial. Meeting the following criteria would justify proceeding to a full trial:

- 313 i) Acceptable to clinicians and patients (according to qualitative interviews)
- 314 ii) Percentage of participants in the intervention who are only provided care
315 according to their treatment subgroup >75%

- 1
2
3 316 iii) Percentage of participants in the Rapid Stratified Telehealth group (medium- and
4
5 317 high-risk) who are comfortable using the PhysiTrack App >75%
6
7
8 318 iv) Percentage of participants in Rapid Stratified Telehealth group (high-risk) who
9
10 319 complete all modules of the self-directed online pain education program >75%
11
12 320 v) Recruitment rate of three or more participants per week over 6 months
13
14 321 vi) Consent rate of 50% or more over 6 months (similar to a UK trial[8])
15
16 322 vii) Loss to follow up <25% at 6 months
17
18 323 viii) Missing data in questionnaires <15%
19
20
21

22 324 **2.7.2. Secondary outcomes**

23
24 325 Waiting times, number of consultations patients receive, intervention and healthcare costs,
25
26 326 clinical outcomes, healthcare use and adverse events will be compared between Rapid
27
28 327 Stratified Telehealth and usual care using descriptive statistics (means and standard
29
30 328 deviations, median and interquartile ranges and counts and percentages, as appropriate) in
31
32 329 STATA version 16.0. No statistical inference testing will be performed as this is a feasibility
33
34 330 study.[20] Data on waiting time and physical function will inform the sample size calculation
35
36 331 for the future trial.
37
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39
40

41 332 **2.7.3. Interview data**

42
43 333 All interview data will be analysed using thematic analysis; a method for identifying, analysing
44
45 334 and reporting patterns within data.[21] Two researchers will independently familiarise
46
47 335 themselves with the interviews (via audio-recordings or transcripts), record initial observations,
48
49 336 and identify concepts relevant to the questions asked. The two researchers will develop a
50
51 337 framework to organise concepts into broader themes and sub-themes in Excel.[21] Any
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53 338 disagreements in categorising concepts into themes and sub-themes will be discussed and
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55 339 resolved. The mapping of themes and sub-themes will be iterative as new data emerges.
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57 340 Interviews will stop once no new themes are identified (data saturation).
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341 **2.8. Patient and public involvement**

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

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

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

364 **3. Ethics and dissemination**

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3 365 **3.1. Ethics approval**
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5 366 This study has been granted ethics approval from the Ethics Review Committee (RPAH
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7 367 Zone: X21-0221). Any protocol deviations will be submitted to the Ethics Review Committee
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9
10 368 for review.
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13 369 **3.2. Data management**
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15 370 All information collected for this trial will be de-identified and kept confidential and secure.
16
17 371 All electronically transcribed data will be securely stored on REDCap hosted by Sydney
18
19 372 Local Health District and managed by the trial physiotherapist. All hard copy study material
20
21 373 will be stored in a locked filing cabinet in the secure office within Royal Prince Alfred
22
23 374 Hospital. Access to data will only be granted to members of the study team. Individual names
24
25 375 of participants will not be considered in data analysis and they will not be identified in
26
27 376 published data. Any data stored for future analysis will be de-identified. All source
28
29 377 documents and trial documentation will be kept in a secure location by the investigators for
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31 378 15 years.
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37 379 **3.3. Trial monitoring and quality assurance**
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39 380 Trial monitoring will be done by the trial physiotherapist and overseen by the Principal
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41 381 Investigator, with frequent contacts by phone and in person to ensure the objectives of the
42
43 382 study are being fulfilled. Monitoring will allow the trial physiotherapist to maintain current
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45 383 knowledge of the study through observation, discussion and to ensure compliance to the
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47 384 study protocol.
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51 385 **3.4. Dissemination plan**
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53 386 The results of the study will be published in peer-reviewed journals. It is expected that the
54
55 387 investigators will author a full report of the quantitative and qualitative findings. Results will
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3 388 likely be presented at national and international conferences. Individual participants will not
4
5 389 be identifiable in any publications or presentations.
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8 390 **4. Conclusion**

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10 391 Rapid Stratified Telehealth could change the way care for LBP, and more broadly
11
12 392 musculoskeletal pain, is delivered in Australia and globally. This new way of freeing up
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14 393 hospital resources for those most in need and giving more Australians access to care in their
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16 394 own home, may ensure the two million Australians with LBP but without private health
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18 395 insurance[2, 22] have faster access to appropriate healthcare. Faster access to care may allow
19
20 396 patients to recover faster, return to work and their usual activities sooner, and avoid worse
21
22 397 symptoms that require more costly, ongoing treatment. Translation of positive findings from a
23
24 398 large multi-site trial not only has the potential to improve the lives of the 570 million people
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26 399 that suffer from LBP worldwide[1] but could allow some of the health resources currently spent
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28 400 on the management of low back pain per year (eg. \$88 billion in the United States[23]; \$5
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30 401 billion in Australia[22]) to be redirected to other areas of need within healthcare.
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3 406 **Authors' contributions**
4

5 407 All authors critically revised the manuscript for important intellectual content and approved
6
7 the final manuscript. Please find below a detailed description of the role of each author:
8

- 9
10 409 - Joshua R Zadro: conception and design, drafting and revision of the manuscript, and
11
12 410 final approval of the version to be published
13
14 411 - Christopher Needs: conception and design, drafting and revision of the manuscript, and
15
16 412 final approval of the version to be published
17
18 413 - Nadine Foster: conception and design, drafting and revision of the manuscript, and final
19
20 414 approval of the version to be published
21
22 415 - David Martens: conception and design, drafting and revision of the manuscript, and
23
24 416 final approval of the version to be published
25
26 417 - Danielle M Coombs: conception and design, drafting and revision of the manuscript,
27
28 418 and final approval of the version to be published
29
30 419 - Gustavo C Machado: conception and design, drafting and revision of the manuscript,
31
32 420 and final approval of the version to be published
33
34 421 - Cameron Adams: conception and design, drafting and revision of the manuscript, and
35
36 422 final approval of the version to be published
37
38 423 - Christopher S Han: conception and design, drafting and revision of the manuscript, and
39
40 424 final approval of the version to be published
41
42 425 - Christopher G Maher: conception and design, drafting and revision of the manuscript,
43
44 426 and final approval of the version to be published
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50
51 427 The Corresponding Author (JZ) attests that all listed authors meet authorship criteria and that
52
53 428 no others meeting the criteria have been omitted. We would also like to acknowledge the
54
55 429 contribution of four consumer advisors whose valuable input helped us refine the protocol for
56
57 430 this trial.
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3 431 **Competing interests:** All authors declare: no support from any organisation for the submitted
4
5 432 work; no financial relationships with any organisations that might have an interest in the
6
7 433 submitted work; no other relationships or activities that could appear to have influenced the
8
9 434 submitted work.

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11
12 435 **Funding source:** This study was funded by an Agency for Clinical Innovation (ACI)
13
14 436 Research Grants Scheme Grant (\$30,000) (funder number N/A). The funder had no influence
15
16 437 on the design, conduct or reporting of this study.

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19 438 **Data availability statement:** There are no data in this study.

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Table 1. Rapid Stratified Telehealth and usual care protocol

Treatment group and sub-group	Intervention protocol
<i>Rapid Stratified Telehealth</i>	
<i>Low risk of persistent pain</i> (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.
<i>Medium risk of persistent pain</i> (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.
<i>High risk of persistent pain</i> (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.

<i>Potential radiculopathy</i> (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).
<i>All participants</i>	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	
<i>All participants</i>	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.

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510 **Figure legends**

511 Figure 1. Trial flow diagram

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For peer review only

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3 513 **Supplementary files**
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5 514 Supplementary File 1. Standard Protocol Items: Recommendations for Interventional Trials
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7 (SPIRIT) checklist.
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10 516 Supplementary File 2. Information pack.
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12 517 Supplementary File 3. Telephone assessment for Rapid Stratified Telehealth group.
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14 518 Supplementary File 4. Treatment recording form.
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17 519 Supplementary File 5. Follow up assessment at 6 weeks and 6 months.
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19 520 Supplementary File 6. Assessment of adverse events.
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21 521 Supplementary File 7. Participant Information Statement and Consent Forms for qualitative
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23 interviews for patients and clinicians.
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26 523 Supplementary File 8. Interview guide.
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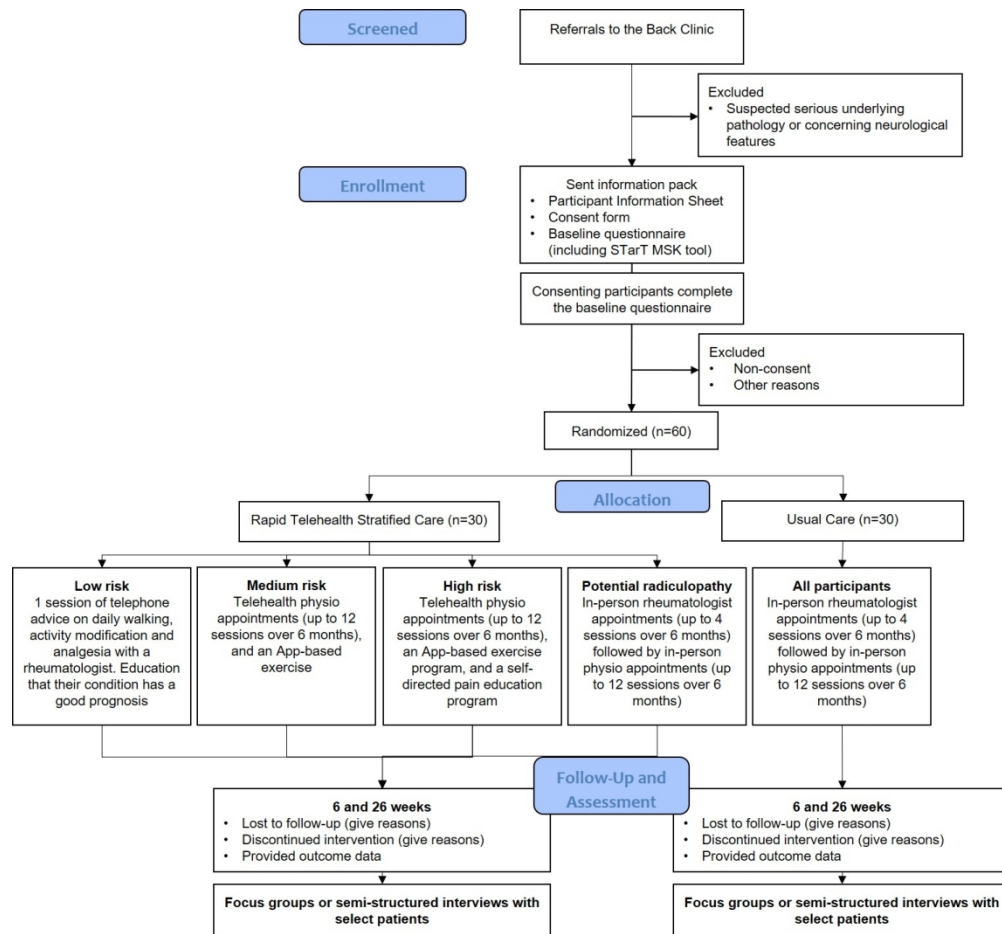


Figure 1. Trial flow diagram

258x239mm (150 x 150 DPI)



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	✓

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2	Objectives	7	Specific objectives or hypotheses	✓
3				
4	Trial design	8	Description of trial design including type of trial (eg,	✓
5			parallel group, crossover, factorial, single group),	
6			allocation ratio, and framework (eg, superiority,	
7			equivalence, noninferiority, exploratory)	
8				
9				
10	Methods: Participants, interventions, and outcomes			
11				
12	Study setting	9	Description of study settings (eg, community clinic,	✓
13			academic hospital) and list of countries where data will	
14			be collected. Reference to where list of study sites can	
15			be obtained	
16				
17	Eligibility criteria	10	Inclusion and exclusion criteria for participants. If	✓
18			applicable, eligibility criteria for study centres and	
19			individuals who will perform the interventions (eg,	
20			surgeons, psychotherapists)	
21				
22				
23	Interventions	11a	Interventions for each group with sufficient detail to	✓
24			allow replication, including how and when they will be	
25			administered	
26				
27				
28		11b	Criteria for discontinuing or modifying allocated	✓
29			interventions for a given trial participant (eg, drug dose	
30			change in response to harms, participant request, or	
31			improving/worsening disease)	
32				
33		11c	Strategies to improve adherence to intervention	N/A
34			protocols, and any procedures for monitoring	
35			adherence (eg, drug tablet return, laboratory tests)	
36				
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38		11d	Relevant concomitant care and interventions that are	✓
39			permitted or prohibited during the trial	
40				
41	Outcomes	12	Primary, secondary, and other outcomes, including the	✓
42			specific measurement variable (eg, systolic blood	
43			pressure), analysis metric (eg, change from baseline,	
44			final value, time to event), method of aggregation (eg,	
45			median, proportion), and time point for each outcome.	
46			Explanation of the clinical relevance of chosen efficacy	
47			and harm outcomes is strongly recommended	
48				
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50	Participant	13	Time schedule of enrolment, interventions (including	✓
51	timeline		any run-ins and washouts), assessments, and visits for	
52			participants. A schematic diagram is highly	
53			recommended (see Figure)	
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2	Sample size	14	Estimated number of participants needed to achieve	✓
3			study objectives and how it was determined, including	
4			clinical and statistical assumptions supporting any	
5			sample size calculations	
6				
7	Recruitment	15	Strategies for achieving adequate participant enrolment	✓
8			to reach target sample size	
9				

Methods: Assignment of interventions (for controlled trials)

Allocation:

14	Sequence	16a	Method of generating the allocation sequence (eg,	✓
15	generation		computer-generated random numbers), and list of any	
16			factors for stratification. To reduce predictability of a	
17			random sequence, details of any planned restriction	
18			(eg, blocking) should be provided in a separate	
19			document that is unavailable to those who enrol	
20			participants or assign interventions	
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24	Allocation	16b	Mechanism of implementing the allocation sequence	✓
25	concealment		(eg, central telephone; sequentially numbered, opaque,	
26	mechanism		sealed envelopes), describing any steps to conceal the	
27			sequence until interventions are assigned	
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30	Implementation	16c	Who will generate the allocation sequence, who will	✓
31			enrol participants, and who will assign participants to	
32			interventions	
33				
34	Blinding	17a	Who will be blinded after assignment to interventions	✓
35	(masking)		(eg, trial participants, care providers, outcome	
36			assessors, data analysts), and how	
37				
38				
39		17b	If blinded, circumstances under which unblinding is	✓
40			permissible, and procedure for revealing a participant's	
41			allocated intervention during the trial	
42				

Methods: Data collection, management, and analysis

45	Data collection	18a	Plans for assessment and collection of outcome,	✓
46	methods		baseline, and other trial data, including any related	
47			processes to promote data quality (eg, duplicate	
48			measurements, training of assessors) and a description	
49			of study instruments (eg, questionnaires, laboratory	
50			tests) along with their reliability and validity, if known.	
51			Reference to where data collection forms can be found,	
52			if not in the protocol	
53				
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55				
56		18b	Plans to promote participant retention and complete	✓
57			follow-up, including list of any outcome data to be	
58			collected for participants who discontinue or deviate	
59			from intervention protocols	
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2	Data	19	Plans for data entry, coding, security, and storage,	✓
3	management		including any related processes to promote data quality	
4			(eg, double data entry; range checks for data values).	
5			Reference to where details of data management	
6			procedures can be found, if not in the protocol	
7				
8	Statistical	20a	Statistical methods for analysing primary and	✓
9	methods		secondary outcomes. Reference to where other details	
10			of the statistical analysis plan can be found, if not in the	
11			protocol	
12				
13				
14		20b	Methods for any additional analyses (eg, subgroup and	N/A
15			adjusted analyses)	
16				
17		20c	Definition of analysis population relating to protocol	✓
18			non-adherence (eg, as randomised analysis), and any	
19			statistical methods to handle missing data (eg, multiple	
20			imputation)	
21				
22				
23	Methods: Monitoring			
24				
25	Data monitoring	21a	Composition of data monitoring committee (DMC);	✓
26			summary of its role and reporting structure; statement	
27			of whether it is independent from the sponsor and	
28			competing interests; and reference to where further	
29			details about its charter can be found, if not in the	
30			protocol. Alternatively, an explanation of why a DMC is	
31			not needed	
32				
33				
34		21b	Description of any interim analyses and stopping	N/A
35			guidelines, including who will have access to these	
36			interim results and make the final decision to terminate	
37			the trial	
38				
39				
40	Harms	22	Plans for collecting, assessing, reporting, and	✓
41			managing solicited and spontaneously reported	
42			adverse events and other unintended effects of trial	
43			interventions or trial conduct	
44				
45				
46	Auditing	23	Frequency and procedures for auditing trial conduct, if	✓
47			any, and whether the process will be independent from	
48			investigators and the sponsor	
49				
50				
51	Ethics and dissemination			
52				
53	Research ethics	24	Plans for seeking research ethics	✓
54	approval		committee/institutional review board (REC/IRB)	
55			approval	
56				
57				
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60				

1				
2	Protocol	25	Plans for communicating important protocol	✓
3	amendments		modifications (eg, changes to eligibility criteria,	
4			outcomes, analyses) to relevant parties (eg,	
5			investigators, REC/IRBs, trial participants, trial	
6			registries, journals, regulators)	
7				
8	Consent or	26a	Who will obtain informed consent or assent from	✓
9	assent		potential trial participants or authorised surrogates, and	
10			how (see Item 32)	
11				
12				
13		26b	Additional consent provisions for collection and use of	N/A
14			participant data and biological specimens in ancillary	
15			studies, if applicable	
16				
17	Confidentiality	27	How personal information about potential and enrolled	✓
18			participants will be collected, shared, and maintained in	
19			order to protect confidentiality before, during, and after	
20			the trial	
21				
22				
23	Declaration of	28	Financial and other competing interests for principal	✓
24	interests		investigators for the overall trial and each study site	
25				
26	Access to data	29	Statement of who will have access to the final trial	✓
27			dataset, and disclosure of contractual agreements that	
28			limit such access for investigators	
29				
30				
31	Ancillary and	30	Provisions, if any, for ancillary and post-trial care, and	N/A
32	post-trial care		for compensation to those who suffer harm from trial	
33			participation	
34				
35	Dissemination	31a	Plans for investigators and sponsor to communicate	✓
36	policy		trial results to participants, healthcare professionals,	
37			the public, and other relevant groups (eg, via	
38			publication, reporting in results databases, or other	
39			data sharing arrangements), including any publication	
40			restrictions	
41				
42				
43				
44		31b	Authorship eligibility guidelines and any intended use of	✓
45			professional writers	
46				
47		31c	Plans, if any, for granting public access to the full	✓
48			protocol, participant-level dataset, and statistical code	
49				
50				
51	Appendices			
52	Informed consent	32	Model consent form and other related documentation	✓
53	materials		given to participants and authorised surrogates	
54				
55	Biological	33	Plans for collection, laboratory evaluation, and storage	N/A
56	specimens		of biological specimens for genetic or molecular	
57			analysis in the current trial and for future use in	
58			ancillary studies, if applicable	
59				
60				

1 *It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013
2 Explanation & Elaboration for important clarification on the items. Amendments to the
3 protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT
4 Group under the Creative Commons "[Attribution-NonCommercial-NoDerivs 3.0 Unported](#)"
5 license.
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Supplementary File 2. Information pack



THE UNIVERSITY OF
SYDNEY

ABN 15 211 513 464

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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

1
2
3 receive based on your risk of persisting pain and presence of other symptoms (like leg pain). We
4 want to see whether the new pathway helps people receive treatment sooner and recover sooner.
5

6 To find out which pathway is best, we will offer half of people the current pathway and half the
7 new pathway. We will monitor the two groups for 6 months and compare what happens between
8 the groups. To ensure the groups are as similar to each other as possible, the group that you will
9 be placed into is by chance. **There is a 50% chance you will be managed according to the new
10 pathway, and a 50% chance you will be managed according to the current pathway.** To make
11 the results of our study fair, we will not tell you which pathway you have been allocated to.
12

13 If you decide you would not like to participate in the research study, you will be managed
14 according to the current pathway. However, your decision whether to participate will not affect
15 your current or future relationship with the researchers or anyone else at the University of Sydney
16 or Royal Prince Alfred Hospital. It also won't affect your position on the waiting list or the quality
17 of care you receive.
18

19 **2. Who is running the study?**

20 This study is funded by the Agency for Clinical Innovation (ACI) New South Wales and the
21 National Health Medical Research Council. Neither funder will benefit commercially from this
22 study. The manufacturers of PhysiTrack, the mobile App you may be provided during the study,
23 do not have any commercial, financial or business interests in this study.
24

25 The people conducting this study are:
26

- 27 • Dr Joshua Zadro, NHMRC Postdoctoral Researcher, Institute for Musculoskeletal Health
28 University of Sydney and Sydney Local Health District
- 29 • Dr Chris Needs, Staff Specialist Rheumatologist, Royal Prince Alfred Hospital, Sydney
30 Local District Health
- 31 • Prof Christopher Maher, Director, Institute for Musculoskeletal Health, University of
32 Sydney and Sydney Local Health District
- 33 • Dr David Martens, Rheumatologist Advanced Trainee, Royal Prince Alfred Hospital,
34 Sydney Local District Health
- 35 • Ms Danielle Coombs, Physiotherapist, Institute for Musculoskeletal Health University of
36 Sydney and Sydney Local Health District
- 37 • Dr Gustavo Machado, NHMRC Postdoctoral Researcher, Institute for Musculoskeletal
38 Health University of Sydney and Sydney Local Health District
- 39 • Mrs Charlotte McLennan, Network Manager, Institute for Musculoskeletal Health
40 University of Sydney and Sydney Local Health District
- 41 • Dr Cameron Adams, Rheumatologist Advanced Trainee, Royal Prince Alfred Hospital,
42 Sydney Local District Health
- 43 • Prof Nadine Foster, Director, Surgical, Treatment and Rehabilitation Service (STARS)
44 Research and Education Alliance, The University of Queensland and Metro North Hospital
45 and Health Service
46

47 **3. Who can take part in the study?**

48 A person will be allowed to participate in this study if he or she:
49

- 50 • is referred to the 'Back Pain Clinic' at Royal Prince Alfred Hospital
- 51 • has low back pain and/or leg pain radiating from the back
52

- 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 participate, 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
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School of Public 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)	<input type="radio"/> Male <input type="radio"/> 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)	<input type="radio"/> Less than 12 weeks <input type="radio"/> Longer than 12 weeks
Language spoken at home other than English	_____
What is your indigenous status? (please tick one only)	<input type="radio"/> Aboriginal <input type="radio"/> Torres Strait Islander <input type="radio"/> Both Aboriginal and Torres Strait Islander <input type="radio"/> Neither Aboriginal nor Torres Strait Islander
Employment Status: (please tick one only)	<input type="radio"/> Not currently employed <input type="radio"/> Currently employed <input type="radio"/> Student <input type="radio"/> Unpaid carer
Education: What option best describes your highest level of education? (please tick one only)	<input type="radio"/> Primary school or less <input type="radio"/> High school (not completed) <input type="radio"/> High school (completed) <input type="radio"/> TAFE/Trade <input type="radio"/> University- undergraduate degree/s (completed) <input type="radio"/> University- postgraduate degree/s e.g. Masters, PhD (completed) <input type="radio"/> Other (please specify) _____

<p>Have you previously taken sick leave due to your low back pain or leg pain radiating from the back? (please tick one only)</p>	<p><input type="radio"/> Yes</p> <p><input type="radio"/> No</p>
--	--

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
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please cross one box for each question below

Yes

No

2) Do you often feel unsure about how to manage your pain condition?	<input type="checkbox"/>	<input type="checkbox"/>
3) Over the last two weeks, have you been bothered a lot by your pain?	<input type="checkbox"/>	<input type="checkbox"/>
4) Have you only been able to walk short distances because of your pain?	<input type="checkbox"/>	<input type="checkbox"/>
5) Have you had troublesome joint or muscle pain in more than one part of your body?	<input type="checkbox"/>	<input type="checkbox"/>
6) Do you think your condition will last a long time?	<input type="checkbox"/>	<input type="checkbox"/>
7) Do you have other important health problems?	<input type="checkbox"/>	<input type="checkbox"/>
8) Has pain made you feel down or depressed in the last two weeks?	<input type="checkbox"/>	<input type="checkbox"/>

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9) Do you feel it is unsafe for a person with a condition like yours to be physically active?	<input type="checkbox"/>	<input type="checkbox"/>
10) Have you had your current pain problem for 6 months or more?	<input type="checkbox"/>	<input type="checkbox"/>

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PROMIS–29 Profile v2.0

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

<u>Physical Function</u>		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?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	Are you able to go up and down stairs at a normal pace?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3	Are you able to go for a walk of at least 15 minutes?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4	Are you able to run errands and shop?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>Anxiety</u>						
In the past 7 days...		Never	Rarely	Sometimes	Often	Always
5	I felt fearful	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6	I found it hard to focus on anything other than my anxiety	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7	My worries overwhelmed me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8	I felt uneasy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>Depression</u>						
In the past 7 days...		Never	Rarely	Sometimes	Often	Always
9	I felt worthless	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10	I felt helpless	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11	I felt depressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12	I felt hopeless	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>Fatigue</u>						
During the past 7 days...		Not at all	A little bit	Somewhat	Quite a bit	Very much
13	I feel fatigued	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14	I have trouble starting things because I am tired	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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? ...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16	How fatigued were you on average?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Sleep Disturbance

In the past 7 days...

		Very poor	Poor	Fair	Good	Very good
17	My sleep quality was	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

In the past 7 days...

		Not at all	A little bit	Somewhat	Quite a bit	Very much
18	My sleep was refreshing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19	I had a problem with my sleep	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20	I had difficulty falling asleep	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22	I have trouble doing all of the family activities that I want to do	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23	I have trouble doing all of my usual work (include work at home)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24	I have trouble doing all of the activities with friends that I want to do	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26	How much did pain interfere with work around the home?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27	How much did pain interfere with your ability to participate in social activities? .	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
28	How much did pain interfere with your household chores?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Pain Intensity

In the past 7 days...

29	How would you rate your pain on average?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
		0	1	2	3	4	5	6	7	8	9	10
		No pain										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)				
<input type="checkbox"/> History of significant trauma	<input type="checkbox"/> History of Cancer	<input type="checkbox"/> Recent bacterial infection	<input type="checkbox"/> Fever	<input type="checkbox"/> IV drug use
<input type="checkbox"/> Immune suppression	<input type="checkbox"/> Recent unexplained weight loss	<input type="checkbox"/> Severe pain when supine/at night	<input type="checkbox"/> Saddle anaesthesia	<input type="checkbox"/> Bladder or bowel dysfunction
<input type="checkbox"/> Neurological deficit in limb	<input type="checkbox"/> Osteoporosis	<input type="checkbox"/> Long term corticosteroid use	<input type="checkbox"/> 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
<i>Patients at low risk of persistent pain (Keele STarT MSK score 0-4) AND no potential radiculopathy</i>	Telephone appointment with Advanced Rheumatology Trainee	
	• Advice on daily walking	<input type="checkbox"/>
	• Advice on activity modification	<input type="checkbox"/>
	• Advice to take simple pain medications	<input type="checkbox"/>
	• Education that their condition has a good prognosis	<input type="checkbox"/>
	• Other advice (Please specify) _____	<input type="checkbox"/>
<i>Patients at medium risk of persistent pain (Keele STarT MSK score 5-8) AND no potential radiculopathy</i>	Virtual physiotherapy appointment	
	• Advice and education to support self-management	<input type="checkbox"/>
	• Advice to exercise	<input type="checkbox"/>
	• Advice to modify activities	<input type="checkbox"/>
	• Advice to lose weight	<input type="checkbox"/>
	• Advice to take simple pain medications	<input type="checkbox"/>
	• App-based exercise program	<input type="checkbox"/>
	• Tick if participant needed to print out the exercise program	<input type="checkbox"/>

	<ul style="list-style-type: none"> • Other intervention (Please specify) _____ 	<input type="checkbox"/>
<i>Patients at high risk of persistent pain (Keele STarT MSK score 9-12) AND no potential radiculopathy</i>	Virtual physiotherapy appointment	
	<ul style="list-style-type: none"> • Advice and education to support self-management 	<input type="checkbox"/>
	<ul style="list-style-type: none"> • Advice to exercise 	<input type="checkbox"/>
	<ul style="list-style-type: none"> • Advice to modify activities 	<input type="checkbox"/>
	<ul style="list-style-type: none"> • Advice to lose weight 	<input type="checkbox"/>
	<ul style="list-style-type: none"> • Advice to take simple pain medications 	<input type="checkbox"/>
	<ul style="list-style-type: none"> • Interventions to address psychological barriers to recovery (e.g. pacing, graded exposure) 	<input type="checkbox"/>
	<ul style="list-style-type: none"> • App-based exercise program 	<input type="checkbox"/>
	<ul style="list-style-type: none"> • Tick if participant needed to print out the exercise program 	<input type="checkbox"/>
	<ul style="list-style-type: none"> • Instructed to complete online pain education modules 	<input type="checkbox"/>
	<ul style="list-style-type: none"> • Tick if participant has completed all online pain education modules 	<input type="checkbox"/>
	<ul style="list-style-type: none"> • Referral to psychologist 	<input type="checkbox"/>
<ul style="list-style-type: none"> • Other intervention (Please specify) _____ 	<input type="checkbox"/>	
<i>Patients with potential radiculopathy</i>	In person rheumatologist appointment	
	<ul style="list-style-type: none"> • Take patients' medical history (including past history) 	<input type="checkbox"/>
	<ul style="list-style-type: none"> • Conduct a physical examination (including a neurological examination) 	<input type="checkbox"/>
	<ul style="list-style-type: none"> • Review any previously undertaken investigations (e.g. imaging, pathology tests) 	<input type="checkbox"/>

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

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”]?

0	1	2	3	4	5	6	7	8	9	10
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

PROMIS–29 Profile v2.0

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

	<u>Physical Function</u>	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?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	Are you able to go up and down stairs at a normal pace?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3	Are you able to go for a walk of at least 15 minutes?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4	Are you able to run errands and shop?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<u>Anxiety</u>					
	In the past 7 days...	Never	Rarely	Sometimes	Often	Always
5	I felt fearful	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6	I found it hard to focus on anything other than my anxiety	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7	My worries overwhelmed me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8	I felt uneasy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<u>Depression</u>					
	In the past 7 days...	Never	Rarely	Sometimes	Often	Always
9	I felt worthless	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10	I felt helpless	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11	I felt depressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12	I felt hopeless	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<u>Fatigue</u>					
	During the past 7 days...	Not at all	A little bit	Somewhat	Quite a bit	Very much
13	I feel fatigued	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14	I have trouble <u>starting</u> things because I am tired	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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? ...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

16	How fatigued were you on average?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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Sleep Disturbance

In the past 7 days...

		Very poor	Poor	Fair	Good	Very good
17	My sleep quality was	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

In the past 7 days...

		Not at all	A little bit	Somewhat	Quite a bit	Very much
18	My sleep was refreshing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

19	I had a problem with my sleep	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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20	I had difficulty falling asleep	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

22	I have trouble doing all of the family activities that I want to do	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
----	---	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------

23	I have trouble doing all of my usual work (include work at home)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
----	--	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------

24	I have trouble doing all of the activities with friends that I want to do	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
----	---	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------

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?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

26	How much did pain interfere with work around the home?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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27	How much did pain interfere with your ability to participate in social activities? .	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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28	How much did pain interfere with your household chores?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
----	---	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------

Pain Intensity

In the past 7 days...

29	How would you rate your pain on average?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		0	1	2	3	4	5	6	7	8	9	10
		No pain										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?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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)

<u>SERIOUS ADVERSE EVENT REPORT</u>					
Study Site:					
Date of report:		<input type="checkbox"/> Initial report <input type="checkbox"/> Follow up report F/up No.: _____			
A. PATIENT DETAILS					
Subject number:		Patient initials:	□□□□	Date of birth:	□□-□□-□□□□
Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female		Height:	□□□□ cm	Weight:	□□□□ kg
B. SERIOUS ADVERSE EVENT DETAILS					
Serious Adverse Event: <i>(Diagnosis where available)</i>				Start date:	□□-□□-□□□□

1 Event Narrative (include relevant symptoms, lab tests performed as required and any other action taken):	
2	
3	
4	
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11	
12	
13	
14 C. SEVERITY OF EVENT	
15 <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Unknown	
16	
17	
18 D. SERIOUSNESS CRITERIA (select all that	
19 <input type="checkbox"/> Fatal (results in death)	
20	
21 <input type="checkbox"/> Life-threatening	
22	
23 <input type="checkbox"/> Requires Hospitalisation or Prolongs	
24 Hospitalisation	
25 (if ticked, complete section H)	
26	
27	
28	
29 <input type="checkbox"/> Results in Persistent or Significant	
30 Disability/Incapacity	
31	
32 <input type="checkbox"/> Causes a Congenital Abnormality/Birth Defect	
33	
34 <input type="checkbox"/> Medically Important/Significant event	
35	
36	
37	
38 E. CAUSALITY	
39	
40 <i>In the investigator's opinion was the adverse event</i>	
41 <i>related to study treatment?</i>	
42	
43 <input type="checkbox"/> Not related	
44	
45 <input type="checkbox"/> Unlikely related	
46	
47 <input type="checkbox"/> Possibly Related	
48	
49 <input type="checkbox"/> Probably Related	
50	
51 <input type="checkbox"/> Definitely Related	
52	
53 <input type="checkbox"/> Not applicable (SAE occurring outside the 6-	
54 week treatment window)	
55	
56	
57	
58 F. EXPECTEDNESS	
59	
60	

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
					<input type="checkbox"/> Ongoing
					<input type="checkbox"/> Ongoing
					<input type="checkbox"/> Ongoing
					<input type="checkbox"/> Ongoing

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

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

For peer review only

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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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

1
2
3 penalty. Whatever your decision, it will not affect your relationship with the Hospital, Local Health
4 District and The University of Sydney, or the standard of care you receive now or in the future.
5

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

7
8 Aside from giving up your time to participate in an interview, we do not expect that there will be
9 any risks or costs associated with taking part in this study.

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

11
12 By participating, you will be contributing to important research that helps us understand whether
13 the new care pathway we are testing is acceptable to patients with back pain. The results may help
14 us refine the care pathway before testing it in large research study.
15

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

17
18 By providing your consent, you are agreeing to us collecting personal information about you for
19 the purposes of this research study. Your information will only be used for the purposes outlined
20 in this Participant Information Statement, unless you consent otherwise.

21
22 Your information will be stored and analysed securely on a research database within the Institute
23 for Musculoskeletal Health, Sydney Local Health District, and your identity/information will be
24 kept strictly confidential, except as required by law. Study findings may be published, but you will
25 not be individually identifiable in these publications.
26

27
28 We will keep the information we collect for this study, and we may use it in future project. By
29 providing your consent you are allowing us to use your information in future projects, however all
30 identifying data will remain strictly confidential. We don't know at this stage what these other
31 projects may involve. We will seek ethical approval before using the information in these future
32 projects.

33
34 If you are allocated to the new pathway, you may be provided with an exercise program delivered
35 via a mobile App (PhysiTrack). No data will be collected through the PhysiTrack App and
36 therefore no data will be sent to the developer. The App will simply be used to show you which
37 exercises to do. PhysiTrack is also not a medical device hence does not require TGA approval.
38 PhysiTrack is simply an App that allows physiotherapists to put together an exercise program to
39 allow you to receive written and video instructions on how to perform the exercises correctly.
40 PhysiTrack is essentially a substitute for drawing an exercise program on a piece of paper. The
41 exercises in PhysiTrack include a range of exercises physiotherapists have been prescribing for
42 patients over many years.
43

44
45 As with any home-exercise program prescribed by a physiotherapist, you are free to stop exercising
46 or using the PhysiTrack app at any time if you experience an increase in your symptoms or are not
47 comfortable performing an exercise.
48

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

50
51 You have a right to receive feedback about the overall results of this study. You can tell us that
52 you wish to receive feedback by ticking a box and leaving your email when you complete the
53 questionnaires. This feedback will be in the form of a one-page lay summary of the results. You
54 will receive this feedback after the study is finished.
55

56 **11. What do I do next?**

1
2
3 When you have read this information, please store it in a safe place. If you understand what you
4 have read and would like to participant, please sign and return the consent form.
5

6 If you would like to know more about the study at any stage and ask questions, please feel free to
7 contact Mr Christopher Han (research assistant) at Christopher.han@sydney.edu.au or (02) 8627
8 7423.
9

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

11 This study has been approved by the Ethics Review Committee (RPAH Zone) of the Sydney Local
12 Health District.
13

14 If you have any complaints or concerns about any aspect of this study, you should call our research
15 team who will do their best to address any issues. If your concerns are not able to be addressed,
16 you can contact the Executive Officer of the Ethics Review Committee on 02 9515 6766 and quote
17 protocol number X21-0221.
18
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21 This information sheet is for you to keep.
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THE UNIVERSITY OF
SYDNEY

ABN 15 211 513 464

Dr Joshua Zadro
Chief Investigator
Research Fellow

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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 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.

- 1
2
3 • I would like to receive a copy of the study results when they become available. My email address
4 is: _____
5
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7
8 • I understand that, during the course of this study, my medical records may be accessed by Sydney
9 Local Health District by regulatory authorities or by the Ethics Committee approving the research in
10 order to verify results and determine that the study is being carried out correctly.
11
12 • I understand that the SLHD software license for REDCap (Research Electronic Data Capture) will be
13 used to manage the collection and storage of my research data.
14
15 • I have had an opportunity to ask questions and I am satisfied with the answers I have received.
16
17 • I freely choose to participate in this study and understand that I can withdraw at any time.
18
19 • I consent to the future use of any data / samples I provide for research purposes. I understand that
20 before they can use any data I provide, they must seek additional ethics approval. YES/ NO
21
22 • I consent for other research collaborators to use any data / samples I provide for future research
23 purposes. I understand that before they can use my data, they must seek additional ethics approval.
24 YES/NO
25
26 • I also understand that the research study is strictly confidential.
27
28 • I hereby agree to participate in this research study.
29
30
31 • I consent to the storage and use of my information collected from me for use, as described in the
32 relevant section of the Participant Information Sheet, for:
33
34 -This specific research project
35 -Other research that is closely related to this research project
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37 -Any future research
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41 Participant Name: _____
42 Participant Signature: _____
43 Date: _____
44 Name of Person conducting informed consent: _____
45 Signature of Person conducting informed consent: _____
46 Date: _____
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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?

1
2
3 By participating, you will be contributing to important research that helps us understand whether
4 the new care pathway we are testing is acceptable to patients with back pain and/or leg pain
5 radiating from the back and clinicians providing care to these patients. The results may help us
6 refine the care pathway before testing it in large research study.
7

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

9
10 By providing your consent, you are agreeing to us collecting personal information about you for
11 the purposes of this research study. Your information will only be used for the purposes outlined
12 in this Participant Information Statement, unless you consent otherwise.
13

14 Your information will be stored and analysed securely on a research database within the Institute
15 for Musculoskeletal Health, Sydney Local Health District, and your identity/information will be
16 kept strictly confidential, except as required by law. Study findings may be published, but you will
17 not be individually identifiable in these publications.
18

19 We will keep the information we collect for this study, and we may use it in future project. By
20 providing your consent you are allowing us to use your information in future projects, however all
21 identifying data will remain strictly confidential. We don't know at this stage what these other
22 projects may involve. We will seek ethical approval before using the information in these future
23 projects.
24

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

26
27 You have a right to receive feedback about the overall results of this study. You can tell us that
28 you wish to receive feedback by ticking a box and leaving your email when you complete the
29 questionnaires. This feedback will be in the form of a one-page lay summary of the results. You
30 will receive this feedback after the study is finished.
31

32 **11. What do I do next?**

33
34 When you have read this information, please store it in a safe place. If you understand what you
35 have read and would like to participate, please sign and return the consent form.
36

37 If you would like to know more about the study at any stage and ask questions, please feel free to
38 contact Mr Christopher Han (research assistant) at Christopher.han@sydney.edu.au or (02) 8627
39 7423.
40

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

42 This study has been approved by the Ethics Review Committee (RPAH Zone) of the Sydney Local
43 Health District.
44

45 If you have any complaints or concerns about any aspect of this study, you should call our research
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47 you can contact the Executive Officer of the Ethics Review Committee on 02 9515 6766 and quote
48 protocol number **xxxx**.
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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.

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50 Signature of Person conducting informed consent: _____
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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

1
2
3 ***Participants with potential radiculopathy (and people in the usual-care group)***
4

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

7 Prompts:

- 8
- 9 • How did you find the appointment(s)? What was helpful? What wasn't?
 - 10 • Can you tell me about the process of scheduling appointments? What was the availability
 - 11 of your rheumatologist and physiotherapist?
 - 12 • Did you always have the same person?
 - 13 • What is it about seeing a rheumatologist or physiotherapist in person that you like or
 - 14 don't like?
 - 15 • How convenient was it for you to travel to and attend a face-to-face appointment(s) at the
 - 16 hospital?
 - 17 • Can you comment on the frequency of your appointments? Is that what you expected?
 - 18 Why or why not?
 - 19 • Do you feel as though you got any benefit from the appointment(s)?
 - 20 • Would you recommend this method of delivering treatment for others? What kinds of
 - 21 people would this approach suit? Who wouldn't it suit?
 - 22 • Do you feel you could have a got a similar benefit from a telephone or virtual
 - 23 consultation(s)?
 - 24 • What else would you liked to have received as part of your treatment during the trial?

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

26 Thank you so much for your time.
27
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32
33 **INTERVIEW GUIDE FOR CLINICIANS**
34

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

36
37 Hi, my name is [name and background]. Thank you for taking part in this interview. Researchers
38 and health professionals at The University of Sydney and Royal Prince Alfred Hospital want to
39 find out whether a new treatment pathway using telephone and virtual appointments, and App-
40 based exercise programs, helps people receive treatment sooner and get better sooner. We also
41 want to see if the new treatment pathway is acceptable to clinicians.
42

43 We would like to ask you questions about the treatment you provided in the Back Clinic as part
44 of the trial. You can change your mind about talking to me at any time before or during the
45 interview and stop the interview at any time.
46

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

48 Thank you [name] for agreeing to take part. We will use your feedback and the feedback of
49 others to write a summary of what people have told us. There will be absolutely no identification
50 of any real names or identification of your professional details.
51
52

53 Are you happy for me to record the interview? Do you have any questions before we start?
54
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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	✓

1	Objectives	7	Specific objectives or hypotheses	✓
2				
3	Trial design	8	Description of trial design including type of trial (eg,	✓
4			parallel group, crossover, factorial, single group),	
5			allocation ratio, and framework (eg, superiority,	
6			equivalence, noninferiority, exploratory)	
7				
8				
9				
10	Methods: Participants, interventions, and outcomes			
11				
12	Study setting	9	Description of study settings (eg, community clinic,	✓
13			academic hospital) and list of countries where data will	
14			be collected. Reference to where list of study sites can	
15			be obtained	
16				
17	Eligibility criteria	10	Inclusion and exclusion criteria for participants. If	✓
18			applicable, eligibility criteria for study centres and	
19			individuals who will perform the interventions (eg,	
20			surgeons, psychotherapists)	
21				
22				
23	Interventions	11a	Interventions for each group with sufficient detail to	✓
24			allow replication, including how and when they will be	
25			administered	
26				
27				
28		11b	Criteria for discontinuing or modifying allocated	✓
29			interventions for a given trial participant (eg, drug dose	
30			change in response to harms, participant request, or	
31			improving/worsening disease)	
32				
33		11c	Strategies to improve adherence to intervention	N/A
34			protocols, and any procedures for monitoring	
35			adherence (eg, drug tablet return, laboratory tests)	
36				
37				
38		11d	Relevant concomitant care and interventions that are	✓
39			permitted or prohibited during the trial	
40				
41	Outcomes	12	Primary, secondary, and other outcomes, including the	✓
42			specific measurement variable (eg, systolic blood	
43			pressure), analysis metric (eg, change from baseline,	
44			final value, time to event), method of aggregation (eg,	
45			median, proportion), and time point for each outcome.	
46			Explanation of the clinical relevance of chosen efficacy	
47			and harm outcomes is strongly recommended	
48				
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50	Participant	13	Time schedule of enrolment, interventions (including	✓
51	timeline		any run-ins and washouts), assessments, and visits for	
52			participants. A schematic diagram is highly	
53			recommended (see Figure)	
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2	Sample size	14	Estimated number of participants needed to achieve	✓
3			study objectives and how it was determined, including	
4			clinical and statistical assumptions supporting any	
5			sample size calculations	
6				
7	Recruitment	15	Strategies for achieving adequate participant enrolment	✓
8			to reach target sample size	
9				

Methods: Assignment of interventions (for controlled trials)

Allocation:

14	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	✓
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24	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	✓
25				
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30	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	✓
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32				
33				
34	Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	✓
35				
36				
37				
38				
39		17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	✓
40				
41				
42				

Methods: Data collection, management, and analysis

45	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	✓
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56		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	✓
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2	Data	19	Plans for data entry, coding, security, and storage,	✓
3	management		including any related processes to promote data quality	
4			(eg, double data entry; range checks for data values).	
5			Reference to where details of data management	
6			procedures can be found, if not in the protocol	
7				
8	Statistical	20a	Statistical methods for analysing primary and	✓
9	methods		secondary outcomes. Reference to where other details	
10			of the statistical analysis plan can be found, if not in the	
11			protocol	
12				
13				
14		20b	Methods for any additional analyses (eg, subgroup and	N/A
15			adjusted analyses)	
16				
17		20c	Definition of analysis population relating to protocol	✓
18			non-adherence (eg, as randomised analysis), and any	
19			statistical methods to handle missing data (eg, multiple	
20			imputation)	
21				
22				
23	Methods: Monitoring			
24				
25	Data monitoring	21a	Composition of data monitoring committee (DMC);	✓
26			summary of its role and reporting structure; statement	
27			of whether it is independent from the sponsor and	
28			competing interests; and reference to where further	
29			details about its charter can be found, if not in the	
30			protocol. Alternatively, an explanation of why a DMC is	
31			not needed	
32				
33				
34		21b	Description of any interim analyses and stopping	N/A
35			guidelines, including who will have access to these	
36			interim results and make the final decision to terminate	
37			the trial	
38				
39				
40	Harms	22	Plans for collecting, assessing, reporting, and	✓
41			managing solicited and spontaneously reported	
42			adverse events and other unintended effects of trial	
43			interventions or trial conduct	
44				
45				
46	Auditing	23	Frequency and procedures for auditing trial conduct, if	✓
47			any, and whether the process will be independent from	
48			investigators and the sponsor	
49				
50				
51	Ethics and dissemination			
52				
53	Research ethics	24	Plans for seeking research ethics	✓
54	approval		committee/institutional review board (REC/IRB)	
55			approval	
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1				
2	Protocol	25	Plans for communicating important protocol	✓
3	amendments		modifications (eg, changes to eligibility criteria,	
4			outcomes, analyses) to relevant parties (eg,	
5			investigators, REC/IRBs, trial participants, trial	
6			registries, journals, regulators)	
7				
8	Consent or	26a	Who will obtain informed consent or assent from	✓
9	assent		potential trial participants or authorised surrogates, and	
10			how (see Item 32)	
11				
12				
13		26b	Additional consent provisions for collection and use of	N/A
14			participant data and biological specimens in ancillary	
15			studies, if applicable	
16				
17	Confidentiality	27	How personal information about potential and enrolled	✓
18			participants will be collected, shared, and maintained in	
19			order to protect confidentiality before, during, and after	
20			the trial	
21				
22				
23	Declaration of	28	Financial and other competing interests for principal	✓
24	interests		investigators for the overall trial and each study site	
25				
26	Access to data	29	Statement of who will have access to the final trial	✓
27			dataset, and disclosure of contractual agreements that	
28			limit such access for investigators	
29				
30				
31	Ancillary and	30	Provisions, if any, for ancillary and post-trial care, and	N/A
32	post-trial care		for compensation to those who suffer harm from trial	
33			participation	
34				
35	Dissemination	31a	Plans for investigators and sponsor to communicate	✓
36	policy		trial results to participants, healthcare professionals,	
37			the public, and other relevant groups (eg, via	
38			publication, reporting in results databases, or other	
39			data sharing arrangements), including any publication	
40			restrictions	
41				
42				
43				
44		31b	Authorship eligibility guidelines and any intended use of	✓
45			professional writers	
46				
47		31c	Plans, if any, for granting public access to the full	✓
48			protocol, participant-level dataset, and statistical code	
49				
50				
51	Appendices			
52	Informed consent	32	Model consent form and other related documentation	✓
53	materials		given to participants and authorised surrogates	
54				
55	Biological	33	Plans for collection, laboratory evaluation, and storage	N/A
56	specimens		of biological specimens for genetic or molecular	
57			analysis in the current trial and for future use in	
58			ancillary studies, if applicable	
59				
60				

1 *It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013
2 Explanation & Elaboration for important clarification on the items. Amendments to the
3 protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT
4 Group under the Creative Commons "[Attribution-NonCommercial-NoDerivs 3.0 Unported](#)"
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BMJ Open

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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3 1 **The feasibility of delivering and evaluating stratified care integrated with telehealth**
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5 2 **(‘Rapid Stratified Telehealth’) for patients with low back pain: protocol for a feasibility**
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7
8 3 **and pilot randomised controlled trial**
9

10 4 Joshua R Zadro^{a*}, Christopher Needs^b, Nadine E Foster^{c,d}, David Martens^b, Danielle M
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12 5 Coombs^a, Gustavo C Machado^a, Cameron Adams^b, Christopher S Han^a, Christopher G Maher^a.

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3 18 **ABSTRACT**
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5 19 **Introduction:** Long waiting time is an important barrier to accessing recommended care for
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7
8 20 low back pain (LBP) in Australia's public health system. This study describes the protocol
9
10 21 for a randomised controlled trial (RCT) that aims to establish the feasibility of delivering and
11
12 22 evaluating stratified care integrated with telehealth ('Rapid Stratified Telehealth') which aims
13
14 23 to reduce waiting times for LBP.

15
16 24 **Methods and analysis:** We will conduct a single-centre feasibility and pilot RCT with nested
17
18 25 qualitative interviews. Sixty participants with LBP newly referred to a hospital outpatient
19
20 26 clinic will be randomised to receive Rapid Stratified Telehealth or usual care. Rapid Stratified
21
22 27 Telehealth involves matching the mode and type of care to participants' risk of persistent
23
24 28 disabling pain (using the Keele STarT MSK Tool) and presence of potential radiculopathy.
25
26 29 'Low risk' patients are matched to one session of advice over the telephone, 'medium risk' to
27
28 30 telehealth physiotherapy plus App-based exercises, 'high risk' to telehealth physiotherapy,
29
30 31 App-based exercises, and an online pain education program, and 'potential radiculopathy'
31
32 32 fast tracked to usual in-person care. Primary outcomes include the feasibility of delivering
33
34 33 Rapid Stratified Telehealth (i.e. acceptability assessed through interviews with clinicians and
35
36 34 patients, intervention fidelity, appointment duration, App useability, and online pain
37
38 35 education program usage) and evaluating Rapid Stratified Telehealth in a future trial (i.e.
39
40 36 recruitment rates, consent rates, loss to follow up, and missing data). Secondary outcomes
41
42 37 include waiting times, number of appointments, intervention and healthcare costs, clinical
43
44 38 outcomes (pain, function, quality of life, satisfaction), healthcare use and adverse events.
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46 39 Quantitative analyses will be descriptive and inform a future adequately-powered RCT.
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48 40 Interview data will be analysed using thematic analysis.
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3 41 **Ethics and dissemination:** This study has received approval from the Ethics Review
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5 42 Committee (RPAH Zone: X21-0221). Results will be published in peer-reviewed journals and
6
7 43 presented at conferences.
8
9

10 44 **Trial registration:** ANZCTR Trial Registration: ACTRN12621001104842.
11

12 45 **Key words:** low back pain; stratified care; telehealth; sciatica; randomised controlled trial;
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14 46 pilot; feasibility.
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3 49 **Strengths and limitations of this study**
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- 6 50 - This will be the first study to investigate the feasibility of delivering and evaluating a
7
8 51 novel intervention integrating stratified care with telehealth ('Rapid Stratified
9
10 52 Telehealth') to reduce waiting times for people with low back pain and ensure more
11
12
13 53 efficient use of health resources
14
15 54 - Feasibility will be established using mixed-methods and pre-specified feasibility targets
16
17 55 - Feasibility will be established in a hospital outpatient clinic, facilitating delivery and
18
19
20 56 evaluation of Rapid Stratified Telehealth in similar clinics
21
22 57 - The use of a feasibility and pilot study design means the findings cannot be used to
23
24 58 make conclusions about the effectiveness of Rapid Stratified Telehealth for reducing
25
26 59 waiting times and improving clinical outcomes in people with low back pain
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29 60 - Given the nature of the intervention, it will not be possible to blind those delivering or
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31 61 receiving the intervention
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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

1
2
3 87 physiotherapists are aware of LBP guidelines[9], it is likely many are aware of or are using
4
5 88 some components of risk stratification for their patients with LBP.
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8 89 Most previous stratified care studies have not considered the mode of care delivery, although
9
10 90 some that do are underway (e.g. stratified care integrated with telehealth for people with neck
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12 91 and/or shoulder complaints[10]). Telehealth provides similar improvements in pain and
13
14 92 function for people with musculoskeletal conditions (including LBP) compared to in-person
15
16 93 care[11, 12] and appears to be cost-effective in some settings[13] (although most trials of
17
18 94 telehealth have not evaluated cost-effectiveness[14]). Combining stratified care with telehealth
19
20 95 could free up clinic-based appointments for patients who need these more, reduce waiting
21
22 96 times, and improve time to intervention.
23
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26
27 97 A telephone assessment and treatment service for patients with LBP and other musculoskeletal
28
29 98 conditions was tested in a large UK RCT (n=2,249)[15] and holds promise for improving
30
31 99 access to effective, affordable care for LBP in Australia. Physiotherapists assessed patients via
32
33 100 telephone supported by a computerised system, to help them diagnose the musculoskeletal
34
35 101 problem and determine whether the patient could be managed with advice, information and
36
37 102 exercise via telephone appointments and postal information, or whether the patient needed
38
39 103 assessment and treatment in person. This approach provided similar improvements in physical
40
41 104 health compared to usual clinic-based care, while reducing waiting times by 27 days and the
42
43 105 number of clinic appointments by 40%. This model of care was acceptable to patients and
44
45 106 clinicians in the UK.[16]
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50
51 107 The LBP Clinic at Royal Prince Alfred Hospital (Sydney, Australia) provides a suitable context
52
53 108 to examine the feasibility of delivering and evaluating stratified care integrated with telehealth
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55 109 in Australia's public health system. This clinic is staffed by physiotherapists and
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57 110 rheumatologists and receives referrals from Primary Care and the Emergency Department. Due
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3 111 to limited capacity for new appointment slots, patients referred from primary care experience
4
5 112 substantial waiting times for appointments (estimated between 3-12 months). There is currently
6
7 113 no strategy for stratifying care based on the complexity of a patient's condition in this clinic
8
9 114 (e.g. risk of persistent pain, potential radiculopathy). Currently, using the referral information
10
11 115 provided, all patients are triaged for potential red flags while the rest are given the next
12
13 116 available in-person appointment. We expect there will be a greater need to focus on increasing
14
15 117 the acceptability of stratified care (vs. telehealth) given this clinic already implemented
16
17 118 telehealth appointments in response to COVID-19.

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22 119 The primary aim of this feasibility and pilot RCT is to determine the feasibility of:

- 23
24 120 i) delivering stratified care integrated with eHealth ('Rapid Stratified Telehealth') for
25
26 121 patients with low back pain referred to a hospital outpatient clinic; and
27
28 122 ii) a future large RCT to test the effectiveness and cost-effectiveness of this new model
29
30 123 of stratified care.

31
32
33 124 The secondary aims are to describe waiting times, number of appointments, intervention and
34
35 125 healthcare costs, clinical outcomes (pain, function, quality of life, satisfaction), healthcare use
36
37 126 and adverse events in the two arms of the trial (Rapid Stratified Telehealth and usual care).

38
39 127 For the future RCT, we hypothesise that Rapid Stratified Telehealth will reduce treatment
40
41 128 waiting times (while not compromising clinical outcomes) compared to usual care, be cost-
42
43 129 effective and safe.

44 45 46 47 48 130 **2. Methods and analysis**

49 50 131 **2.1. Study design**

51
52 132 We will conduct a single-blind, single-site, two-arm, parallel feasibility and pilot RCT with
53
54 133 nested qualitative interviews. The trial has been prospectively registered at the Australian and
55
56 134 New Zealand Clinical trial registry (ACTRN12621001104842) and will be reported in
57
58
59 135 accordance with the CONSORT extension for randomised pilot and feasibility trials.[17] The

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3 136 nested qualitative study of clinician and patient acceptability of Rapid Stratified Telehealth
4
5 137 will be reported according to the COREQ (Consolidated Criteria for Reporting Qualitative
6
7
8 138 Research).[18] This protocol has been reported according to SPIRIT (Standard Protocol
9
10 139 Items: Recommendations for Interventional Trials) (Supplementary File 1).[19]
11
12

13 140 **2.2. Participants and recruitment**

15 141 Sixty participants will be recruited from the LBP Clinic (hospital outpatient clinic where
16
17 142 rheumatologists typically refer patients who would benefit from exercise and other
18
19
20 143 physiotherapy-related interventions to physiotherapy) at Royal Prince Alfred Hospital,
21
22 144 Sydney, Australia, over a 6-month period (expected September 2021 to February 2022). New
23
24 145 referrals will be screened by a rheumatologist according to the inclusion and exclusion
25
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27 146 criteria (Box 1). Our target sample size of 60 is based on a rule of thumb for feasibility
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29 147 studies.[20]
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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

149

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

159 **2.3. Data collection**

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

176 **2.4. Interventions and procedures**

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

- 178 1. Rapid Stratified Telehealth;
- 179 2. Usual Care

180 The secure random allocation schedule will be computer-generated independently and kept
181 off site. Randomisation will be blocked to ensure equal numbers in both groups. Risk
182 subgroups, as assessed by the Keele STarT MSK tool (low, medium, high risk), and the
183 presence of radicular pain (single item question in the baseline questionnaire), will be used as

1
2
3 184 stratification variables. This will ensure the intervention and control groups have a similar
4
5 185 proportion of participants in the four subgroups (Table 1). The allocation schedule will be
6
7
8 186 concealed from potential participants and from all on-site staff associated with the trial. The
9
10 187 trial physiotherapist will contact the central randomisation unit by telephone or email to be
11
12 188 notified of the treatment assignment.

15 189 **2.4.1. Rapid Stratified Telehealth**

16
17 190 The mode and type of care will be matched to the patient's risk of persistent disabling pain,
18
19 191 categorised as low, medium or high (using the Keele STarT MSK Tool[21]), as well as the
20
21 192 presence of potential (or suspected) radiculopathy (score of 3 or more on a clinician-
22
23 193 developed screening questionnaire administered via telephone; Supplementary File 3). The
24
25 194 presence of potential radiculopathy was used for subgrouping as per the telephone assessment
26
27 195 and treatment UK trial[15, 22] and based on the preference of clinicians working in the LBP
28
29 196 Clinic. Table 1 describes the intervention.

34 197 **2.4.2. Usual care**

35
36 198 The usual care protocol is in Table 1.

37
38
39 199 Since this is a pragmatic comparison of two real-life models of care, there is no restriction on
40
41 200 participants' healthcare use outside the study. Participants who withdraw from the trial will
42
43 201 re-join the waiting list in the position they would have likely been had they not participated.

47 202 **2.5. Outcomes**

48
49 203 The primary outcomes are feasibility measures. Feasibility outcomes for 'delivering' Rapid
50
51 204 Stratified Telehealth include:

- 54 205 • Clinician and patient acceptability of the intervention (through semi-structured
55
56 206 interviews with clinicians and focus groups with patients where possible; see section
57
58 207 2.6)

- 1
2
3 208 • Percentage of participants who are only provided care that matches the protocol for
4
5 209 their treatment subgroup ('treatment fidelity' as assessed by treatment recording
6
7 210 forms developed for this trial; Supplementary File 4). Clinicians will be instructed to
8
9 211 be consistent when reporting treatment choices in the treatment recording forms and
10
11 212 clinical notes. Treatment recording forms will be audited throughout the trial.
12
13 213 Clinicians will be informed if they are providing care that does not match the protocol
14
15 214 for a given subgroup and work with one of the trial investigators to overcome any
16
17 215 barriers to implementing the protocol
18
19 216 • Mean or median appointment times for each stratified group (treatment stage) and
20
21 217 whether this changes over time
22
23 218 • Self-reported useability of the PhysiTrack App provided to participants in the Rapid
24
25 219 Virtual Stratified Care group (medium- and high-risk) assessed using the System
26
27 220 Usability Scale (SUS) at 6 months, 0 to 100 score. Score above 70 indicates above
28
29 221 average usability (as assessed by System Useability Scale, Supplementary File 5)[23,
30
31 222 24]
32
33 223 • Percentage of participants in Rapid Stratified Telehealth group (high-risk) who
34
35 224 complete all modules of the online pain education program (Supplementary File 4)
36
37
38 225 Feasibility outcomes for 'evaluating' Rapid Stratified Telehealth in a future multi-centre
39
40 226 randomised controlled trial include:
41
42
43 227 • Number of participants recruited per week
44
45 228 • Number of eligible participants per week
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47 229 • Percentage of participants who consent to be part of the study from those who were
48
49 230 eligible (consent rate)
50
51 231 • Percentage of participants lost to follow-up at 6 weeks and 6 months
52
53 232 • Percentage of missing data for outcome measures at 6 weeks and 6 months
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3 233 Based on a 2021 Cochrane review on strategies to improve retention to RCTs,[25] we will
4
5 234 implement the following:

- 8 235 • Paid return postage envelopes
- 10 236 • Including a pen with posted questionnaires
- 12 237 • Pre-notifications and reminders via SMS or email

15 238 Secondary outcomes include treatment waiting time (i.e. time in days from LBP Clinic
16
17 239 receiving referral to first treatment; either face-to-face or telehealth), the number of
18
19 240 consultations patients receive, intervention and healthcare costs, clinical outcomes, healthcare
20
21 241 use and adverse events. Since waiting time is an outcome, we will create separate waiting
22
23 242 lists for each group and adjust for time staff spend assessing and treating patients from each
24
25 243 list.

29 244 We will collect data on the cost of intervention delivery and healthcare use. Costs will be
30
31 245 considered from a health system perspective. Intervention costs will be based on clinician
32
33 246 time and wage, the cost of PhysiTrack licences and other resources required to deliver the
34
35 247 intervention. Costs related to the LBP Clinic will be determined using local costing models in
36
37 248 consultation with local management. Healthcare use costs will be estimated from data on
38
39 249 healthcare use (see below) and allow for estimates of costs to the healthcare system, outside
40
41 250 the LBP Clinic.

45 251 Clinical outcomes and healthcare use will be obtained at baseline immediately prior to
46
47 252 randomisation, and at 6 weeks and 6 months post-randomisation (Supplementary File 6).

50 253 Adverse events data will be collected at 2 weeks, 6 weeks and 6 months post-randomisation
51
52 254 (Supplementary File 7). Data will be collected via email, postal mail or telephone (based on
53
54 255 participant preference). Data collected by telephone will be performed by a blinded assessor.

56 256 The success of blinding will be checked at the 6-week and 6-month assessment by asking the
57
58
59
60

257 assessor if they have become unblinded. If the assessor becomes unblinded at 6 weeks, a new
258 assessor will be used for the 6-month assessment. All personnel responsible for collecting
259 data will be appropriately trained.

260 Clinical outcomes include:

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

265 *2. Pain measured* using a 0–10 Numerical Pain Rating Scale (NPRS). Participants will be
266 asked to rate their average pain over the past 24 hours on a 0–10 numerical rating scale
267 anchored at each end with “no pain” and “worst pain imaginable”. The NPRS is a valid and
268 reliable tool for measuring acute and chronic pain.[27]

269 *3. Quality of life* using the PROMIS-29 Profile v2.0. This questionnaire assesses pain
270 intensity, using a 0–10 NPRS (as above), and seven other health domains (physical function,
271 anxiety, depression, fatigue, sleep disturbance, ability to participate in social roles and
272 activities, pain interference) each including multiple items scored on a 5-point Likert Scale.
273 Summary scores for physical and mental health have been shown to be a reliable and valid
274 measure of quality of life in people with chronic conditions.[28]

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

279 For healthcare use, participants will be asked if they have used or are currently using any
280 healthcare services (e.g. GP, physiotherapy, imaging), or community health or other services

1
2
3 281 (e.g. meals on wheels) for their LBP. Participants will also be asked whether they are
4
5 282 currently taking any prescription or over the counter medication for their LBP, and to specify
6
7
8 283 the type and dose of their medication.
9

10 284 We will collect data on adverse events (AEs) and serious adverse events (SAEs; those which
11
12 285 are life threatening, result in hospitalisation, significant disability or incapacity, or death). At
13
14
15 286 2 weeks, 6 weeks and 6 months, participants will be asked whether they have developed a
16
17 287 new medical condition or experienced an exacerbation of an existing condition since
18
19 288 beginning the study or last follow-up point (e.g. dizziness, increased pain). If the participant
20
21 289 answers yes, they will be asked to describe this. When an AE or SAE occurs that is
22
23 290 potentially related to the treatments provided in the trial, the trial physiotherapist will record
24
25 291 all the relevant information regarding the AE/SAE, including the type of event, the start and
26
27 292 stop dates, the action taken, and causality of the event (Supplementary File 7). The Principal
28
29 293 Investigator will be responsible for reporting SAEs to the Ethics committee.
30
31
32

33 34 294 **2.6. Semi-structured interviews and focus groups**

35 36 295 **2.6.1. Participants and recruitment**

37
38
39 296 To explore the acceptability of Rapid Stratified Telehealth, we will conduct semi-structured
40
41 297 interviews with the physiotherapists and rheumatologists delivering Rapid Stratified
42
43 298 Telehealth and focus groups (where possible) with 15 patients who were managed using
44
45 299 Rapid Stratified Telehealth. Exact numbers may vary based on saturation of elicited themes.
46
47
48 300 We will purposively sample patients to achieve diversity in age, gender, ethnicity, treatment
49
50 301 subgroup, and response to the intervention. We will seek participation from patients at the 6-
51
52 302 month follow-up and from clinicians after all patients have been recruited.
53

54
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56 303 The trial physiotherapist will email or post clinicians and patients a Participant Information
57
58 304 Statement and Participant Consent Form for the qualitative interviews and arrange a time for
59
60

1
2
3 305 an intervention or focus group (Supplementary File 8). Clinicians and patients will be made
4
5 306 aware that participation is voluntary, and that non-consent to participate or withdrawal from
6
7
8 307 this study will have no repercussions.
9

10 308 **2.6.2. Data collection**

11 309 Interviews and focus groups will be conducted via telephone or videoconference (e.g. Zoom)
12
13 310 or face-to-face at the Institute for Musculoskeletal Health, Royal Prince Alfred Hospital,
14
15 311 depending on clinician and patient preferences. Interviews and focus groups will be conducted
16
17 312 by a researcher with experience in conducting qualitative interviews. One-on-one interviews
18
19 313 with clinicians will last about 30 minutes and be audio-recorded and transcribed verbatim for
20
21 314 analysis. Focus groups will last about 1 hour, include a maximum of 8 participants and be
22
23 315 audio-recorded and transcribed verbatim for analysis. Where patients are unable to participate
24
25 316 in a focus group, one-on-one interviews will be offered.
26
27
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29
30

31 317 Interviews and focus groups will explore clinician and patient acceptability of Rapid Stratified
32
33 318 Telehealth. Specifically, what worked, what didn't work, and the pros and cons of the two
34
35 319 models of care from a clinician and patient perspective, and the perceived barriers and
36
37 320 facilitators for evaluating Rapid Stratified Telehealth in a multi-site trial from a clinician
38
39 321 perspective. Throughout the interviews and focus groups, clinicians and patients will be invited
40
41 322 to share their perspectives of the Rapid Stratified Telehealth approach and suggest
42
43 323 modifications that would increase its appeal and effectiveness for clinicians and patients. The
44
45 324 interview guide is in Supplementary File 9.
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49

50 325 The researcher facilitating the interviews and focus groups will take notes to highlight key
51
52 326 themes that emerge and direct further questioning. This will also enable the facilitator to
53
54 327 summarise information back to clinicians and patients at the end of the interview and give them
55
56 328 an opportunity to provide further information. Clinicians and patients will have the opportunity
57
58 329 to review the transcript of their interviews and focus groups prior to data analysis if they wish.
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60

330 2.7. Statistical analysis

331 2.7.1. Feasibility outcomes

332 The main analysis will focus on feasibility (process) outcomes and will investigate feasibility
333 outcomes for delivering Rapid Stratified Telehealth (acceptability, percentage of participants
334 in the intervention who are only provided care according to their treatment subgroup,
335 appointment durations, percentage of participants in the intervention who are comfortable
336 using the App and complete the online pain education program) and feasibility outcomes for
337 evaluating Rapid Stratified Telehealth in a future multi-centre randomised controlled trial
338 (recruitment rates, consent rates, percentage loss to follow up, and percentage missing data).

339 These data will be summarised using descriptive statistics (means and standard deviations,
340 median and interquartile ranges and counts and percentages, as appropriate).

341 The research team will review the feasibility outcomes at the completion of the study and
342 make a judgement about whether to proceed to planning an adequately powered, multi-site
343 trial. Meeting the following criteria would justify proceeding to a full trial:

- 344 i) Acceptable to clinicians and patients (according to qualitative interviews)
- 345 ii) Percentage of participants in the intervention who are only provided care
346 according to their treatment subgroup >75%
- 347 iii) Mean or median self-reported useability scores of the PhysiTrack App provided to
348 participants in the Rapid Virtual Stratified Care group (medium- and high-risk) >
349 70/100
- 350 iv) Percentage of participants in Rapid Stratified Telehealth group (high-risk) who
351 complete all modules of the self-directed online pain education program >75%
- 352 v) Recruitment rate of three or more participants per week over 6 months
- 353 vi) Consent rate of 50% or more over 6 months (similar to a UK trial[15])
- 354 vii) Loss to follow up <25% at 6 months

355 viii) Missing data in questionnaires <15%

356 **2.7.2. Secondary outcomes**

357 Waiting times, number of consultations patients receive, intervention and healthcare costs,
358 clinical outcomes, healthcare use and adverse events will be compared between Rapid
359 Stratified Telehealth and usual care using descriptive statistics (means and standard
360 deviations, median and interquartile ranges and counts and percentages, as appropriate) in
361 STATA version 16.0. No statistical inference testing will be performed as this is a feasibility
362 study.[29] Between-group mean differences and post-intervention standard deviations for
363 waiting time and physical function and/or the best available evidence from other trials in
364 similar topic areas will inform the sample size calculation for the future trial.

365 **2.7.3. Interview data**

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

374 **2.8. Patient and public involvement**

375 Physiotherapists working in the LBP Clinic and other members of the research team
376 discussed the protocol with four patients with LBP. Feedback was sought on study processes
377 (e.g. recruitment), study materials (e.g. participant information sheets, consent forms,

1
2
3 378 questionnaires), and the Rapid Stratified Telehealth intervention. Several changes to the
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5 379 protocol were made based on feedback from consumers.
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7

8 380 We initially thought baseline questionnaires (e.g. to assess potential radiculopathy) could
9
10 381 replace the initial telephone assessment by the Rheumatology Advanced trainee for participants
11
12 382 in the Rapid Stratified Telehealth group. However, consumers expressed that initial contact
13
14 383 with a Rheumatology Advanced trainee would reassure patients that their condition was not
15
16 384 serious, and that they had not been forgotten while on the waiting list. Consumers provided
17
18 385 positive feedback on the App-based exercise program and online pain education program.
19
20 386 Some consumers thought these tools may help patients access treatment earlier than if they
21
22 387 waited for an in-person appointment, reduce the risk of developing persistent symptoms, and
23
24 388 eliminate the need for in-person care entirely. Given concerns from consumers that older
25
26 389 patients might not be able to use the App-based exercise program or access the online pain
27
28 390 education program, we have allowed up to 12 telehealth consultations with a physiotherapist
29
30 391 over 6 months to facilitate use to these tools, and the option of being scheduled for a face-to-
31
32 392 face appointment if patients are not improving or dissatisfied with their care.
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39 393 Regarding the dissemination of the results of this study, participants will be offered to receive
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41 394 feedback about the overall results of this study when completing the baseline questionnaire.
42
43 395 This feedback will be in the form of a one-page lay summary of the results. Individual
44
45 396 participant results will be available on request from the Principal Investigator.
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49 397 **3. Ethics and dissemination**

50 51 398 **3.1. Ethics approval**

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53 399 This study has been granted ethics approval from the Ethics Review Committee (RPAH
54
55 400 Zone: X21-0221). Any protocol deviations will be submitted to the Ethics Review Committee
56
57 401 for review.
58
59
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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.

1
2
3 426 **Authors' contributions**
4

5 427 All authors critically revised the manuscript for important intellectual content and approved
6
7 the final manuscript. Please find below a detailed description of the role of each author:
8

- 9
10 429 - Joshua R Zadro: conception and design, drafting and revision of the manuscript, and
11
12 430 final approval of the version to be published
13
14 431 - Christopher Needs: conception and design, drafting and revision of the manuscript, and
15
16 432 final approval of the version to be published
17
18 433 - Nadine Foster: conception and design, drafting and revision of the manuscript, and final
19
20 434 approval of the version to be published
21
22 435 - David Martens: conception and design, drafting and revision of the manuscript, and
23
24 436 final approval of the version to be published
25
26 437 - Danielle M Coombs: conception and design, drafting and revision of the manuscript,
27
28 438 and final approval of the version to be published
29
30 439 - Gustavo C Machado: conception and design, drafting and revision of the manuscript,
31
32 440 and final approval of the version to be published
33
34 441 - Cameron Adams: conception and design, drafting and revision of the manuscript, and
35
36 442 final approval of the version to be published
37
38 443 - Christopher S Han: conception and design, drafting and revision of the manuscript, and
39
40 444 final approval of the version to be published
41
42 445 - Christopher G Maher: conception and design, drafting and revision of the manuscript,
43
44 446 and final approval of the version to be published
45
46
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49

50
51 447 The Corresponding Author (JZ) attests that all listed authors meet authorship criteria and that
52
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54
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56
57 450 this trial.
58
59
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1
2
3 451 **Competing interests:** All authors declare: no support from any organisation for the submitted
4
5 452 work; no financial relationships with any organisations that might have an interest in the
6
7 453 submitted work; no other relationships or activities that could appear to have influenced the
8
9 454 submitted work.

10
11
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13
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15
16 457 on the design, conduct or reporting of this study.

17
18
19 458 **Data availability statement:** Individual participant data (IPD) for this trial will be available
20
21 459 following publication of this study. This includes baseline and post-intervention data. Data
22
23 460 will be available to anyone upon reasonable request and with ethics approval (if applicable).
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3 462 **References**
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Table 1. Rapid Stratified Telehealth and usual care protocol

Treatment group and subgroup	Intervention protocol
<i>Rapid Stratified Telehealth</i>	
<i>Low risk of persistent pain</i> (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.
<i>Medium risk of persistent pain</i> (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.
<i>High risk of persistent pain</i> (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

	<p>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.</p>
<p><i>Potential radiculopathy</i> (score of 3 or more on a clinician-developed screening questionnaire; see Supplementary File 3)</p>	<p>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).</p>
<p><i>All participants</i></p>	<p>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.</p>
<p><i>Usual care</i></p>	
<p><i>All participants</i></p>	<p>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.</p>

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3 551 **Figure legends**
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5 552 Figure 1. Trial flow diagram
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3 554 **Supplementary files**
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5 555 Supplementary File 1. Standard Protocol Items: Recommendations for Interventional Trials
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7 (SPIRIT) checklist.
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10 557 Supplementary File 2. Information pack.
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12 558 Supplementary File 3. Telephone assessment for Rapid Stratified Telehealth group.
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14 559 Supplementary File 4. Treatment recording form.
15

16 560 Supplementary File 5. System Useability Scale.
17

18 561 Supplementary File 6. Follow up assessment at 6 weeks and 6 months.
19

20 562 Supplementary File 7. Assessment of adverse events.
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22 563 Supplementary File 8. Participant Information Statement and Consent Forms for qualitative
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24 interviews for patients and clinicians.
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27 564
28 565 Supplementary File 9. Interview guide.
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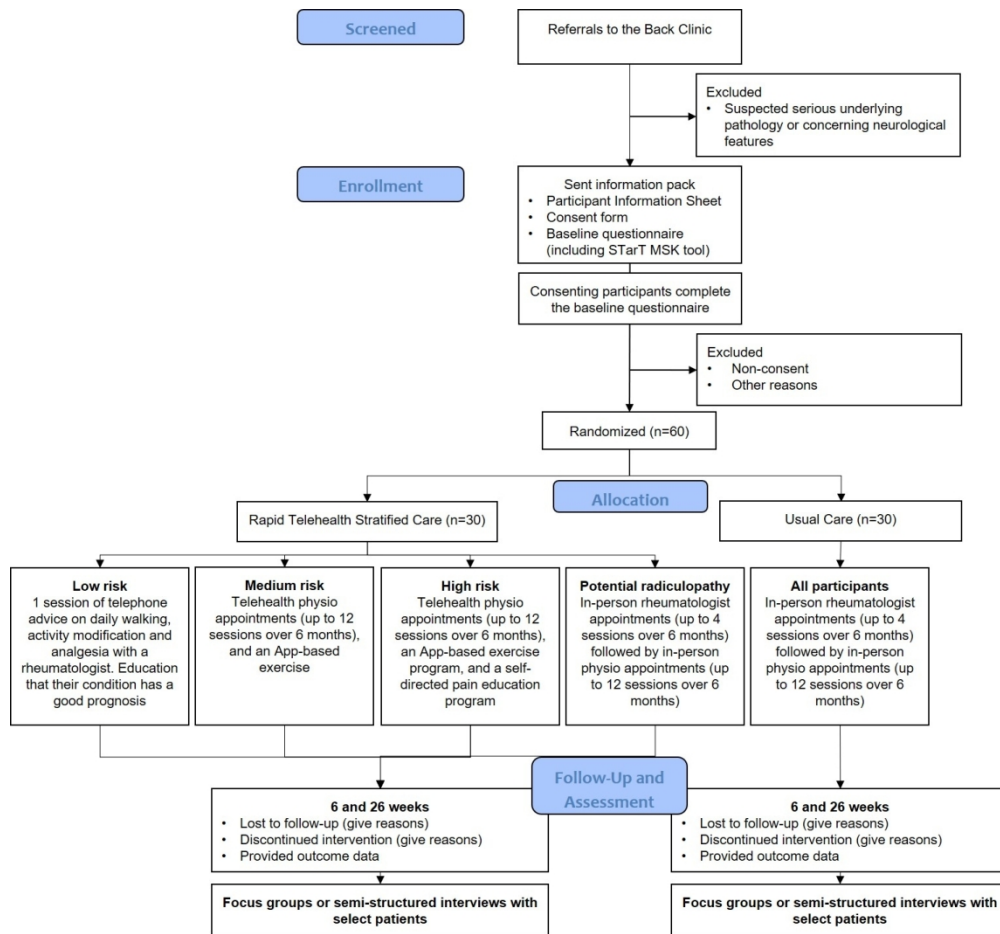


Figure 1. Trial flow diagram

258x239mm (150 x 150 DPI)



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	✓

1				
2	Objectives	7	Specific objectives or hypotheses	✓
3				
4	Trial design	8	Description of trial design including type of trial (eg,	✓
5			parallel group, crossover, factorial, single group),	
6			allocation ratio, and framework (eg, superiority,	
7			equivalence, noninferiority, exploratory)	
8				
9				
10	Methods: Participants, interventions, and outcomes			
11				
12	Study setting	9	Description of study settings (eg, community clinic,	✓
13			academic hospital) and list of countries where data will	
14			be collected. Reference to where list of study sites can	
15			be obtained	
16				
17	Eligibility criteria	10	Inclusion and exclusion criteria for participants. If	✓
18			applicable, eligibility criteria for study centres and	
19			individuals who will perform the interventions (eg,	
20			surgeons, psychotherapists)	
21				
22				
23	Interventions	11a	Interventions for each group with sufficient detail to	✓
24			allow replication, including how and when they will be	
25			administered	
26				
27				
28		11b	Criteria for discontinuing or modifying allocated	✓
29			interventions for a given trial participant (eg, drug dose	
30			change in response to harms, participant request, or	
31			improving/worsening disease)	
32				
33		11c	Strategies to improve adherence to intervention	N/A
34			protocols, and any procedures for monitoring	
35			adherence (eg, drug tablet return, laboratory tests)	
36				
37				
38		11d	Relevant concomitant care and interventions that are	✓
39			permitted or prohibited during the trial	
40				
41	Outcomes	12	Primary, secondary, and other outcomes, including the	✓
42			specific measurement variable (eg, systolic blood	
43			pressure), analysis metric (eg, change from baseline,	
44			final value, time to event), method of aggregation (eg,	
45			median, proportion), and time point for each outcome.	
46			Explanation of the clinical relevance of chosen efficacy	
47			and harm outcomes is strongly recommended	
48				
49				
50	Participant	13	Time schedule of enrolment, interventions (including	✓
51	timeline		any run-ins and washouts), assessments, and visits for	
52			participants. A schematic diagram is highly	
53			recommended (see Figure)	
54				
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2	Sample size	14	Estimated number of participants needed to achieve	✓
3			study objectives and how it was determined, including	
4			clinical and statistical assumptions supporting any	
5			sample size calculations	
6				
7	Recruitment	15	Strategies for achieving adequate participant enrolment	✓
8			to reach target sample size	
9				

Methods: Assignment of interventions (for controlled trials)

Allocation:

14	Sequence	16a	Method of generating the allocation sequence (eg,	✓
15	generation		computer-generated random numbers), and list of any	
16			factors for stratification. To reduce predictability of a	
17			random sequence, details of any planned restriction	
18			(eg, blocking) should be provided in a separate	
19			document that is unavailable to those who enrol	
20			participants or assign interventions	
21				
22				
23				
24	Allocation	16b	Mechanism of implementing the allocation sequence	✓
25	concealment		(eg, central telephone; sequentially numbered, opaque,	
26	mechanism		sealed envelopes), describing any steps to conceal the	
27			sequence until interventions are assigned	
28				
29				
30	Implementation	16c	Who will generate the allocation sequence, who will	✓
31			enrol participants, and who will assign participants to	
32			interventions	
33				
34	Blinding	17a	Who will be blinded after assignment to interventions	✓
35	(masking)		(eg, trial participants, care providers, outcome	
36			assessors, data analysts), and how	
37				
38				
39		17b	If blinded, circumstances under which unblinding is	✓
40			permissible, and procedure for revealing a participant's	
41			allocated intervention during the trial	
42				

Methods: Data collection, management, and analysis

45	Data collection	18a	Plans for assessment and collection of outcome,	✓
46	methods		baseline, and other trial data, including any related	
47			processes to promote data quality (eg, duplicate	
48			measurements, training of assessors) and a description	
49			of study instruments (eg, questionnaires, laboratory	
50			tests) along with their reliability and validity, if known.	
51			Reference to where data collection forms can be found,	
52			if not in the protocol	
53				
54				
55				
56		18b	Plans to promote participant retention and complete	✓
57			follow-up, including list of any outcome data to be	
58			collected for participants who discontinue or deviate	
59			from intervention protocols	
60				

1				
2	Data	19	Plans for data entry, coding, security, and storage,	✓
3	management		including any related processes to promote data quality	
4			(eg, double data entry; range checks for data values).	
5			Reference to where details of data management	
6			procedures can be found, if not in the protocol	
7				
8	Statistical	20a	Statistical methods for analysing primary and	✓
9	methods		secondary outcomes. Reference to where other details	
10			of the statistical analysis plan can be found, if not in the	
11			protocol	
12				
13				
14		20b	Methods for any additional analyses (eg, subgroup and	N/A
15			adjusted analyses)	
16				
17		20c	Definition of analysis population relating to protocol	✓
18			non-adherence (eg, as randomised analysis), and any	
19			statistical methods to handle missing data (eg, multiple	
20			imputation)	
21				
22				
23	Methods: Monitoring			
24				
25	Data monitoring	21a	Composition of data monitoring committee (DMC);	✓
26			summary of its role and reporting structure; statement	
27			of whether it is independent from the sponsor and	
28			competing interests; and reference to where further	
29			details about its charter can be found, if not in the	
30			protocol. Alternatively, an explanation of why a DMC is	
31			not needed	
32				
33				
34		21b	Description of any interim analyses and stopping	N/A
35			guidelines, including who will have access to these	
36			interim results and make the final decision to terminate	
37			the trial	
38				
39				
40	Harms	22	Plans for collecting, assessing, reporting, and	✓
41			managing solicited and spontaneously reported	
42			adverse events and other unintended effects of trial	
43			interventions or trial conduct	
44				
45				
46	Auditing	23	Frequency and procedures for auditing trial conduct, if	✓
47			any, and whether the process will be independent from	
48			investigators and the sponsor	
49				
50				
51	Ethics and dissemination			
52				
53	Research ethics	24	Plans for seeking research ethics	✓
54	approval		committee/institutional review board (REC/IRB)	
55			approval	
56				
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1				
2	Protocol	25	Plans for communicating important protocol	✓
3	amendments		modifications (eg, changes to eligibility criteria,	
4			outcomes, analyses) to relevant parties (eg,	
5			investigators, REC/IRBs, trial participants, trial	
6			registries, journals, regulators)	
7				
8	Consent or	26a	Who will obtain informed consent or assent from	✓
9	assent		potential trial participants or authorised surrogates, and	
10			how (see Item 32)	
11				
12				
13		26b	Additional consent provisions for collection and use of	N/A
14			participant data and biological specimens in ancillary	
15			studies, if applicable	
16				
17	Confidentiality	27	How personal information about potential and enrolled	✓
18			participants will be collected, shared, and maintained in	
19			order to protect confidentiality before, during, and after	
20			the trial	
21				
22				
23	Declaration of	28	Financial and other competing interests for principal	✓
24	interests		investigators for the overall trial and each study site	
25				
26	Access to data	29	Statement of who will have access to the final trial	✓
27			dataset, and disclosure of contractual agreements that	
28			limit such access for investigators	
29				
30				
31	Ancillary and	30	Provisions, if any, for ancillary and post-trial care, and	N/A
32	post-trial care		for compensation to those who suffer harm from trial	
33			participation	
34				
35	Dissemination	31a	Plans for investigators and sponsor to communicate	✓
36	policy		trial results to participants, healthcare professionals,	
37			the public, and other relevant groups (eg, via	
38			publication, reporting in results databases, or other	
39			data sharing arrangements), including any publication	
40			restrictions	
41				
42				
43				
44		31b	Authorship eligibility guidelines and any intended use of	✓
45			professional writers	
46				
47		31c	Plans, if any, for granting public access to the full	✓
48			protocol, participant-level dataset, and statistical code	
49				
50	Appendices			
51				
52	Informed consent	32	Model consent form and other related documentation	✓
53	materials		given to participants and authorised surrogates	
54				
55	Biological	33	Plans for collection, laboratory evaluation, and storage	N/A
56	specimens		of biological specimens for genetic or molecular	
57			analysis in the current trial and for future use in	
58			ancillary studies, if applicable	
59				
60				

1 *It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013
2 Explanation & Elaboration for important clarification on the items. Amendments to the
3 protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT
4 Group under the Creative Commons "[Attribution-NonCommercial-NoDerivs 3.0 Unported](#)"
5 license.
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For peer review only

Supplementary File 2. Information pack



THE UNIVERSITY OF
SYDNEY

ABN 15 211 513 464

**School of Public Health
Faculty of Medicine and Health**

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Web: <http://www.sydney.edu.au>

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

1
2
3 receive based on your risk of persisting pain and presence of other symptoms (like leg pain). We
4 want to see whether the new pathway helps people receive treatment sooner and recover sooner.
5

6 To find out which pathway is best, we will offer half of people the current pathway and half the
7 new pathway. We will monitor the two groups for 6 months and compare what happens between
8 the groups. To ensure the groups are as similar to each other as possible, the group that you will
9 be placed into is by chance. **There is a 50% chance you will be managed according to the new
10 pathway, and a 50% chance you will be managed according to the current pathway.** To make
11 the results of our study fair, we will not tell you which pathway you have been allocated to.
12

13 If you decide you would not like to participate in the research study, you will be managed
14 according to the current pathway. However, your decision whether to participate will not affect
15 your current or future relationship with the researchers or anyone else at the University of Sydney
16 or Royal Prince Alfred Hospital. It also won't affect your position on the waiting list or the quality
17 of care you receive.
18

19 **2. Who is running the study?**

20 This study is funded by the Agency for Clinical Innovation (ACI) New South Wales and the
21 National Health Medical Research Council. Neither funder will benefit commercially from this
22 study. The manufacturers of PhysiTrack, the mobile App you may be provided during the study,
23 do not have any commercial, financial or business interests in this study.
24

25 The people conducting this study are:
26

- 27 • Dr Joshua Zadro, NHMRC Postdoctoral Researcher, Institute for Musculoskeletal Health
28 University of Sydney and Sydney Local Health District
- 29 • Dr Chris Needs, Staff Specialist Rheumatologist, Royal Prince Alfred Hospital, Sydney
30 Local District Health
- 31 • Prof Christopher Maher, Director, Institute for Musculoskeletal Health, University of
32 Sydney and Sydney Local Health District
- 33 • Dr David Martens, Rheumatologist Advanced Trainee, Royal Prince Alfred Hospital,
34 Sydney Local District Health
- 35 • Ms Danielle Coombs, Physiotherapist, Institute for Musculoskeletal Health University of
36 Sydney and Sydney Local Health District
- 37 • Dr Gustavo Machado, NHMRC Postdoctoral Researcher, Institute for Musculoskeletal
38 Health University of Sydney and Sydney Local Health District
- 39 • Mrs Charlotte McLennan, Network Manager, Institute for Musculoskeletal Health
40 University of Sydney and Sydney Local Health District
- 41 • Dr Cameron Adams, Rheumatologist Advanced Trainee, Royal Prince Alfred Hospital,
42 Sydney Local District Health
- 43 • Prof Nadine Foster, Director, Surgical, Treatment and Rehabilitation Service (STARS)
44 Research and Education Alliance, The University of Queensland and Metro North Hospital
45 and Health Service
- 46 • Mr Christopher Han, Physiotherapist Research Assistant, Institute for Musculoskeletal
47 Health, University of Sydney and Sydney Local Health District
- 48
- 49
- 50
- 51
- 52

53 **3. Who can take part in the study?**

54 A person will be allowed to participate in this study if he or she:
55
56
57
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- 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

1
2
3 in a large future study. The results will help us develop better ways to improve the quality of care
4 provided to patients.
5

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

7
8 All data collected will be entered electronically and stored on a research database named REDCap
9 (Research Electronic Data Capture). This is a secure, web-based, non-commercial, data
10 management tool designed for research purposes, hosted, and backed up on the Sydney Local
11 Health District servers on a daily basis. No personnel other than the researchers will have access
12 to the research documents. The data will be analysed by the researchers at the Royal Prince Alfred
13 Hospital. All data for use in journal publications and presentations will be de-identified. The files
14 will be retained for 15 years from the day the study is completed. Once this retention expires, the
15 files will be disposed of using the Royal Prince Alfred Hospital confidential waste disposal service.
16 The data may be used for future research purposes; however, Human Research Ethics Committee
17 (HREC) approval will be sought prior to any future use of the data. It will not be shared with local
18 or international collaborators.
19
20
21
22

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

24
25 You have a right to receive feedback about the overall results of this study. You can tell us that
26 you wish to receive feedback by ticking a box and leaving your email when you complete the
27 consent form. This feedback will be in the form of a one-page lay summary of the results. You
28 will receive this feedback after the study is finished.
29

30 **11. What do I do next?**

31
32 When you have read this information, please store it in a safe place. If you understand what you
33 have read and would like to participate, please sign and return the consent form.

34
35 If you would like to know more about the study at any stage and ask questions, please feel free to
36 contact Mr Christopher Han (research assistant) at Christopher.han@sydney.edu.au or (02) 8627
37 7423.

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

39
40 This study has been approved by the Ethics Review Committee (RPAH Zone) of the Sydney Local
41 Health District.

42
43 If you have any complaints or concerns about any aspect of this study, you should call our research
44 team who will do their best to address any issues. If your concerns are not able to be addressed,
45 you can contact the Executive Officer of the Ethics Review Committee on 02 9515 6766 and quote
46 protocol number X21-0221.
47

48 This information sheet is for you to keep.
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**School of Public Health
Faculty of Medicine and Health**

ABN 15 211 513 464

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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.

- 1
2
3 • I would like to receive a copy of the study results when they become available. My email address
4
5 is: _____
6
7
- 8 • I understand that, during the course of this study, my medical records may be accessed by Sydney
9 Local Health District by regulatory authorities or by the Ethics Committee approving the research in
10 order to verify results and determine that the study is being carried out correctly.
11
- 12 • I understand that the SLHD software license for REDCap (Research Electronic Data Capture) will be
13 used to manage the collection and storage of my research data.
14
- 15
- 16 • I have had an opportunity to ask questions and I am satisfied with the answers I have received.
17
- 18 • I freely choose to participate in this study and understand that I can withdraw at any time.
19
- 20
- 21 • I consent to the future use of any data I provide for research purposes. I understand that before the
22 researchers can use any data I provide; they must seek additional ethics approval. YES/ NO
23
- 24 • I consent for other research collaborators to use any data I provide for future research purposes. I
25 understand that before they can use my data, they must seek additional ethics approval. YES/NO
26
- 27
- 28 • I also understand that the research study is strictly confidential.
29
- 30 • I hereby agree to participate in this research study.
31
- 32
- 33 • I consent to the storage and use of my information collected from me for use, as described in the
34 relevant section of the Participant Information Sheet, for:
35 -This specific research project
36 -Other research that is closely related to this research project
37 -Any future research
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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: _____

Review only

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)	<input type="radio"/> Male <input type="radio"/> 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)	<input type="radio"/> Less than 12 weeks <input type="radio"/> Longer than 12 weeks
Do you have pain that starts from your back and goes below your knee?	<input type="radio"/> Yes <input type="radio"/> No
Language spoken at home other than English	_____
What is your indigenous status? (please tick one only)	<input type="radio"/> Aboriginal <input type="radio"/> Torres Strait Islander <input type="radio"/> Both Aboriginal and Torres Strait Islander <input type="radio"/> Neither Aboriginal nor Torres Strait Islander
Employment Status: (please tick one only)	<input type="radio"/> Not currently employed <input type="radio"/> Currently employed <input type="radio"/> Student <input type="radio"/> Unpaid carer
Education: What option best describes your highest level of education? (please tick one only)	<input type="radio"/> Primary school or less <input type="radio"/> High school (not completed) <input type="radio"/> High school (completed) <input type="radio"/> TAFE/Trade <input type="radio"/> University- undergraduate degree/s (completed) <input type="radio"/> 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
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please cross one box for each question below

Yes

No

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

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

For peer review only

PROMIS–29 Profile v2.0

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

<u>Physical Function</u>		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?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	Are you able to go up and down stairs at a normal pace?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3	Are you able to go for a walk of at least 15 minutes?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4	Are you able to run errands and shop?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>Anxiety</u>						
In the past 7 days...		Never	Rarely	Sometimes	Often	Always
5	I felt fearful	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6	I found it hard to focus on anything other than my anxiety	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7	My worries overwhelmed me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8	I felt uneasy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>Depression</u>						
In the past 7 days...		Never	Rarely	Sometimes	Often	Always
9	I felt worthless	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10	I felt helpless	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11	I felt depressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12	I felt hopeless	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>Fatigue</u>						
During the past 7 days...		Not at all	A little bit	Somewhat	Quite a bit	Very much
13	I feel fatigued	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14	I have trouble <u>starting</u> things because I am tired	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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? ...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16	How fatigued were you on average?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Sleep Disturbance

In the past 7 days...

		Very poor	Poor	Fair	Good	Very good
17	My sleep quality was	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

In the past 7 days...

		Not at all	A little bit	Somewhat	Quite a bit	Very much
18	My sleep was refreshing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19	I had a problem with my sleep	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20	I had difficulty falling asleep	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22	I have trouble doing all of the family activities that I want to do	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23	I have trouble doing all of my usual work (include work at home)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24	I have trouble doing all of the activities with friends that I want to do	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26	How much did pain interfere with work around the home?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27	How much did pain interfere with your ability to participate in social activities? .	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
28	How much did pain interfere with your household chores?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Pain Intensity

In the past 7 days...

29	How would you rate your pain on average?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
		0	1	2	3	4	5	6	7	8	9	10
		No pain										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)				
<input type="checkbox"/> History of significant trauma	<input type="checkbox"/> History of Cancer	<input type="checkbox"/> Recent bacterial infection	<input type="checkbox"/> Fever	<input type="checkbox"/> IV drug use
<input type="checkbox"/> Immune suppression	<input type="checkbox"/> Recent unexplained weight loss	<input type="checkbox"/> Severe pain when supine/at night	<input type="checkbox"/> Saddle anaesthesia	<input type="checkbox"/> Bladder or bowel dysfunction
<input type="checkbox"/> Neurological deficit in limb	<input type="checkbox"/> Osteoporosis	<input type="checkbox"/> Long term corticosteroid use	<input type="checkbox"/> 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
<i>Patients at low risk of persistent pain (Keele STarT MSK score 0-4) AND no potential radiculopathy</i>	Telephone appointment with Advanced Rheumatology Trainee	
	• Advice on daily walking	<input type="checkbox"/>
	• Advice on activity modification	<input type="checkbox"/>
	• Advice to take simple pain medications	<input type="checkbox"/>
	• Education that their condition has a good prognosis	<input type="checkbox"/>
	• Other advice (Please specify) _____	<input type="checkbox"/>
<i>Patients at medium risk of persistent pain (Keele STarT MSK score 5-8) AND no potential radiculopathy</i>	Virtual physiotherapy appointment	
	• Advice and education to support self-management	<input type="checkbox"/>
	• Advice to exercise	<input type="checkbox"/>
	• Advice to modify activities	<input type="checkbox"/>
	• Advice to lose weight	<input type="checkbox"/>
	• Advice to take simple pain medications	<input type="checkbox"/>
	• App-based exercise program	<input type="checkbox"/>
	• Tick if participant needed to print out the exercise program	<input type="checkbox"/>

	<ul style="list-style-type: none"> • Other intervention (Please specify) _____ 	<input type="checkbox"/>
<i>Patients at high risk of persistent pain (Keele STarT MSK score 9-12) AND no potential radiculopathy</i>	Virtual physiotherapy appointment	
	<ul style="list-style-type: none"> • Advice and education to support self-management 	<input type="checkbox"/>
	<ul style="list-style-type: none"> • Advice to exercise 	<input type="checkbox"/>
	<ul style="list-style-type: none"> • Advice to modify activities 	<input type="checkbox"/>
	<ul style="list-style-type: none"> • Advice to lose weight 	<input type="checkbox"/>
	<ul style="list-style-type: none"> • Advice to take simple pain medications 	<input type="checkbox"/>
	<ul style="list-style-type: none"> • Interventions to address psychological barriers to recovery (e.g. pacing, graded exposure) 	<input type="checkbox"/>
	<ul style="list-style-type: none"> • App-based exercise program 	<input type="checkbox"/>
	<ul style="list-style-type: none"> • Tick if participant needed to print out the exercise program 	<input type="checkbox"/>
	<ul style="list-style-type: none"> • Instructed to complete online pain education modules 	<input type="checkbox"/>
	<ul style="list-style-type: none"> • Tick if participant has completed all online pain education modules 	<input type="checkbox"/>
<ul style="list-style-type: none"> • Referral to psychologist 	<input type="checkbox"/>	
<ul style="list-style-type: none"> • Other intervention (Please specify) _____ 	<input type="checkbox"/>	
<i>Patients with potential radiculopathy</i>	In person rheumatologist appointment	
	<ul style="list-style-type: none"> • Take patients' medical history (including past history) 	<input type="checkbox"/>
	<ul style="list-style-type: none"> • Conduct a physical examination (including a neurological examination) 	<input type="checkbox"/>
	<ul style="list-style-type: none"> • Review any previously undertaken investigations (e.g. imaging, pathology tests) 	<input type="checkbox"/>

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

Supplementary File 5. System Usability Scale

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	Strongly disagree				Strongly agree
1. I think that I would like to use this system frequently	1	2	3	4	5
2. I found the system unnecessarily complex	1	2	3	4	5
3. I thought the system was easy to use	1	2	3	4	5
4. I think that I would need the support of a technical person to be able to use this system	1	2	3	4	5
5. I found the various functions in this system were well integrated	1	2	3	4	5
6. I thought there was too much inconsistency in this system	1	2	3	4	5
7. I would imagine that most people would learn to use this system very quickly	1	2	3	4	5
8. I found the system very cumbersome to use	1	2	3	4	5
9. I felt very confident using the system	1	2	3	4	5
10. I needed to learn a lot of things before I could get going with this system	1	2	3	4	5

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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”]?

0	1	2	3	4	5	6	7	8	9	10
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

For peer review only

PROMIS–29 Profile v2.0

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

<u>Physical Function</u>		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?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	Are you able to go up and down stairs at a normal pace?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3	Are you able to go for a walk of at least 15 minutes?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4	Are you able to run errands and shop?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>Anxiety</u>		Never	Rarely	Sometimes	Often	Always
In the past 7 days...						
5	I felt fearful	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6	I found it hard to focus on anything other than my anxiety	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7	My worries overwhelmed me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8	I felt uneasy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>Depression</u>		Never	Rarely	Sometimes	Often	Always
In the past 7 days...						
9	I felt worthless	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10	I felt helpless	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11	I felt depressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12	I felt hopeless	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>Fatigue</u>		Not at all	A little bit	Somewhat	Quite a bit	Very much
During the past 7 days...						
13	I feel fatigued	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14	I have trouble <u>starting</u> things because I am tired	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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? ...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16	How fatigued were you on average?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Sleep Disturbance

In the past 7 days...

		Very poor	Poor	Fair	Good	Very good
17	My sleep quality was	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

In the past 7 days...

		Not at all	A little bit	Somewhat	Quite a bit	Very much
18	My sleep was refreshing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19	I had a problem with my sleep	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20	I had difficulty falling asleep	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22	I have trouble doing all of the family activities that I want to do	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23	I have trouble doing all of my usual work (include work at home)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24	I have trouble doing all of the activities with friends that I want to do	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26	How much did pain interfere with work around the home?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27	How much did pain interfere with your ability to participate in social activities? .	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
28	How much did pain interfere with your household chores?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Pain Intensity

In the past 7 days...

29	How would you rate your pain on average?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
		0	1	2	3	4	5	6	7	8	9	10
		No pain										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?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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)

<u>SERIOUS ADVERSE EVENT REPORT</u>					
Study Site:					
Date of report:		<input type="checkbox"/> Initial report <input type="checkbox"/> Follow up report F/up No.: _____			
A. PATIENT DETAILS					
Subject number:		Patient initials:	____	Date of birth:	____-____-____
Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female		Height:	____ cm	Weight:	____ kg
B. SERIOUS ADVERSE EVENT DETAILS					
Serious Adverse Event: <i>(Diagnosis where available)</i>				Start date:	____-____-____

1 Event Narrative (include relevant symptoms, lab tests performed as required and any other action taken):	
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3	
4	
5	
6	
7	
8	
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14 C. SEVERITY OF EVENT	
15 <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Unknown	
16	
17	
18 D. SERIOUSNESS CRITERIA (select all that	
19 <input type="checkbox"/> Fatal (results in death)	
20	
21 <input type="checkbox"/> Life-threatening	
22	
23 <input type="checkbox"/> Requires Hospitalisation or Prolongs	
24 Hospitalisation	
25 (if ticked, complete section H)	
26	
27	
28	
29	
30 <input type="checkbox"/> Results in Persistent or Significant	
31 Disability/Incapacity	
32	
33 <input type="checkbox"/> Causes a Congenital Abnormality/Birth Defect	
34	
35 <input type="checkbox"/> Medically Important/Significant event	
36	
37	
38 E. CAUSALITY	
39	
40 <i>In the investigator's opinion was the adverse event</i>	
41 <i>related to study treatment?</i>	
42	
43 <input type="checkbox"/> Not related	
44	
45 <input type="checkbox"/> Unlikely related	
46	
47 <input type="checkbox"/> Possibly Related	
48	
49 <input type="checkbox"/> Probably Related	
50	
51 <input type="checkbox"/> Definitely Related	
52	
53 <input type="checkbox"/> Not applicable (SAE occurring outside the 6-	
54 week treatment window)	
55	
56	
57	
58 F. EXPECTEDNESS	
59	
60	

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
					<input type="checkbox"/> Ongoing
					<input type="checkbox"/> Ongoing
					<input type="checkbox"/> Ongoing
					<input type="checkbox"/> Ongoing

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

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

For peer review only

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2
3 **Supplementary File 8. Participant Information Statement and Consent Forms**
4 **for qualitative interviews with patients and clinicians**
5
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7



8
9 THE UNIVERSITY OF
10 **SYDNEY**

11 ABN 15 211 513 464

School of Public Health
Faculty of Medicine and Health

12
13
14 **Dr Joshua Zadro**
15 *Chief Investigator*
16 *Research Fellow*

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

29
30 PARTICIPANT INFORMATION STATEMENT

31
32
33 **1. What is this study about?**

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

40
41 Participation in this research study is voluntary.

42
43 By giving your consent to take part in this study you are telling us that you:

- 44 ✓ Understand what you have read
45 ✓ Agree to take part in the research study as outlined below
46 ✓ Agree to the use of your personal information as described
47

48 This Participant Information Statement is yours to keep.

49
50 Your decision whether to participate will not affect your current or future relationship with the
51 researchers or anyone else at the University of Sydney or Royal Prince Alfred Hospital. It also
52 won't affect the quality of care you receive.
53

54 **2. Who is running the study?**
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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?

1
2
3 Participation in this study is entirely voluntary. You are not obliged to participate. If you do
4 participate, you can withdraw at any time without having to give any reason and without any
5 penalty. Whatever your decision, it will not affect your relationship with the Hospital, Local Health
6 District and The University of Sydney, or the standard of care you receive now or in the future.
7

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

9
10 Aside from giving up your time to participate in an interview, we do not expect that there will be
11 any risks or costs associated with taking part in this study.
12

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

14 By participating, you will be contributing to important research that helps us understand whether
15 the new care pathway we are testing is acceptable to patients with back pain. The results may help
16 us refine the care pathway before testing it in large research study.
17

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

19
20 By providing your consent, you are agreeing to us collecting personal information about you for
21 the purposes of this research study. Your information will only be used for the purposes outlined
22 in this Participant Information Statement, unless you consent otherwise.
23

24 Your information will be stored and analysed securely on a research database within the Institute
25 for Musculoskeletal Health, Sydney Local Health District, and your identity/information will be
26 kept strictly confidential, except as required by law. Study findings may be published, but you will
27 not be individually identifiable in these publications.
28

29 We will keep the information we collect for this study, and we may use it in future project. By
30 providing your consent you are allowing us to use your information in future projects, however all
31 identifying data will remain strictly confidential. We don't know at this stage what these other
32 projects may involve. We will seek ethical approval before using the information in these future
33 projects.
34

35 If you are allocated to the new pathway, you may be provided with an exercise program delivered
36 via a mobile App (PhysiTrack). No data will be collected through the PhysiTrack App and
37 therefore no data will be sent to the developer. The App will simply be used to show you which
38 exercises to do. PhysiTrack is also not a medical device hence does not require TGA approval.
39 PhysiTrack is simply an App that allows physiotherapists to put together an exercise program to
40 allow you to receive written and video instructions on how to perform the exercises correctly.
41 PhysiTrack is essentially a substitute for drawing an exercise program on a piece of paper. The
42 exercises in PhysiTrack include a range of exercises physiotherapists have been prescribing for
43 patients over many years.
44

45
46 As with any home-exercise program prescribed by a physiotherapist, you are free to stop exercising
47 or using the PhysiTrack app at any time if you experience an increase in your symptoms or are not
48 comfortable performing an exercise.
49

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

51
52 You have a right to receive feedback about the overall results of this study. You can tell us that
53 you wish to receive feedback by ticking a box and leaving your email when you complete the
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3 questionnaires. This feedback will be in the form of a one-page lay summary of the results. You
4 will receive this feedback after the study is finished.
5

6 **11. What do I do next?**

7
8 When you have read this information, please store it in a safe place. If you understand what you
9 have read and would like to participate, please sign and return the consent form.

10
11 If you would like to know more about the study at any stage and ask questions, please feel free to
12 contact Mr Christopher Han (research assistant) at Christopher.han@sydney.edu.au or (02) 8627
13 7423.

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

15
16 This study has been approved by the Ethics Review Committee (RPAH Zone) of the Sydney Local
17 Health District.

18
19 If you have any complaints or concerns about any aspect of this study, you should call our research
20 team who will do their best to address any issues. If your concerns are not able to be addressed,
21 you can contact the Executive Officer of the Ethics Review Committee on 02 9515 6766 and quote
22 protocol number X21-0221.
23

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26 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
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.

- 1
2
3 • I would like to receive a copy of the study results when they become available. My email address
4
5 is: _____
6
7
- 8 • I understand that, during the course of this study, my medical records may be accessed by Sydney
9 Local Health District by regulatory authorities or by the Ethics Committee approving the research in
10 order to verify results and determine that the study is being carried out correctly.
11
- 12 • I understand that the SLHD software license for REDCap (Research Electronic Data Capture) will be
13 used to manage the collection and storage of my research data.
14
15
- 16 • I have had an opportunity to ask questions and I am satisfied with the answers I have received.
17
- 18 • I freely choose to participate in this study and understand that I can withdraw at any time.
19
- 20 • I consent to the future use of any data / samples I provide for research purposes. I understand that
21 before they can use any data I provide, they must seek additional ethics approval. YES/ NO
22
23
- 24 • I consent for other research collaborators to use any data / samples I provide for future research
25 purposes. I understand that before they can use my data, they must seek additional ethics approval.
26 YES/NO
27
- 28
- 29 • I also understand that the research study is strictly confidential.
30
- 31 • I hereby agree to participate in this research study.
32
33
- 34 • I consent to the storage and use of my information collected from me for use, as described in the
35 relevant section of the Participant Information Sheet, for:
36 -This specific research project
37 -Other research that is closely related to this research project
38 -Any future research
39
40

41 Participant Name: _____

42 Participant Signature: _____

43 Date: _____

44 Name of Person conducting informed consent: _____

45 Signature of Person conducting informed consent: _____

46 Date: _____
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Email: joshua.zadro@sydney.edu.au
Web: <http://www.sydney.edu.au>

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
- 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.

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

1
2
3 Aside from giving up your time to participate in an interview, we do not expect that there will be
4 any risks or costs associated with taking part in this study.
5

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

7
8 By participating, you will be contributing to important research that helps us understand whether
9 the new care pathway we are testing is acceptable to patients with back pain and/or leg pain
10 radiating from the back and clinicians providing care to these patients. The results may help us
11 refine the care pathway before testing it in large research study.
12

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

14
15 By providing your consent, you are agreeing to us collecting personal information about you for
16 the purposes of this research study. Your information will only be used for the purposes outlined
17 in this Participant Information Statement, unless you consent otherwise.

18
19 Your information will be stored and analysed securely on a research database within the Institute
20 for Musculoskeletal Health, Sydney Local Health District, and your identity/information will be
21 kept strictly confidential, except as required by law. Study findings may be published, but you will
22 not be individually identifiable in these publications.

23
24 We will keep the information we collect for this study, and we may use it in future project. By
25 providing your consent you are allowing us to use your information in future projects, however all
26 identifying data will remain strictly confidential. We don't know at this stage what these other
27 projects may involve. We will seek ethical approval before using the information in these future
28 projects.
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30 **10. Will I be told the results of the study?**

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32 You have a right to receive feedback about the overall results of this study. You can tell us that
33 you wish to receive feedback by ticking a box and leaving your email when you complete the
34 questionnaires. This feedback will be in the form of a one-page lay summary of the results. You
35 will receive this feedback after the study is finished.
36

37 **11. What do I do next?**

38
39 When you have read this information, please store it in a safe place. If you understand what you
40 have read and would like to participant, please sign and return the consent form.

41
42 If you would like to know more about the study at any stage and ask questions, please feel free to
43 contact Mr Christopher Han (research assistant) at Christopher.han@sydney.edu.au or (02) 8627
44 7423.

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

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

49
50 If you have any complaints or concerns about any aspect of this study, you should call our research
51 team who will do their best to address any issues. If your concerns are not able to be addressed,
52 you can contact the Executive Officer of the Ethics Review Committee on 02 9515 6766 and quote
53 protocol number **xxxx**.
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57 This information sheet is for you to keep.
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For peer review only



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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.

- 1
2
3 • I would like to receive a copy of the study results when they become available. My email address
4
5 is: _____
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- 8 • I understand that, during the course of this study, my medical records may be accessed by Sydney
9 Local Health District by regulatory authorities or by the Ethics Committee approving the research in
10 order to verify results and determine that the study is being carried out correctly.
11
- 12 • I understand that the SLHD software license for REDCap (Research Electronic Data Capture) will be
13 used to manage the collection and storage of my research data.
14
15
- 16 • I have had an opportunity to ask questions and I am satisfied with the answers I have received.
17
- 18 • I freely choose to participate in this study and understand that I can withdraw at any time.
19
- 20 • I consent to the future use of any data / samples I provide for research purposes. I understand that
21 before they can use any data I provide, they must seek additional ethics approval. YES/ NO
22
23
- 24 • I consent for other research collaborators to use any data / samples I provide for future research
25 purposes. I understand that before they can use my data, they must seek additional ethics approval.
26 YES/NO
27
- 28
- 29 • I also understand that the research study is strictly confidential.
30
- 31 • I hereby agree to participate in this research study.
32
33
- 34 • I consent to the storage and use of my information collected from me for use, as described in the
35 relevant section of the Participant Information Sheet, for:
36 -This specific research project
37 -Other research that is closely related to this research project
38 -Any future research
39
40
41

Participant Name: _____
Participant Signature: _____
Date: _____
Name of Person conducting informed consent: _____
Signature of Person conducting informed consent: _____
Date: _____

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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

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3 ***Participants with potential radiculopathy (and people in the usual-care group)***
4

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

7 Prompts:

- 8
- 9 • How did you find the appointment(s)? What was helpful? What wasn't?
 - 10 • Can you tell me about the process of scheduling appointments? What was the availability
 - 11 of your rheumatologist and physiotherapist?
 - 12 • Did you always have the same person?
 - 13 • What is it about seeing a rheumatologist or physiotherapist in person that you like or
 - 14 don't like?
 - 15 • How convenient was it for you to travel to and attend a face-to-face appointment(s) at the
 - 16 hospital?
 - 17 • Can you comment on the frequency of your appointments? Is that what you expected?
 - 18 Why or why not?
 - 19 • Do you feel as though you got any benefit from the appointment(s)?
 - 20 • Would you recommend this method of delivering treatment for others? What kinds of
 - 21 people would this approach suit? Who wouldn't it suit?
 - 22 • Do you feel you could have a got a similar benefit from a telephone or virtual
 - 23 consultation(s)?
 - 24 • What else would you liked to have received as part of your treatment during the trial?
 - 25
 - 26
 - 27

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

29 Thank you so much for your time.
30
31
32

33 **INTERVIEW GUIDE FOR CLINICIANS**
34

35 (Questions do not have to be asked in this order, and not all questions have to be covered.)
36

37 Hi, my name is [name and background]. Thank you for taking part in this interview. Researchers
38 and health professionals at The University of Sydney and Royal Prince Alfred Hospital want to
39 find out whether a new treatment pathway using telephone and virtual appointments, and App-
40 based exercise programs, helps people receive treatment sooner and get better sooner. We also
41 want to see if the new treatment pathway is acceptable to clinicians.
42

43 We would like to ask you questions about the treatment you provided in the Back Clinic as part
44 of the trial. You can change your mind about talking to me at any time before or during the
45 interview and stop the interview at any time.
46

47 Are you happy to continue? [If no, thank them for their time and end interview; if yes continue.]
48

49 Thank you [name] for agreeing to take part. We will use your feedback and the feedback of
50 others to write a summary of what people have told us. There will be absolutely no identification
51 of any real names or identification of your professional details.
52

53 Are you happy for me to record the interview? Do you have any questions before we start?
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3 **CONTEXT: TO UNDERSTAND WHAT WORKED, WHAT DIDN'T WORK, AND WHY/
4 WHY NOT FOR THE TWO METHODS OF SERVICE DELIVERY**
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6 1. Let's first talk about the way your service normally operates.

7
8 Prompt:

- 9 • How often would you typically see patients? Do you have a waiting list? How long is that
10 waiting list usually?
11

12 2. Please tell me about your overall experiences coordinating the Rapid Stratified Telehealth
13 trial.
14

15 Prompts:

- 16 • What pleased you about the trial?
17 • What surprised you?
18 • What were your concerns?
19 • What would you do differently?
20
21

22 3. How did the clinicians and patients involved in the trial respond to being involved?
23

24 4. Please tell us about the recruitment process for the trial.
25

26 Prompts:

- 27 • How did you manage the logistics of recruitment?
28 • Was there any difficulty in recruiting participants? If so, please describe.
29

30 **CONTEXT: TO UNDERSTAND THE PERCEIVED BARRIERS/ FACILITATORS FOR
31 EVALUATING IN A LARGE, MULTI-SITE TRIAL**
32

33 5. On the basis of your experience in the trial, how easy do you think it will be to introduce
34 delivering this model of care in other outpatient musculoskeletal settings?
35

36 6. Has the COVID-19 crisis changed your or your colleagues' attitudes towards delivering
37 rehabilitation remotely?
38

39 7. Looking back on the approach used to deliver treatment using eHealth in the trial – are there
40 any aspects of the intervention that could have been delivered differently?
41

42 Prompts:

- 43 • Could participants at high-risk of persistent pain be better managed with face-to-face
44 appointments?
45 • Could participants with potential radiculopathy be managed equally effectively with
46 virtual appointments?
47

48 8. What is the potential for eHealth-based stratified care to provide more patients with treatment
49 sooner? How important is it to cut down waiting lists?
50

51 9. Thinking about what you have learnt from your experiences in the trial – what are the pros and
52 cons of using eHealth-based stratified care, from patients' perspectives?
53

54 Prompts:

- 55 • What are the main advantages for patients compared to usual practice?
56
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- 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.



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	✓

1	Objectives	7	Specific objectives or hypotheses	✓
2				
3	Trial design	8	Description of trial design including type of trial (eg,	✓
4			parallel group, crossover, factorial, single group),	
5			allocation ratio, and framework (eg, superiority,	
6			equivalence, noninferiority, exploratory)	
7				
8				
9				
10	Methods: Participants, interventions, and outcomes			
11				
12	Study setting	9	Description of study settings (eg, community clinic,	✓
13			academic hospital) and list of countries where data will	
14			be collected. Reference to where list of study sites can	
15			be obtained	
16				
17	Eligibility criteria	10	Inclusion and exclusion criteria for participants. If	✓
18			applicable, eligibility criteria for study centres and	
19			individuals who will perform the interventions (eg,	
20			surgeons, psychotherapists)	
21				
22				
23	Interventions	11a	Interventions for each group with sufficient detail to	✓
24			allow replication, including how and when they will be	
25			administered	
26				
27				
28		11b	Criteria for discontinuing or modifying allocated	✓
29			interventions for a given trial participant (eg, drug dose	
30			change in response to harms, participant request, or	
31			improving/worsening disease)	
32				
33		11c	Strategies to improve adherence to intervention	N/A
34			protocols, and any procedures for monitoring	
35			adherence (eg, drug tablet return, laboratory tests)	
36				
37				
38		11d	Relevant concomitant care and interventions that are	✓
39			permitted or prohibited during the trial	
40				
41	Outcomes	12	Primary, secondary, and other outcomes, including the	✓
42			specific measurement variable (eg, systolic blood	
43			pressure), analysis metric (eg, change from baseline,	
44			final value, time to event), method of aggregation (eg,	
45			median, proportion), and time point for each outcome.	
46			Explanation of the clinical relevance of chosen efficacy	
47			and harm outcomes is strongly recommended	
48				
49				
50	Participant	13	Time schedule of enrolment, interventions (including	✓
51	timeline		any run-ins and washouts), assessments, and visits for	
52			participants. A schematic diagram is highly	
53			recommended (see Figure)	
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2	Sample size	14	Estimated number of participants needed to achieve	✓
3			study objectives and how it was determined, including	
4			clinical and statistical assumptions supporting any	
5			sample size calculations	
6				
7	Recruitment	15	Strategies for achieving adequate participant enrolment	✓
8			to reach target sample size	
9				

Methods: Assignment of interventions (for controlled trials)

Allocation:

14	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	✓
15				
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24	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	✓
25				
26				
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30	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	✓
31				
32				
33				
34	Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	✓
35				
36				
37				
38				
39		17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	✓
40				
41				
42				

Methods: Data collection, management, and analysis

45	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	✓
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56		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	✓
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2	Data	19	Plans for data entry, coding, security, and storage,	✓
3	management		including any related processes to promote data quality	
4			(eg, double data entry; range checks for data values).	
5			Reference to where details of data management	
6			procedures can be found, if not in the protocol	
7				
8	Statistical	20a	Statistical methods for analysing primary and	✓
9	methods		secondary outcomes. Reference to where other details	
10			of the statistical analysis plan can be found, if not in the	
11			protocol	
12				
13				
14		20b	Methods for any additional analyses (eg, subgroup and	N/A
15			adjusted analyses)	
16				
17		20c	Definition of analysis population relating to protocol	✓
18			non-adherence (eg, as randomised analysis), and any	
19			statistical methods to handle missing data (eg, multiple	
20			imputation)	
21				
22				
23	Methods: Monitoring			
24				
25	Data monitoring	21a	Composition of data monitoring committee (DMC);	✓
26			summary of its role and reporting structure; statement	
27			of whether it is independent from the sponsor and	
28			competing interests; and reference to where further	
29			details about its charter can be found, if not in the	
30			protocol. Alternatively, an explanation of why a DMC is	
31			not needed	
32				
33				
34		21b	Description of any interim analyses and stopping	N/A
35			guidelines, including who will have access to these	
36			interim results and make the final decision to terminate	
37			the trial	
38				
39				
40	Harms	22	Plans for collecting, assessing, reporting, and	✓
41			managing solicited and spontaneously reported	
42			adverse events and other unintended effects of trial	
43			interventions or trial conduct	
44				
45				
46	Auditing	23	Frequency and procedures for auditing trial conduct, if	✓
47			any, and whether the process will be independent from	
48			investigators and the sponsor	
49				
50				
51	Ethics and dissemination			
52				
53	Research ethics	24	Plans for seeking research ethics	✓
54	approval		committee/institutional review board (REC/IRB)	
55			approval	
56				
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1				
2	Protocol	25	Plans for communicating important protocol	✓
3	amendments		modifications (eg, changes to eligibility criteria,	
4			outcomes, analyses) to relevant parties (eg,	
5			investigators, REC/IRBs, trial participants, trial	
6			registries, journals, regulators)	
7				
8	Consent or	26a	Who will obtain informed consent or assent from	✓
9	assent		potential trial participants or authorised surrogates, and	
10			how (see Item 32)	
11				
12				
13		26b	Additional consent provisions for collection and use of	N/A
14			participant data and biological specimens in ancillary	
15			studies, if applicable	
16				
17	Confidentiality	27	How personal information about potential and enrolled	✓
18			participants will be collected, shared, and maintained in	
19			order to protect confidentiality before, during, and after	
20			the trial	
21				
22				
23	Declaration of	28	Financial and other competing interests for principal	✓
24	interests		investigators for the overall trial and each study site	
25				
26	Access to data	29	Statement of who will have access to the final trial	✓
27			dataset, and disclosure of contractual agreements that	
28			limit such access for investigators	
29				
30				
31	Ancillary and	30	Provisions, if any, for ancillary and post-trial care, and	N/A
32	post-trial care		for compensation to those who suffer harm from trial	
33			participation	
34				
35	Dissemination	31a	Plans for investigators and sponsor to communicate	✓
36	policy		trial results to participants, healthcare professionals,	
37			the public, and other relevant groups (eg, via	
38			publication, reporting in results databases, or other	
39			data sharing arrangements), including any publication	
40			restrictions	
41				
42				
43				
44		31b	Authorship eligibility guidelines and any intended use of	✓
45			professional writers	
46				
47		31c	Plans, if any, for granting public access to the full	✓
48			protocol, participant-level dataset, and statistical code	
49				
50				
51	Appendices			
52	Informed consent	32	Model consent form and other related documentation	✓
53	materials		given to participants and authorised surrogates	
54				
55	Biological	33	Plans for collection, laboratory evaluation, and storage	N/A
56	specimens		of biological specimens for genetic or molecular	
57			analysis in the current trial and for future use in	
58			ancillary studies, if applicable	
59				
60				

1 *It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013
2 Explanation & Elaboration for important clarification on the items. Amendments to the
3 protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT
4 Group under the Creative Commons "[Attribution-NonCommercial-NoDerivs 3.0 Unported](#)"
5 license.
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For peer review only