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# BMJ Open

## Evaluation of two electronic-rehabilitation programmes for persistent knee pain: protocol for a randomised feasibility trial

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## 33 **ABSTRACT**

### 35 **Introduction**

36 Persistent, knee pain is a common cause of disability. Education and exercise treatment are  
37 advocated in all clinical guidelines; however, the increasing prevalence of persistent knee pain  
38 presents challenges for health services regarding appropriate and scalable delivery of these  
39 treatments. Digital technologies may help address this, and this trial will evaluate the feasibility and  
40 acceptability of two electronic-rehabilitation (e-rehabilitation) interventions: 'My Knee UK' and  
41 'Group E-Rehab'.

### 43 **Methods and analysis**

44 This protocol describes a non-blinded, randomised feasibility trial with three parallel groups. The  
45 trial aims to recruit 90 participants (45 years or older) with a history of persistent knee pain  
46 consistent with a clinical diagnosis of knee osteoarthritis (OA). Participants will be randomly assigned  
47 in a 1:1:1 allocation ratio. The 'My Knee UK' intervention arm will receive a self-directed  
48 unsupervised Internet-based home exercise programme plus short message service (SMS) support  
49 (targeting exercise behaviour change) for 12-weeks; the 'Group E-Rehab' intervention arm will  
50 receive group-based physiotherapist-prescribed home exercises delivered via videoconferencing  
51 accompanied by Internet-interactive educational sessions for 12-weeks; the control arm will receive  
52 usual physiotherapy care or continue with their usual self-management (depending on their  
53 recruitment path). Feasibility variables, patient-reported outcomes and clinical findings measured at  
54 baseline, three and nine-months will be assessed and integrated with qualitative interview data from  
55 a sub-set of Group E-Rehab and My Knee UK participants. If considered feasible and acceptable, a  
56 definitive randomised controlled trial can be conducted to investigate the clinical- and cost-  
57 effectiveness of one or both interventions with a view to implementation in routine care.

1  
2 59 **Ethics and dissemination**  
3

4 60 The trial was approved by the West of Scotland Research Ethics Committee 5 (Reference:  
5  
6 61 20/WS/0006). The results of the study will be disseminated to study participants, the study grant  
7  
8 62 funder, and will be submitted for publication in peer-reviewed journals.  
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13 64 **Trial registration number**  
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15 65 ISRCTN: 15564385.  
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2 67 **ARTICLE SUMMARY**  
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5 68 **Strengths and limitations of this study**  
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- 7 69 • The interventions being investigated are accessed/delivered remotely and do not require  
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9 70 any face-to-face contact. This also means that participants do not have to travel to  
10  
11 71 appointments, which can be beneficial for some individuals.  
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13  
14 72 • Patient and public involvement alongside expert review conducted during the first phase  
15  
16 73 ensured the content, appearance, and delivery of the interventions during the trial phase  
17  
18 74 were tailored to the needs of individuals with persistent knee pain.  
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21 75 • The mixed methods approach to data collection and analysis will provide a greater  
22  
23 76 understanding of the feasibility and acceptability of the two digital health interventions.  
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25 77 • It is not possible to blind the participants, physiotherapists or the trials staff administering  
26  
27 78 the study, however, the trial statistician will remain blinded to group allocation until the  
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29 79 database has been locked.  
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32 80 • Participants need to have an active email account , a mobile phone, and access to a  
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34 81 computer or tablet with Internet access suitable for receiving/making video calls, which may  
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36 82 exclude some individuals.  
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## 85 INTRODUCTION

86 Persistent or chronic knee pain, often with associated stiffness and functional limitations, is a  
87 common problem in older and middle-aged adults.[1,2] A leading cause is osteoarthritis (OA) and in  
88 2020, the pooled global prevalence of knee OA in individuals aged 40 and over was reported to be  
89 around 23%, with a positive correlation between prevalence and increased age.[3] Approximately  
90 10% of adults in the United Kingdom (UK) have a clinical diagnosis of OA, with symptomatic knee OA  
91 being the commonest site.[4] It is estimated that by 2035 the number of people with knee OA in the  
92 UK could reach 8.3 million.[5] Exercise and access to appropriate education are advocated in all  
93 clinical guidelines as core treatments for persistent knee pain. However, with the increasing  
94 prevalence of persistent knee pain and current treatment delivery strategies not always addressing  
95 patient needs, managing these patients is challenging.[6]

96  
97 Physiotherapists are key in providing education, exercises, and self-management support to improve  
98 symptoms and function for individuals with knee OA.[7] It has previously been observed that  
99 physiotherapists can effectively deliver OA rehabilitation interventions remotely using video  
100 technologies,[8–10] which is increasingly important given the adoption of telehealth during the  
101 Covid-19 pandemic[11–13]. It has been reported that since the onset of Covid-19, 88% of 50-64 year  
102 olds, 75% of 65-74 year olds and 46% of those aged 75 or over use the Internet almost every day or  
103 every day.[14] These data support the assumption that some, but not all older individuals could  
104 access Internet-based electronic interventions.

105  
106 Digital health interventions for knee pain have been developed and delivered by physiotherapists in  
107 Australia; and there is evidence to suggest they can improve knee pain and function[9,15] and are  
108 generally accepted by patients with knee OA.[16] Such digital health interventions may be useful in  
109 other large health services (such as in the UK) as an alternative to “in person” clinic appointments,  
110 particularly where physiotherapy services are overstretched[17] and waiting times are prolonged



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2 111 due to the Covid-19 pandemic,[18] or where individuals are unable to attend physiotherapy sessions  
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4 112 due to mobility problems and/or lack of transport.[19–21]  
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## 8 114 **Aims and objectives**

9  
10 115 This trial aims to evaluate the feasibility and acceptability of two different electronic-rehabilitation  
11  
12 116 (e-rehabilitation) interventions in individuals with persistent knee pain. One comprises a self-  
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14 117 directed Internet-based home exercise programme with exercise behaviour change support  
15  
16 118 provided via automated SMS ('My Knee UK'). The second is a group-based home exercise  
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18 119 programme with Internet-interactive education sessions ('Group E-Rehab'), where the home  
19  
20 120 exercise programme is prescribed and monitored by a physiotherapist using videoconferencing. The  
21  
22 121 trial will also explore the effect of each e-rehabilitation programme on pain and other symptoms  
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24 122 compared to the control arm and provide a report on any additional resources (e.g. additional  
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26 123 NHS/private healthcare services) used by participants during the trial.  
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## 33 125 **METHODS**

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### 38 127 **Trial design**

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40 128 This is an unblinded, single-centre, randomised feasibility trial with three parallel arms (two e-  
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42 129 rehabilitation treatment arms and one control arm). The study protocol was designed to conform to  
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44 130 the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines[22,23]  
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46 131 and the extension of the Consolidated Standards of Reporting Trials (CONSORT) statement for  
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48 132 randomised pilot and feasibility trials.[24] Trial phases are outlined in Figure 1.  
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54 134 *(Insert **Figure 1**: Study flow diagram.)*  
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2 137 In line with the recently published CONSERVE 2021 Statement and guidelines,[25] several protocol  
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4 138 changes were made in response to the Covid-19 pandemic (Supplement 1).

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9 **140 Patient and Public Involvement**

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11 141 Members of the NIHR Leeds Biomedical Research Centre Patient and Public Involvement (PPI) group  
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13 142 provided input into the trial design and outcome measures through focus group discussions during  
14  
15 143 the funding application stages. PPI was subsequently used to provide input into the refinement of  
16  
17 144 the two e-rehabilitation programmes during the first phase of the study. Additionally, two PPI  
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19 145 representatives are members of the Project Advisory Group and help review content and assist with  
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21 146 key decisions throughout the trial.

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27 **148 Participants**

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29 149 The target population is adults with persistent knee pain who meet the eligibility criteria (Table 1).  
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31 150 Potential participants have either been referred to musculoskeletal (MSK) services for assessment or  
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33 151 have previously received physiotherapy for persistent knee pain; are participants from past studies  
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35 152 that have consented to future contact; have responded to a media campaign advertising for  
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37 153 volunteers (Figure 1).

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42 **155 Table 1:** Trial eligibility criteria.

Inclusion Criteria	Exclusion Criteria
Adults > 45 years	Inflammatory arthritis (including gout)
Knee pain > 3 months and on most days of previous month	A joint replacement in the study knee
Knee pain during walking $\geq 4$ on an 11-point numerical rating scale[26]	An injection into the study knee joint within the last month
Activity-related knee joint pain	An arthroscopy of the study knee joint in the last three months
Has a mobile phone, active email account, and computer with Internet access suitable for receiving and making video calls if required.	Enrolled in another research study involving an intervention for OA treatment or management
	Unable to comply with the study protocol
	Unable to understand written and spoken English.

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## 177 **Digital health intervention treatment arms**

178 The e-rehabilitation interventions were adapted for use in the UK (My Knee UK) or developed  
179 (Group E-Rehab) during Phase 1 of the study. Feedback relating to usability and content, gathered  
180 using online think-aloud interviews and expert review groups, was used to refine the programmes  
181 prior to starting the trial. The results from Phase 1, which supports the robustness of the  
182 development of intervention content, will be published separately.

### 183 *My Knee UK*

184 This is a 12-week Internet-based home exercise intervention that was modified from 'My Knee  
185 Exercise' (<https://mykneeexercise.org.au>), a 24-week intervention created and trialled in Australia  
186 by Nelligan et al.[15,27] This intervention provides guidance, via a website, for participants to  
187 undertake an unsupervised, self-directed lower limb strengthening programme supported by online  
188 OA educational information and advice (Table 2). The strengthening programme was reduced from  
189 the 24-week Australian version to what was considered a less burdensome 12-week programme by  
190 clinical members of the research team.[28] The exercise programme was reviewed and refined by  
191 research team and PPI members of the Project Advisory group, with input from an MSK  
192 physiotherapist expert review group.

193 In this trial, three muscle strengthening exercises are introduced in Programme One (weeks 1-6), and  
194 two additional strengthening exercises are added in Programme Two (weeks 7-12). The website (My  
195 Knee UK) encourages participants to perform their unsupervised home-based exercises at least  
196 three times a week and gives instructions about tailoring and progressing each exercise to their own  
197 ability/needs. Exercise logbooks and physical activity planners are available to download from the  
198 website to print or complete electronically. Participants are encouraged to access the website at  
199 leisure throughout the 12-week intervention and can phone/email a trial physiotherapist if they  
200 have any concerns or experience difficulties with the exercise programme.

1  
2 184 Participants receive exercise-related behaviour change messages throughout the My Knee UK  
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4 185 intervention via automated SMS delivered to their mobile phones (SMS Solutions Australia,  
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6 186 Melbourne, Australia). The SMS library uses behaviour change theory to identify and address key  
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8 187 barriers to and facilitators of home-exercise programme adherence[29] and has been shown to  
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10 188 increase adherence to unsupervised home-based strengthening exercises.[30] The 24-week SMS  
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12 189 script, developed by Nelligan et al.[31] with input from academics, physiotherapists, and consumers,  
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14 190 was modified for use with the 12-week My Knee UK intervention by increasing the frequency of  
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16 191 facilitator messages (from between 0 & 2 to between 1 & 3 per week), enabling the full BCT message  
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18 192 library to be used (Table 2).  
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211 **Table 2:** Summary of the My Knee UK rehabilitation programme.

Webpage Tab	Contents	
1. Home	Introductory video (from Prof Conaghan) How to use the website and beginning your programme 'Contact Us' for help tab	
2. My Knee Education	2.1. My knee education introduction 2.2. Understanding knee osteoarthritis (OA) 2.3. Understanding knee pain 2.4. Knee pain treatments 2.5. Exercise as treatment 2.6. Recommended exercise 2.7. Managing exercise pain 2.8. How to start in the exercise	
3. My Knee Strength	3.1. My knee strength introduction 3.2. How to start your knee exercises 3.3. Organise your exercise equipment 3.4. Tips for starting and sticking to exercise 3.5. Your mobile phone text message support  <b>Exercise Programme One (weeks 1-6)</b> Exercise instructions and videos (incl. self-tailoring exercise guides) a) Sitting knee extension, b) Side steps, c) Calf raises.  <b>Exercise Programme One (weeks 2-7)</b> Exercise instructions and videos (incl. self-tailoring exercise guides) a) Sitting knee extension, b) Side steps, c) Calf raises, d) Mini (wall) squats, e) Chair rises (sit-to-stands).	
4. My Knee Activity	4.1. My knee activity introduction 4.2. Why increase physical activity? 4.3. How to increase physical activity 4.4. Track your daily steps 4.5. Activity pacing 4.6. Make a physical activity plan 4.7. Record your progress 4.8. Physical activity success stories (videos)	
5. My Knee Tools	Contains all the resources used throughout the website in one place.	
<b>Examples of facilitator and barrier behaviour change messages[30,31]</b>		
<b>Facilitator</b>	Hi [name], fitting in regular knee exercise is hard. The reason we are recommending weekly exercise is because exercise works best when it's a regular thing. Exercising longer term can lead to lasting benefits in your knee health.	Do you have a goal you'd like to achieve if your knee improved? Think about what your goal is. Achieving your knee goals is the reward for doing the exercise programme.
<b>Barrier</b>	[Name] It's okay to pull back the intensity of exercises if you're feeling concerned. The important thing is that you do the exercises regularly. Gradually build up again as the knee becomes more stable & your confidence increases.	[Name] It can be hard to remember. We suggest making the exercises a habit. Set aside the same time each day to do them. It's much harder to forget when something is a daily routine.

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2 213 *Group E-Rehab*  
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5 214 Group E-Rehab is a 12-week e-rehabilitation intervention comprising six Internet-interactive  
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7 215 education sessions and the same five lower limb strengthening exercises as My Knee UK. However,  
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9 216 unlike those allocated to My Knee UK, Group E-Rehab participants receive seven group-based  
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11 217 exercise sessions delivered remotely by a physiotherapist (Table 3) via the videoconferencing  
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13 218 platform Zoom (Zoom Video Communications Inc., San Jose, USA) in weeks 1, 2, 3, 5, 7, 9, and 12  
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15 219 (Table 3). The physiotherapist demonstrates/teaches the leg strengthening exercises (limited to  
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17 220 three exercises in the first three classes), and conducts a 30-second chair sit-to-stand test[32]  
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19 221 remotely at the start of each class as a baseline measure and indication of progress. The  
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21 222 physiotherapist monitors the sit-to-stand assessment alongside exercise quality, technique, and  
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23 223 effort during the classes, and uses these measures to tailor the exercises to meet each participant's  
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25 224 needs. Group sessions last 45-60 minutes, and each group contains four-seven participants.  
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31 226 Interactive educational sessions developed for the Group E-Rehab intervention, available through  
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33 227 the digital presentation programme Microsoft Sway,[33] cover knee OA self-management and  
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35 228 include optional quizzes with automated feedback, plus self-assessment questionnaires to make the  
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37 229 sessions more personalised (Table 3). Participants are advised that, although they can access the  
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39 230 Sway education sessions in any order and at their leisure during the 12-week intervention, working  
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41 231 through all six in the first 6-weeks will give them more opportunities to ask questions and/or discuss  
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43 232 the contents during the online exercise classes. The physiotherapist provides dedicated time for this  
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45 233 during each online class as well as reminding participants to engage with the education sessions and  
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47 234 encouraging them to do their exercises at least three times each week. Participants are emailed  
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49 235 exercise logbooks and physical activity planners to download.  
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55 237 Two Leeds Community MSK and Rehabilitation Service physiotherapists with current registration to  
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57 238 practice in the UK were identified to deliver the Group E-Rehab intervention based on their clinical  
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59 239 skills and experience. In preparation for the trial, both attended an external one-day motivational  
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2 240 interviewing training course (Et al Training, Leeds, UK). To facilitate consistent delivery of the  
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4 241 intervention, particularly the exercise component, the physiotherapists completed practice Zoom  
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6 242 classes and follow a comprehensive guidance document (written and provided by the study  
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8 243 Advanced Practice Physiotherapist [CC] and DGW).  
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267 **Table 3:** Summary of the Group E-Rehab rehabilitation programme.

<p><b><u>Sway Session 1: Pain and the Knee Joint</u></b></p> <p>1.1 About the Knee joint Anatomy and physiology / Using the knee joint</p> <p>1.2 What is Pain</p> <p>1.3 What causes knee pain Knee Osteoarthritis (OA) / Some facts about OA</p> <p>1.4 The Pain cycle</p> <p>1.5 Pain Management Activity / Conventional medicine Complementary and alternative medicine Other ways of managing knee pain</p> <p>1.6 Test your knowledge (quiz)</p>	<p><b><u>Sway Session 2: Physical Activity</u></b></p> <p>2.1 The Benefits of Exercise and Physical Activity Reducing the risk of falling How physically active am I? (quiz)</p> <p>2.2 Building an active lifestyle Aerobic and cardiovascular exercise Physical Activity Recommendations</p> <p>2.3 Exercise, general physical activity, and Joint Pain Planning and recording physical activity Tracking your daily steps</p> <p>2.4 The Group E-Rehab Home Exercise Programme Format of the sessions / equipment Leg strengthening programme</p> <p>2.5 Will I get New Aches and Pains if I exercise?</p> <p>2.6 Physical activity quiz</p>
<p><b><u>Sway Session 3: Goal Setting</u></b></p> <p>3.1 Do my knee symptoms hold me back (quiz)</p> <p>3.2 What are goals</p> <p>3.3 Why and How should I set goals?</p> <p>3.4 SMART goals Example of a SMART goal</p> <p>3.5 Goal Planning and Implementation</p> <p>3.6 Problem Solving Problem solving example</p> <p>3.7 Reward yourself</p> <p>3.8 Goal setting and chronic pain (quiz)</p>	<p><b><u>Sway Session 4: Pacing Skills</u></b></p> <p>4.1 Activity levels and Pain</p> <p>4.2 Flare ups</p> <p>4.3 Balancing Activity and Rest Boom Bust (Overactivity/underactivity) cycle Activity rest cycle</p> <p>4.4 Pacing your activity levels Putting Pacing into practice</p> <p>4.5 Pacing and chronic pain quiz (quiz)</p> <p>4.6 Managing at Work</p>
<p><b><u>Sway Session 5: Communication and Emotional Wellbeing</u></b></p> <p>5.1 How well do I communicate with people? (quiz)</p> <p>5.2 The importance of Effective Communication Making others aware (inc. professionals)</p> <p>5.3 Communication Styles Assertive Communication</p> <p>5.5 The Importance of Emotional Wellbeing</p> <p>5.6 Managing Emotions, Acceptance, and Feeling Positive Getting and Staying Connected Distraction techniques / Mindfulness</p> <p>5.7 Managing Setbacks</p> <p>5.8 Emotions and Chronic Pain (quiz)</p> <p>5.9 Online Arthritis Support</p>	<p><b><u>Sway Session 6: Staying Healthy</u></b></p> <p>6.1 Good Health</p> <p>6.2 Healthy Eating</p> <p>6.3 Getting Enough Sleep Sleep and Pain / Sleeping well</p> <p>6.4 Relax and Unwind</p> <p>6.5 Good Health Quiz (quiz)</p> <p>6.6 Summary</p> <p>6.7 What Happens Next? Continuing exercises and activities</p>
<p><b><u>Home-based Leg Strengthening Exercises</u></b></p> <p><b>Physiotherapist-led group-based exercise classes via Zoom in weeks 1, 2, 3, 5, 7, 9, and 12.</b></p> <p>Weeks 1-6 (3 exercises): a) Sitting knee extension, b) Side steps, c) Calf raises (weeks 1-6).</p> <p>Weeks 7-12 (5 exercises): Exercises a to c plus - d) Mini (wall) squats, e) Chair rises (sit-to-stands).</p> <ul style="list-style-type: none"> <li>• 30 second sit-to-stand test done at the start of every physio-led Zoom class.</li> <li>• Classes include time for discussing the self-directed Sway educational sessions.</li> </ul>	



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2 268 **Control arm**

3  
4 269 Participants allocated to the control group could receive any usual care intervention, ranging from  
5  
6 270 no healthcare practitioner input to one or two physiotherapy sessions (delivered in-person or  
7  
8 271 remotely by telephone or videoconferencing), to advice and guidance about self-management. The  
9  
10 272 type of intervention that control group participants receive depends on their recruitment path.  
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15 274 **Enrolment**

16  
17 275 Participants are enrolled once they have been screened for eligibility by telephone (visit 1) and their  
18  
19 276 informed, written postal consent has been countersigned by a delegated member of the research  
20  
21 277 team (Supplement 2). Eligible consenting participants complete a postal baseline questionnaire (visit  
22  
23 278 2) prior to randomisation.  
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29 280 **Randomisation and blinding**

30  
31 281 Participants are randomised (by DGW) to one of the three groups using a 1:1:1 allocation ratio.  
32  
33 282 Random allocation sequences with varying block length (3, 6 and 9), stratified by sex, are generated  
34  
35 283 using an external password-protected web-based randomisation system (Sealed Envelope Ltd.  
36  
37 284 London, UK). A dummy randomisation list[34], created using the same settings but different random  
38  
39 285 seed number, was set up and then checked by the trial statistician (EMAH) before the trial  
40  
41 286 randomisation list was created.  
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44 287

45  
46 288 The nature of this feasibility trial means it is not possible to blind participants, physiotherapists  
47  
48 289 delivering the Group E-Rehab intervention, or the study team managing the trial. However, the trial  
49  
50 290 statistician will remain blinded to group allocation until all preliminary data checks have been  
51  
52 291 performed at a blinded data review meeting and the database has been locked.  
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## 293 **Trial data collection and outcomes**

### 294 *Follow-up visits*

295 Follow-up postal questionnaires are sent out at three months (visit 3), which is the end of the  
296 intervention treatment period, and at nine months (visit 4). Participants who withdraw from the trial  
297 early will not be replaced and will be requested to complete the next scheduled follow-up  
298 questionnaire. The schedule of enrolment and data collected during the trial is detailed in Table 4.

299

### 300 *Outcomes*

301 Patient-reported outcomes covering pain, function, and health-related quality-of-life will be  
302 measured alongside basic clinical findings at baseline and at the three-month (12-week) and nine-  
303 month follow-up time points (Figure 1 and Table 4). These include validated outcome measures used  
304 with OA patients and in knee OA clinical trials.[35–38] Data on the number of contacts made with  
305 hospital and community health services and any costs incurred due to their knee pain (e.g.  
306 prescription, travel costs to attend appointments), will be collected at the three and nine-month  
307 time points.

308

### 309 *Data management and monitoring*

310 Identifiable data will be locked in a filing cabinet in the Leeds Institute of Rheumatic and  
311 Musculoskeletal Medicine (LIRMM) research offices or held in an encrypted file stored on a  
312 password-protected University of Leeds server, with access limited to the study team.  
313 Pseudonymised data will be entered onto a password-protected Access database, developed in line  
314 with the LIRMM Data Quality Management System Standard Operating Procedures. Data will be  
315 periodically internally verified and audited. Data will be stored in a de-identified manner for 5 years  
316 after the final publication.

317

318

319

320 **Table 4:** SPIRIT (Standard Protocol Items for Randomized Trials) schedule of enrolment,  
 321 interventions, and assessments.

TIMEPOINT	STUDY PERIOD			
	Enrolment	Randomisation	Follow-Up	Close-Out
	-1	0	3-Months +/- 4 weeks	9-Months +/- 4 weeks
<b>ENROLMENT:</b>				
Initial contact & study information	X			
Eligibility screen	X			
Informed consent	X			
Allocation		X		
<b>INTERVENTIONS:</b>				
Group E-Rehab			←————→	
'My Knee UK' Group			←————→	
Control Group (duration of treatment will be variable)			←-----→	
<b>ASSESSMENTS:</b>				
<b>Clinical information</b>				
Age, gender, ethnicity		X		
Previous joint surgery		X		
Employment & physical activity		X		
Height & weight		X		
History of current knee pain		X		
General health & medication use		X	X	X
<b>Patient-reported outcomes</b>				
Joint pain manikin		X	X	X
Knee pain frequency (5-point scale)		X	X	X
Confidence & motivation to do exercises (11-point NRS)		X	X	X
Global change (7-point Likert scale)		X	X	X
WOMAC (Pain, function & stiffness)		X	X	X
ASES		X	X	X
HADS		X	X	X
Generic health status (EQ-5D-5L)		X	X	X
Health-related quality of life (SF-12)		X	X	X
Resource use			X	X
Abbreviations: NRS: numeric rating scale. WOMAC: The Western Ontario and McMaster Universities Osteoarthritis Index. ASES: Arthritis Self-Efficacy Scale. HADS: Hospital Anxiety and Depression Scale. EQ-5D-5L: European Quality of Life-Five Dimension-Five Level Scale. SF-12: 12-Item Short Form Survey.				

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2 323 Physiotherapists will record the time taken to administer and lead the Group E-Rehab exercise  
3  
4 324 classes and if a trial physiotherapist is contacted by a My Knee UK participant for help or advice, this  
5  
6 325 will also be recorded. This data will contribute to estimating the cost of delivering the Group E-  
7  
8 326 Rehab and My Knee UK interventions.  
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11 327  
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13 328 Descriptive data relating to exercise adherence relevant to each treatment arm will be collected at  
14  
15 329 the end of the 12-week intervention phase. The web analytics service Google Analytics[39] will be  
16  
17 330 used to record the number of times each participant accesses the My Knee UK website and the  
18  
19 331 duration of their website access. The weekly number of home-based exercise sessions completed  
20  
21 332 (self-reported in response to the automated SMS message) will also be recorded. Group E-Rehab  
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23 333 data will include the number of Zoom exercise classes attended and the number of Sway educational  
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25 334 sessions accessed, along with the time spent engaged with each session.  
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### 31 336 *Nested qualitative study*

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34 337 A sub-sample of consenting participants, purposively sampled by age, sex, and having received the  
35  
36 338 My Knee UK or Group E-Rehab intervention, will undergo individual in-depth remote  
37  
38 339 (videoconference or telephone) interviews where the acceptability of the two e-rehabilitation  
39  
40 340 interventions will be explored. Interviews will focus on participants' experiences of being in the trial  
41  
42 341 and will comprise questions specific to each intervention. It is anticipated around 20 individuals will  
43  
44 342 be interviewed with the final number being determined once data saturation has been reached,  
45  
46 343 which will be when there is consensus amongst the research team that minimal new information is  
47  
48 344 being generated. Participants will be interviewed either on completion of the 3-month follow-up  
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50 345 questionnaire (visit 3), or at the end of follow-up on completion of the 9-month questionnaire (visit  
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52 346 4).  
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58 348 Semi-structured videoconference interviews with the two physiotherapists who delivered the Group  
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60 349 E-Rehab Zoom classes will be conducted. This is to gain insight about the preparation they received,

1  
2 350 thoughts about its acceptability, their experience of delivering the intervention and any barriers to  
3  
4 351 delivering it effectively that they identified.

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8 353 **Planned analyses**

9  
10 354 The intention-to-treat participant population will be used. A full statistical analysis plan (SAP V1.0,  
11  
12 355 04/01/2021) was written prior to commencement of recruitment.

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17 357 *Sample size*

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20 358 A total sample size of 90 participants (30 per arm), based on established principles for a feasibility  
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22 359 study[40], will be adequate for evaluating feasibility and collecting sufficient data to inform the  
23  
24 360 sample size in a definitive randomised controlled trial (RCT).

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29 362 *Feasibility and proof-of-concept*

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32 363 As a feasibility study, inferential statistics will be limited. Analysis will focus on descriptive statistics,  
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34 364 including measures of frequency (e.g. percent), central tendency (e.g. mean, median), and dispersion  
35  
36 365 or variation (e.g. standard deviation, inter-quartile range, confidence interval estimation), rather  
37  
38 366 than formal hypothesis testing. Data will provide an estimate of recruitment and retention rates and  
39  
40 367 the correlation between baseline and follow-up measurements, to inform the sample size required  
41  
42 368 for a definitive RCT. In line with CONSORT[24] the choice of primary outcome for the definitive study  
43  
44 369 will be informed by the results of the feasibility study and guided by a previous study,[10] but  
45  
46 370 candidate variables will be The Western Ontario and McMaster Universities Osteoarthritis Index  
47  
48 371 (WOMAC), pain and physical function domain scores. Published minimum clinically important  
49  
50 372 differences (MCID) reported for the candidate primary outcomes will be used when calculating  
51  
52 373 sample size.[41] If the difference between the groups favours one or both intervention arms over  
53  
54 374 the control arm, and the two-sided 85% confidence interval around the difference includes the  
55  
56 375 MCID, we will proceed to design a definitive trial provided feasibility criteria are met.[42] Attrition  
57  
58 376 will be examined to identify any factors that may be systematically affecting drop-out, and

1  
2 377 continuous measures of adherence within each treatment arm will be summarised. The cost of  
3  
4 378 delivering the e-rehabilitation interventions will be estimated and alongside this, a descriptive report  
5  
6 379 on the use of additional resources (e.g. the type of resources, number of contacts, and any costs  
7  
8 380 incurred) will be produced.  
9

10 381

### 13 382 *Safety analyses*

16 383 Adverse events (AEs) or serious adverse events (SAEs) will be recorded and coded to indicate the  
17  
18 384 major event category but, as this is not a clinical trial of an investigational medicinal product,  
19  
20 385 severity will not be graded. The frequency of all treatment-related AEs and SAEs recorded during the  
21  
22 386 trial period will be displayed as the number of participants experiencing the AEs/SAEs, the  
23  
24 387 percentage of participants, and the number of AEs/SAEs will be presented both overall and by  
25  
26 388 treatment arm.  
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### 32 390 *Qualitative study*

35 391 Data derived from the participant and semi-structured physiotherapist interviews will be transcribed  
36  
37 392 verbatim. Transcripts will be analysed using framework analysis.[43]  
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39 393

### 42 394 **Feasibility trial outcome**

44 395 Data from the feasibility trial and follow-up nested qualitative study will be integrated to support the  
45  
46 396 case for determining whether one or both e-rehabilitation interventions are feasible, acceptable and  
47  
48 397 have the potential to be implemented in practice. The qualitative and quantitative data will enable  
49  
50 398 the potential for My Knee UK and/or Group E-Rehab to be introduced as alternative models of  
51  
52 399 services delivery to be explored. The feasibility trial will be deemed successful if the results  
53  
54 400 demonstrate that (1) participants and physiotherapists find one or both intervention(s) acceptable  
55  
56 401 (using data from the nested qualitative study), (2) it is possible to calculate a manageable sample  
57  
58 402 size for use in a definitive RCT, (3) attrition at visit 3 (3-months) is no more than 30% and (4) at least  
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403 40% of eligible patients are recruited to the trial. If one or both e-rehabilitation interventions are

1  
2 404 acceptable, the intention is to develop the protocol for and conduct a definitive RCT with a health  
3  
4 405 economic component. This will be sufficiently powered for testing the wider use of My Knee UK  
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6 406 and/or Group E-Rehab (depending on feasibility trial outcome) as a prescribed treatment for  
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8 407 individuals with persistent knee pain.  
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## 14 15 410 **DISCUSSION**

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18 411 The growing prevalence of persistent knee pain and OA requires the development and  
19  
20 412 implementation of effective and accessible treatments that enable these patients to manage their  
21  
22 413 symptoms. These treatments should be convenient for patients and should not overburden local  
23  
24 414 MSK physiotherapy services. Current evidence suggests that for chronic conditions such as OA,  
25  
26 415 digital technologies can be used to deliver self-management programmes electronically.[9,44]  
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31 417 This trial aims to evaluate the feasibility and acceptability of two different e-rehabilitation  
32  
33 418 interventions (Group E-Rehab and My Knee UK) in individuals with persistent knee pain. Education,  
34  
35 419 advice about increasing general physical activity levels, and strengthening exercises that can be  
36  
37 420 tailored to individual needs are pivotal components of both interventions. Muscle strengthening  
38  
39 421 programmes are beneficial in reducing pain and improving physical function in people with knee  
40  
41 422 OA.[45] In this trial, the home-based lower-limb strengthening exercise programme is either  
42  
43 423 prescribed and monitored by a physiotherapist as a group-based intervention using  
44  
45 424 videoconferencing (Group E-Rehab), or it is self-directed (accessed via the My Knee UK website). It is  
46  
47 425 believed that the e-rehabilitation interventions under investigation in this trial will provide patients  
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49 426 with access to the digital tools and resources needed for self-managing their knee pain and  
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51 427 symptoms, and that one or both interventions could eventually be implemented within the NHS.  
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1  
2 429 **Ethics and dissemination**  
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4 430 This feasibility trial and current protocol (v5.0, 25/01/2022) was approved by the West of Scotland  
5  
6 431 Research Ethics Committee 5 (REC5), reference number 20/WS/0006 prior to commencing  
7  
8 432 recruitment, which is ongoing. The study is sponsored by the University of Leeds (Research Integrity  
9  
10 433 and Governance), UK and is registered with the ISRCTN (Reference: 15564385; Supplement 3). All  
11  
12 434 individuals assisting with the trial will be informed of any protocol amendments, which will be  
13  
14 435 approved by the Sponsor before being submitted to the REC/HRA for approval. The results will be  
15  
16 436 disseminated to the study grant funder, submitted for publication in peer-reviewed journals and  
17  
18 437 where requested, a summary of the study findings will be disseminated to study participants. No  
19  
20 438 study participants will be identifiable in the study results.  
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26 440 **Data availability statement**  
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28 441 The full protocol and statistical analysis plan will be available via the University of Leeds data  
29  
30 442 repository. The full anonymised trial data set and statistical codes will be available 12 months  
31  
32 443 following publication upon request.  
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## 455 **Competing interests**

456 None declared.

## 458 **Author contributions**

459 RSH, RKN and KLB co-developed the Australian SMS programme and My Knee Exercise website.  
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461 SRK, KLB, CC, EMAH, GAM, MC and DGW designed this protocol. EMAH produced the statistical  
462 analysis plan. The UK exercise and SMS programmes were developed by PGC, CC, DGW and MC,  
463 DGW respectively. DGW designed the UK version of the website (My Knee UK), created the  
464 Microsoft Sway education package, is leading the coordination of the study, and drafted the  
465 manuscript. All authors contributed to manuscript reviewing and editing and approved the final  
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7  
8 476 submit for publication.  
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2 616 **TABLE AND FIGURE TITLES AND LEGENDS**  
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4  
5 617 Table 1: Trial eligibility criteria.  
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7 618 Figure 1: Study flow diagram.  
8

9 619 Table 2: Summary of the My Knee UK rehabilitation programme.  
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11 620 Table 3: Summary of the Group E-Rehab rehabilitation programme.  
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13  
14 621 Table 4: SPIRIT (Standard Protocol Items for Randomized Trials) schedule of enrolment,  
15 622 interventions, and assessments.

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17 623 [NRS: numeric rating scale; WOMAC: The Western Ontario and McMaster Universities  
18 624 Osteoarthritis Index; ASES: Arthritis Self-Efficacy Scale; HADS: Hospital Anxiety and  
19 625 Depression Scale; EQ-5D-5L; European Quality of Life-Five Dimension-Five Level Scale; SF-12:  
20 626 12-Item Short Form Survey]  
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26 629 **SUPPLEMENTS**  
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29 630 Supplement 1: Protocol modifications made to mitigate the effects of the Covid-19 Pandemic  
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31 631 Supplement 2: Sample participant consent form for the Phase 2 trial  
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33 632 Supplement 3: Trial registration  
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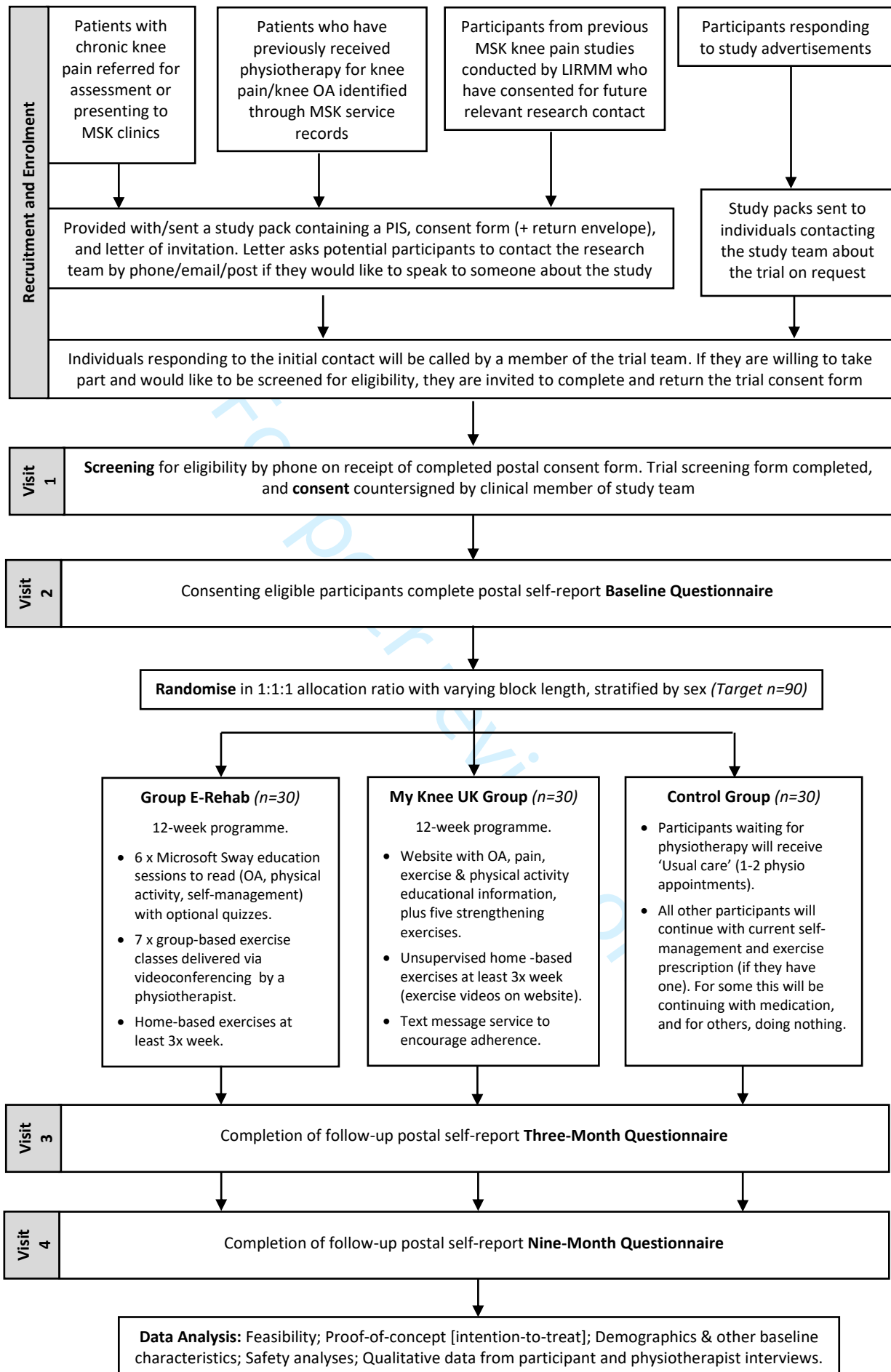


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2 SUPPLEMENT 1  
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45 **Protocol modifications made to mitigate the effects of the Covid-19 Pandemic**  
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- 7 1. Changes arising from the Covid-19 pandemic mean that routine physiotherapy appointments  
8 are now more likely to be remote rather than face-to-face. Currently, most appointments are  
9 taking place over the telephone or in some case, via video consultation, rather than being face-  
10 to-face in a clinic. Prior to starting the recruitment process for the feasibility trial, the protocol  
11 and participant documents were amended to reflect these changes. This means that potential  
12 participants will be fully aware that if they enter the study and are allocated to the control  
13 group, if they are current patients who will receive usual care, then their physiotherapy  
14 appointments are unlikely to be face-to-face, particularly if Covid-19 restrictions are still in  
15 place.  
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- 30 2. Given the current and potential future restrictions arising from the Covid-19 pandemic,  
31 interviews with the physiotherapists and sub-sample of participants from the trial during the  
32 nested qualitative study phase will be done remotely.  
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- 39 3. Current Covid-19 restrictions mean that only skeleton staff members from the research team  
40 were physically going into the office. This would have caused a delay in responding to the initial  
41 postal response to enquiries from potential participants. To avoid this, the invitation letter was  
42 amended slightly so that if anyone receiving the study information is interested in joining the  
43 study, they are asked to contact the study team via email or phone instead of returning a paper  
44 contact form.  
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- 54 4. A delayed start due to Covid-19 has resulted in shortened timeframe for recruitment, with the  
55 risk that reaching the target of 90 participants within the study timeframe would not be  
56 achievable. To mitigate this, additional ways of identifying and recruiting participants were  
57 added to the protocol. This included:  
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- Searching local Trust MSK service records for potentially eligible patients who have previously received physio for knee pain.
- Using Participant identification Centres (PICs) who have the appropriate approval and model agreement in place to carrying out a search of their patient records database to identify individuals that meet a study's eligibility criteria.
- A database search of participants from previous University of Leeds studies who have consented to be contacted about future relevant research studies.
- A media campaign with physical posters/flyers in clinics, waiting rooms or local community centres, and an electronic poster/advert that can be distributed digitally (e.g. email, University or Trust websites), and used via social media.

Participants recruited via MSK waiting lists or clinics (current patients) will continue to receive a physio appointment (usual care) if they are randomised to the control group or if they subsequently withdraw. However, the amendment will affect participants identified via service records, database searches, media campaigns or PICs if they are randomised to the control group or later withdraw from the trial. Participants recruited using these methods (i.e. not via the MSK waiting list or clinics), will be asked to continue with whatever exercises, treatment, or self-management they were doing before joining the trial.

## SUPPLEMENT 2

## Sample participant consent form for the Phase 2 trial



## UNIVERSITY OF LEEDS

Leeds Institute of Rheumatic and Musculoskeletal Medicine

2<sup>nd</sup> Floor, Chapel Allerton Hospital

Chapelton Road, Leeds, LS7 4SA

Email: [e.rehab@leeds.ac.uk](mailto:e.rehab@leeds.ac.uk)

Tel: 0113 392 4965

Participant Identification Number

**CONSENT FORM** (IRAS Reference: 269827)**Evaluation of electronic-rehabilitation programmes for chronic knee pain****Phase 2: Feasibility trial**Please initial  
each box

1	I confirm that I have read the information sheet dated 18/05/2021 (version 3.0) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2	I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, and without my legal rights or medical care being affected.	
3	I understand that, even if I withdraw from this study, the information already collected from me will be used in analysing the results of this study.	
4	I understand that the group sessions will be recorded and any identifiable audio and visual data from these recordings will be stored securely and not shared.	
5	I understand that the information collected during this study may be used to support other research in the future and may be shared anonymously with other researchers.	
6	I agree to my personal information being stored for the purposes of this study. I understand that any information which could identify me will be kept strictly confidential.	
7	I understand that relevant sections of the data collected during the study, may be looked at by individuals from the University of Leeds (sponsors) or from regulatory authorities where it is relevant to my taking part in this research.	
8	I understand that my GP will be informed about my participation in this study.	
9	I agree to take part in the above study.	

**After initialling the boxes, please print and sign your name (participant), add the date, and fill out the participant contact details on the next page before returning the form.**

\_\_\_\_\_  
Name of Participant (PRINTED)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

**Please remember to fill in your contact details at the bottom of the page.**

The contact slip will be removed and destroyed after we have put your details on to our secure Subject Screening Log, which is used by the research team for contacting you about the study.

\_\_\_\_\_  
Name of Researcher

\_\_\_\_\_  
\*Date

\_\_\_\_\_  
Signature

When completed: 1 for participant; 1 for researcher site file. \*Will be signed by researcher on a different day.

**Participant Contact Details**

Telephone Number(s): \_\_\_\_\_

Email Address: \_\_\_\_\_

IRAS ID	Project Title	Document Type	Version #	Date	Page
269827	E-rehab for Knee Pain	Phase 2 Trial Patient Consent Form	4.0	10/09/2021	Page 2 of 2

## SUPPLEMENT 3

## Trial registration

Data category	Information
Registry identifying number	ISRCTN15564385
Date of registration	07/02/2020
Prospective/Retrospective	Prospectively registered
Additional identifiers	CPMS 43473, IRAS 269827
Sources of monetary support	Versus Arthritis; National Institute for Health Research (NIHR) (UK)
Sponsor	University of Leeds
Contact information	Dr Dawn Groves-Williams; d.groves-williams@leeds.ac.uk Dr Sarah Kingsbury; s.r.kingsbury@leeds.ac.uk
Short/public title	E-rehab for Knee Pain
Scientific title	Evaluation of electronic-rehabilitation programmes for chronic knee pain
Countries of recruitment	United Kingdom
Condition category	Musculoskeletal Diseases
Condition	Chronic knee pain
Interventions	Access to <b>My Knee UK</b> website containing exercise videos and self-management resources for 12 weeks. Support via SMS messages <b>Group E-Rehab:</b> access to online educational and self-management resources plus 7 online group physiotherapy classes over 12-weeks <b>Control Group:</b> depending on their recruitment path – will receive usual physiotherapy care or continue with usual self-management
Key inclusion and exclusion criteria	Type: Adults $\geq$ 18 years; both sexes; no healthy volunteers Inclusion: knee pain > 3 months and on most days of previous month; activity-related joint pain; pain during walking $\geq$ 4 on an 11-point scale Exclusion: Inflammatory arthritis/gout; Joint replacement in study knee; injection within last month; arthroscopy within last 3-months
Study design	Mixed methods interventional randomised controlled feasibility trial with follow-up interviews Primary: Interventional; Secondary: Randomised controlled trial; Trial setting: Community; Trial type: treatment
Target sample size	90 (30 in each group)
Date of first enrolment	22/04/2021
Recruitment status	Recruiting
Overall trial status	Ongoing
Key outcomes	Primary: Feasibility and acceptability of the two different electronic-rehabilitation programmes Additional: the effect of each electronic-rehabilitation programme on pain and other symptoms compared to the control arm; report any additional resources used by participants during the trial

# Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

## Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRIT reporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin J, Dickersin K, Hróbjartsson A, Schulz KF, Parulekar WR, Krleža-Jerić K, Laupacis A, Moher D. SPIRIT 2013 Explanation and Elaboration: Guidance for protocols of clinical trials. *BMJ*. 2013;346:e7586

		Reporting Item	Page Number
<b>Administrative information</b>			
Title	<a href="#">#1</a>	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	<a href="#">#2a</a>	Trial identifier and registry name. If not yet registered, name of intended registry	4
Trial registration: data set	<a href="#">#2b</a>	All items from the World Health Organization Trial Registration Data Set	Suppl 3
Protocol version	<a href="#">#3</a>	Date and version identifier	21
Funding	<a href="#">#4</a>	Sources and types of financial, material, and other support	23-24
Roles and responsibilities: contributorship	<a href="#">#5a</a>	Names, affiliations, and roles of protocol contributors	1,23



1	Roles and	<a href="#">#5b</a>	Name and contact information for the trial sponsor	22
2	responsibilities:			
3	sponsor contact			
4	information			
5				
6				
7	Roles and	<a href="#">#5c</a>	Role of study sponsor and funders, if any, in study	24
8	responsibilities:		design; collection, management, analysis, and	
9	sponsor and funder		interpretation of data; writing of the report; and the	
10			decision to submit the report for publication, including	
11			whether they will have ultimate authority over any of	
12			these activities	
13				
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17	Roles and	<a href="#">#5d</a>	Composition, roles, and responsibilities of the	8,23
18	responsibilities:		coordinating centre, steering committee, endpoint	
19	committees		adjudication committee, data management team, and	
20			other individuals or groups overseeing the trial, if	
21			applicable (see Item 21a for data monitoring committee)	
22				
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24				
25				
26	<b>Introduction</b>			
27				
28	Background and	<a href="#">#6a</a>	Description of research question and justification for	6-7
29	rationale		undertaking the trial, including summary of relevant	
30			studies (published and unpublished) examining benefits	
31			and harms for each intervention	
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34				
35	Background and	<a href="#">#6b</a>	Explanation for choice of comparators	7
36	rationale: choice of			
37	comparators			
38				
39				
40	Objectives	<a href="#">#7</a>	Specific objectives or hypotheses	7
41				
42				
43	Trial design	<a href="#">#8</a>	Description of trial design including type of trial (eg,	3,7
44			parallel group, crossover, factorial, single group),	
45			allocation ratio, and framework (eg, superiority,	
46			equivalence, non-inferiority, exploratory)	
47				
48				
49	<b>Methods:</b>			
50	<b>Participants,</b>			
51	<b>interventions, and</b>			
52	<b>outcomes</b>			
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55				
56	Study setting	<a href="#">#9</a>	Description of study settings (eg, community clinic,	Fg1
57			academic hospital) and list of countries where data will	
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		be collected. Reference to where list of study sites can be obtained	
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4	Eligibility criteria	<a href="#">#10</a> Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Fg1
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11	Interventions: description	<a href="#">#11a</a> Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	9-15
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16	Interventions: modifications	<a href="#">#11b</a> Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	N/A
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23	Interventions: adherence	<a href="#">#11c</a> Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	9,12
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27			
28	Interventions: concomitant care	<a href="#">#11d</a> Relevant concomitant care and interventions that are permitted or prohibited during the trial	8(Tb11)
29			
30			
31			
32	Outcomes	<a href="#">#12</a> Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	16-19
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43	Participant timeline	<a href="#">#13</a> Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	17(Tb14)
44			
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50	Sample size	<a href="#">#14</a> Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	19
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57	Recruitment	<a href="#">#15</a> Strategies for achieving adequate participant enrolment to reach target sample size	8, Fig1
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**Methods:****Assignment of interventions (for controlled trials)**

Allocation: sequence generation	<a href="#">#16a</a>	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
Allocation concealment mechanism	<a href="#">#16b</a>	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	15
Allocation: implementation	<a href="#">#16c</a>	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	15
Blinding (masking)	<a href="#">#17a</a>	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	15
Blinding (masking): emergency unblinding	<a href="#">#17b</a>	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
<b>Methods: Data collection, management, and analysis</b>			
Data collection plan	<a href="#">#18a</a>	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.	16

		Reference to where data collection forms can be found, if not in the protocol	
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4	Data collection plan:	<a href="#">#18b</a> Plans to promote participant retention and complete	16
5	retention	follow-up, including list of any outcome data to be	
6		collected for participants who discontinue or deviate	
7		from intervention protocols	
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9			
10	Data management	<a href="#">#19</a> Plans for data entry, coding, security, and storage,	16
11		including any related processes to promote data quality	
12		(eg, double data entry; range checks for data values).	
13		Reference to where details of data management	
14		procedures can be found, if not in the protocol	
15			
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18			
19	Statistics: outcomes	<a href="#">#20a</a> Statistical methods for analysing primary and secondary	19-21
20		outcomes. Reference to where other details of the	
21		statistical analysis plan can be found, if not in the	
22		protocol	
23			
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25			
26	Statistics: additional	<a href="#">#20b</a> Methods for any additional analyses (eg, subgroup and	3,18
27	analyses	adjusted analyses)	
28			
29			
30	Statistics: analysis	<a href="#">#20c</a> Definition of analysis population relating to protocol non-	19
31	population and	adherence (eg, as randomised analysis), and any	
32	missing data	statistical methods to handle missing data (eg, multiple	
33		imputation)	
34			
35			
36	<b>Methods: Monitoring</b>		
37			
38			
39	Data monitoring:	<a href="#">#21a</a> Composition of data monitoring committee (DMC);	N/A
40	formal committee	summary of its role and reporting structure; statement of	(non-
41		whether it is independent from the sponsor and	CTIMP)
42		competing interests; and reference to where further	
43		details about its charter can be found, if not in the	
44		protocol. Alternatively, an explanation of why a DMC is	
45		not needed	
46			
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49			
50	Data monitoring:	<a href="#">#21b</a> Description of any interim analyses and stopping	N/A
51	interim analysis	guidelines, including who will have access to these	
52		interim results and make the final decision to terminate	
53		the trial	
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56			
57	Harms	<a href="#">#22</a> Plans for collecting, assessing, reporting, and managing	20
58		solicited and spontaneously reported adverse events	
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and other unintended effects of trial interventions or trial conduct

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3			
4	Auditing	<a href="#">#23</a>	Frequency and procedures for auditing trial conduct, if 16
5			any, and whether the process will be independent from
6			investigators and the sponsor
7			
8			
9	<b>Ethics and</b>		
10	<b>dissemination</b>		
11			
12			
13	Research ethics	<a href="#">#24</a>	Plans for seeking research ethics committee / 4,22
14	approval		institutional review board (REC / IRB) approval
15			
16			
17	Protocol amendments	<a href="#">#25</a>	Plans for communicating important protocol 21-22
18			modifications (eg, changes to eligibility criteria,
19			outcomes, analyses) to relevant parties (eg,
20			investigators, REC / IRBs, trial participants, trial
21			registries, journals, regulators)
22			
23			
24			
25	Consent or assent	<a href="#">#26a</a>	Who will obtain informed consent or assent from 15
26			potential trial participants or authorised surrogates, and
27			how (see Item 32)
28			
29			
30	Consent or assent:	<a href="#">#26b</a>	Additional consent provisions for collection and use of N/A
31	ancillary studies		participant data and biological specimens in ancillary
32			studies, if applicable
33			
34			
35			
36	Confidentiality	<a href="#">#27</a>	How personal information about potential and enrolled 16,22
37			participants will be collected, shared, and maintained in
38			order to protect confidentiality before, during, and after
39			the trial
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42			
43	Declaration of	<a href="#">#28</a>	Financial and other competing interests for principal 22
44	interests		investigators for the overall trial and each study site
45			
46			
47	Data access	<a href="#">#29</a>	Statement of who will have access to the final trial 22
48			dataset, and disclosure of contractual agreements that
49			limit such access for investigators
50			
51			
52	Ancillary and post trial	<a href="#">#30</a>	Provisions, if any, for ancillary and post-trial care, and N/A
53	care		for compensation to those who suffer harm from trial
54			participation
55			
56			
57	Dissemination policy:	<a href="#">#31a</a>	Plans for investigators and sponsor to communicate trial 4, 22
58	trial results		results to participants, healthcare professionals, the
59			

public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions

Dissemination policy: authorship	<a href="#">#31b</a>	Authorship eligibility guidelines and any intended use of professional writers	31
Dissemination policy: reproducible research	<a href="#">#31c</a>	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	22

## Appendices

Informed consent materials	<a href="#">#32</a>	Model consent form and other related documentation given to participants and authorised surrogates	Suppl 2
Biological specimens	<a href="#">#33</a>	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

None The SPIRIT Explanation and Elaboration paper is distributed under the terms of the Creative Commons Attribution License CC-BY-NC. This checklist can be completed online using <https://www.goodreports.org/>, a tool made by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)

# BMJ Open

## Evaluation of two electronic-rehabilitation programmes for persistent knee pain: protocol for a randomised feasibility trial

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2022-063608.R1
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# 1 Evaluation of two electronic-rehabilitation programmes for persistent 2 knee pain: protocol for a randomised feasibility trial

3  
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## 22 23 **KEYWORDS**

24 Pain management

25 Rheumatology

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27 Telemedicine

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For peer review only

## 33 **ABSTRACT**

### 35 **Introduction**

36 Persistent, knee pain is a common cause of disability. Education and exercise treatment are  
37 advocated in all clinical guidelines; however, the increasing prevalence of persistent knee pain  
38 presents challenges for health services regarding appropriate and scalable delivery of these  
39 treatments. Digital technologies may help address this, and this trial will evaluate the feasibility and  
40 acceptability of two electronic-rehabilitation (e-rehabilitation) interventions: 'My Knee UK' and  
41 'Group E-Rehab'.

### 43 **Methods and analysis**

44 This protocol describes a non-blinded, randomised feasibility trial with three parallel groups. The  
45 trial aims to recruit 90 participants (45 years or older) with a history of persistent knee pain  
46 consistent with a clinical diagnosis of knee osteoarthritis (OA). Participants will be randomly assigned  
47 in a 1:1:1 allocation ratio. The 'My Knee UK' intervention arm will receive a self-directed  
48 unsupervised Internet-based home exercise programme plus short message service (SMS) support  
49 (targeting exercise behaviour change) for 12-weeks; the 'Group E-Rehab' intervention arm will  
50 receive group-based physiotherapist-prescribed home exercises delivered via videoconferencing  
51 accompanied by Internet-interactive educational sessions for 12-weeks; the control arm will receive  
52 usual physiotherapy care or continue with their usual self-management (depending on their  
53 recruitment path). Feasibility variables, patient-reported outcomes and clinical findings measured at  
54 baseline, three and nine-months will be assessed and integrated with qualitative interview data from  
55 a sub-set of Group E-Rehab and My Knee UK participants. If considered feasible and acceptable, a  
56 definitive randomised controlled trial can be conducted to investigate the clinical- and cost-  
57 effectiveness of one or both interventions with a view to implementation in routine care.

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1  
2 59 **Ethics and dissemination**  
3

4 60 The trial was approved by the West of Scotland Research Ethics Committee 5 (Reference:  
5  
6 61 20/WS/0006). The results of the study will be disseminated to study participants, the study grant  
7  
8 62 funder, and will be submitted for publication in peer-reviewed journals.  
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13 64 **Trial registration number**  
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15 65 ISRCTN: 15564385.  
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For peer review only

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2 67 **ARTICLE SUMMARY**  
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5 68 **Strengths and limitations of this study**  
6

- 7 69 • This study does not require any face-to-face contact as the interventions are accessed  
8 and/or delivered remotely.  
9  
10 70  
11  
12 71 • The digital health interventions being investigated have been tailored to the needs of  
13 individuals with persistent knee pain based on feedback from patient and public  
14 72 involvement and expert review groups conducted during Phase 1.  
15  
16 73  
17  
18 74 • Data will be collected and analysed using a mixed methods approach to provide a greater  
19 understanding of the feasibility and acceptability of the two digital health interventions.  
20 75  
21  
22 76 • Participants, physiotherapists, and the trials staff administering the study cannot be blinded,  
23 however, the trial statistician will remain blinded to group allocation until the database has  
24 77 been locked.  
25  
26 78  
27  
28 79 • The interventions require participants to have an active email account, mobile phone, and  
29 access to a computer or tablet with Internet access suitable for receiving/making video calls.  
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## 83 INTRODUCTION

84 Persistent or chronic knee pain, often with associated stiffness and functional limitations, is a  
85 common problem in older and middle-aged adults.[1,2] A leading cause is osteoarthritis (OA) and in  
86 2020, the pooled global prevalence of knee OA in individuals aged 40 and over was reported to be  
87 around 23%, with a positive correlation between prevalence and increased age.[3] Approximately  
88 10% of adults in the United Kingdom (UK) have a clinical diagnosis of OA, with symptomatic knee OA  
89 being the commonest site.[4] It is estimated that by 2035 the number of people with knee OA in the  
90 UK could reach 8.3 million.[5] Exercise and access to appropriate education are advocated in all  
91 clinical guidelines as core treatments for persistent knee pain. However, with the increasing  
92 prevalence of persistent knee pain and current treatment delivery strategies not always addressing  
93 patient needs, managing these patients is challenging.[6]

94  
95 Physiotherapists are key in providing education, exercises, and self-management support to improve  
96 symptoms and function for individuals with knee OA.[7] It has previously been observed that  
97 physiotherapists can effectively deliver OA rehabilitation interventions remotely using video  
98 technologies,[8–10] which is increasingly important given the adoption of telehealth during the  
99 Covid-19 pandemic[11–13]. It has been reported that since the onset of Covid-19, 88% of 50-64 year  
100 olds, 75% of 65-74 year olds and 46% of those aged 75 or over use the Internet almost every day or  
101 every day.[14] These data support the assumption that some, but not all older individuals could  
102 access Internet-based electronic interventions.

103  
104 Digital health interventions for knee pain have been developed and delivered by physiotherapists in  
105 Australia; and there is evidence to suggest they can improve knee pain and function[9,15] and are  
106 generally accepted by patients with knee OA.[16] Such digital health interventions may be useful in  
107 other large health services (such as in the UK) as an alternative to “in person” clinic appointments,  
108 particularly where physiotherapy services are overstretched[17] and waiting times are prolonged

1  
2 109 due to the Covid-19 pandemic,[18] or where individuals are unable to attend physiotherapy sessions  
3  
4 110 due to mobility problems and/or lack of transport.[19–21]  
5

6 111  
7

## 8 112 **Aims and objectives**

9  
10 113 This trial aims to evaluate the feasibility and acceptability of two different electronic-rehabilitation  
11  
12 114 (e-rehabilitation) interventions in individuals with persistent knee pain. One comprises a self-  
13  
14 115 directed Internet-based home exercise programme with exercise behaviour change support  
15  
16 116 provided via automated SMS ('My Knee UK'). The second is a group-based home exercise  
17  
18 117 programme with Internet-interactive education sessions ('Group E-Rehab'), where the home  
19  
20 118 exercise programme is prescribed and monitored by a physiotherapist using videoconferencing. The  
21  
22 119 trial will also explore the effect of each e-rehabilitation programme on pain and other symptoms  
23  
24 120 compared to the control arm and provide a report on any additional resources (e.g. additional  
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26 121 NHS/private healthcare services) used by participants during the trial.  
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## 33 123 **METHODS**

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### 38 125 **Trial design**

39  
40 126 This is an unblinded, single-centre, randomised feasibility trial with three parallel arms (two e-  
41  
42 127 rehabilitation treatment arms and one control arm). The study protocol was designed to conform to  
43  
44 128 the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines[22,23]  
45  
46 129 and the extension of the Consolidated Standards of Reporting Trials (CONSORT) statement for  
47  
48 130 randomised pilot and feasibility trials.[24] The feasibility trial (Phase 2) opened to recruitment in  
49  
50 131 March 2021 and the planned study end date is June 2023. Trial phases are outlined in Figure 1.  
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56 133 *(Insert **Figure 1**: Study flow diagram.)*  
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2 136 In line with the recently published CONSERVE 2021 Statement and guidelines,[25] several protocol  
3  
4 137 changes were made in response to the Covid-19 pandemic (Supplement 1).

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9 **139 Patient and Public Involvement**

10  
11 140 Members of the NIHR Leeds Biomedical Research Centre Patient and Public Involvement (PPI) group  
12  
13 141 provided input into the trial design and outcome measures through focus group discussions during  
14  
15 142 the funding application stages. PPI was subsequently used to provide input into the refinement of  
16  
17 143 the two e-rehabilitation programmes during the first phase of the study. Additionally, two PPI  
18  
19 144 representatives are members of the Project Advisory Group and help review content and assist with  
20  
21 145 key decisions throughout the trial.  
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27 **147 Participants**

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29 148 The target population is adults with persistent knee pain who meet the eligibility criteria (Table 1).  
30  
31 149 Potential participants have either been referred to musculoskeletal (MSK) services for assessment or  
32  
33 150 have previously received physiotherapy for persistent knee pain; are participants from past studies  
34  
35 151 that have consented to future contact; have responded to a media campaign advertising for  
36  
37 152 volunteers (Figure 1).  
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39

40 153

41  
42 **154 Table 1:** Trial eligibility criteria.  
43

Inclusion Criteria	Exclusion Criteria
Adults $\geq$ 45 years	Inflammatory arthritis (including gout)
Knee pain > 3 months and on most days of previous month	A joint replacement in the study knee
Knee pain during walking $\geq$ 4 on an 11-point numerical rating scale[26]	An injection into the study knee joint within the last month
Activity-related knee joint pain	An arthroscopy of the study knee joint in the last three months
Has a mobile phone, active email account, and computer with Internet access suitable for receiving and making video calls if required.	Enrolled in another research study involving an intervention for OA treatment or management
	Unable to comply with the study protocol
	Unable to understand written and spoken English.

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2 156 **Digital health intervention treatment arms**

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4 157 The e-rehabilitation interventions were adapted for use in the UK (My Knee UK) or developed  
5  
6 158 (Group E-Rehab) during Phase 1 of the study. Feedback relating to usability and content, gathered  
7  
8 159 using online think-aloud interviews and expert review groups, was used to refine the programmes  
9  
10  
11 160 prior to starting the trial. The results from Phase 1, which supports the robustness of the  
12  
13 161 development of intervention content, will be published separately.  
14

15 162

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18 163 *My Knee UK*

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21 164 This is a 12-week Internet-based home exercise intervention that was modified from 'My Knee  
22  
23 165 Exercise' (<https://mykneeexercise.org.au>), a 24-week intervention created and trialled in Australia  
24  
25 166 by Nelligan et al.[15,27] This intervention provides guidance, via a website, for participants to  
26  
27 167 undertake an unsupervised, self-directed lower limb strengthening programme supported by online  
28  
29  
30 168 OA educational information and advice (Table 2). The strengthening programme was reduced from  
31  
32 169 the 24-week Australian version to what was considered a less burdensome 12-week programme by  
33  
34 170 clinical members of the research team.[28] The exercise programme was reviewed and refined by  
35  
36 171 research team and PPI members of the Project Advisory group, with input from an MSK  
37  
38 172 physiotherapist expert review group.  
39

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42  
43 174 In this trial, three muscle strengthening exercises are introduced in Programme One (weeks 1-6), and  
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45 175 two additional strengthening exercises are added in Programme Two (weeks 7-12). The website (My  
46  
47 176 Knee UK) encourages participants to perform their unsupervised home-based exercises at least  
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49  
50 177 three times a week and gives instructions about tailoring and progressing each exercise to their own  
51  
52 178 ability/needs. Exercise logbooks and physical activity planners are available to download from the  
53  
54 179 website to print or complete electronically. Participants are encouraged to access the website at  
55  
56 180 leisure throughout the 12-week intervention and can phone/email a trial physiotherapist if they  
57  
58  
59 181 have any concerns or experience difficulties with the exercise programme.  
60

182

1  
2 183 Participants receive exercise-related behaviour change messages throughout the My Knee UK  
3  
4 184 intervention via automated SMS delivered to their mobile phones (SMS Solutions Australia,  
5  
6 185 Melbourne, Australia). The SMS library uses behaviour change theory to identify and address key  
7  
8 186 barriers to and facilitators of home-exercise programme adherence[29] and has been shown to  
9  
10 187 increase adherence to unsupervised home-based strengthening exercises.[30] The 24-week SMS  
11  
12 188 script, developed by Nelligan et al.[31] with input from academics, physiotherapists, and consumers,  
13  
14 189 was modified for use with the 12-week My Knee UK intervention by increasing the frequency of  
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16 190 facilitator messages (from between 0 & 2 to between 1 & 3 per week), enabling the full BCT message  
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18 191 library to be used (Table 2).  
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210 **Table 2:** Summary of the My Knee UK rehabilitation programme.

Webpage Tab	Contents	
<b>1. Home</b>	Introductory video (from Prof Conaghan) How to use the website and beginning your programme 'Contact Us' for help tab	
<b>2. My Knee Education</b>	2.1. My knee education introduction 2.2. Understanding knee osteoarthritis (OA) 2.3. Understanding knee pain 2.4. Knee pain treatments 2.5. Exercise as treatment 2.6. Recommended exercise 2.7. Managing exercise pain 2.8. How to start in the exercise	
<b>3. My Knee Strength</b>	3.1. My knee strength introduction 3.2. How to start your knee exercises 3.3. Organise your exercise equipment 3.4. Tips for starting and sticking to exercise 3.5. Your mobile phone text message support  <b>Exercise Programme One (weeks 1-6)</b> Exercise instructions and videos (incl. self-tailoring exercise guides) a) Sitting knee extension, b) Side steps, c) Calf raises.  <b>Exercise Programme One (weeks 2-7)</b> Exercise instructions and videos (incl. self-tailoring exercise guides) a) Sitting knee extension, b) Side steps, c) Calf raises, d) Mini (wall) squats, e) Chair rises (sit-to-stands).	
<b>4. My Knee Activity</b>	4.1. My knee activity introduction 4.2. Why increase physical activity? 4.3. How to increase physical activity 4.4. Track your daily steps 4.5. Activity pacing 4.6. Make a physical activity plan 4.7. Record your progress 4.8. Physical activity success stories (videos)	
<b>5. My Knee Tools</b>	Contains all the resources used throughout the website in one place.	
<b>Examples of facilitator and barrier behaviour change messages[30,31]</b>		
<b>Facilitator</b>	Hi [name], fitting in regular knee exercise is hard. The reason we are recommending weekly exercise is because exercise works best when it's a regular thing. Exercising longer term can lead to lasting benefits in your knee health.	Do you have a goal you'd like to achieve if your knee improved? Think about what your goal is. Achieving your knee goals is the reward for doing the exercise programme.
<b>Barrier</b>	[Name] It's okay to pull back the intensity of exercises if you're feeling concerned. The important thing is that you do the exercises regularly. Gradually build up again as the knee becomes more stable & your confidence increases.	[Name] It can be hard to remember. We suggest making the exercises a habit. Set aside the same time each day to do them. It's much harder to forget when something is a daily routine.

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1  
2 212 *Group E-Rehab*  
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5 213 Group E-Rehab is a 12-week e-rehabilitation intervention comprising six Internet-interactive  
6  
7 214 education sessions and the same five lower limb strengthening exercises as My Knee UK. However,  
8  
9 215 unlike those allocated to My Knee UK, Group E-Rehab participants receive seven group-based  
10  
11 216 exercise sessions delivered remotely by a physiotherapist (Table 3) via the videoconferencing  
12  
13 217 platform Zoom (Zoom Video Communications Inc., San Jose, USA) in weeks 1, 2, 3, 5, 7, 9, and 12  
14  
15 218 (Table 3). The physiotherapist demonstrates/teaches the leg strengthening exercises (limited to  
16  
17 219 three exercises in the first three classes), and conducts a 30-second chair sit-to-stand test[32]  
18  
19 220 remotely at the start of each class as a baseline measure and indication of progress. The  
20  
21 221 physiotherapist monitors the sit-to-stand assessment alongside exercise quality, technique, and  
22  
23 222 effort during the classes, and uses these measures to tailor the exercises to meet each participant's  
24  
25 223 needs. Group sessions last 45-60 minutes, and each group contains four-seven participants.  
26  
27 224  
28  
29 225 Interactive educational sessions developed for the Group E-Rehab intervention, available through  
30  
31 226 the digital presentation programme Microsoft Sway,[33] cover knee OA self-management and  
32  
33 227 include optional quizzes with automated feedback, plus self-assessment questionnaires to make the  
34  
35 228 sessions more personalised (Table 3). Participants are advised that, although they can access the  
36  
37 229 Sway education sessions in any order and at their leisure during the 12-week intervention, working  
38  
39 230 through all six in the first 6-weeks will give them more opportunities to ask questions and/or discuss  
40  
41 231 the contents during the online exercise classes. The physiotherapist provides dedicated time for this  
42  
43 232 during each online class as well as reminding participants to engage with the education sessions and  
44  
45 233 encouraging them to do their exercises at least three times each week. Participants are emailed  
46  
47 234 exercise logbooks and physical activity planners to download.  
48  
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54 235  
55  
56 236 Two Leeds Community MSK and Rehabilitation Service physiotherapists with current registration to  
57  
58 237 practice in the UK were identified to deliver the Group E-Rehab intervention based on their clinical  
59  
60 238 skills and experience. In preparation for the trial, both attended an external one-day motivational

1  
2 239 interviewing training course (Et al Training, Leeds, UK). To facilitate consistent delivery of the  
3  
4 240 intervention, particularly the exercise component, the physiotherapists completed practice Zoom  
5  
6 241 classes and follow a comprehensive guidance document (written and provided by the study  
7  
8 242 Advanced Practice Physiotherapist [CC] and DGW).  
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266 **Table 3:** Summary of the Group E-Rehab rehabilitation programme.

<p><b><u>Sway Session 1: Pain and the Knee Joint</u></b></p> <p>1.1 About the Knee joint Anatomy and physiology / Using the knee joint</p> <p>1.2 What is Pain</p> <p>1.3 What causes knee pain Knee Osteoarthritis (OA) / Some facts about OA</p> <p>1.4 The Pain cycle</p> <p>1.5 Pain Management Activity / Conventional medicine Complementary and alternative medicine Other ways of managing knee pain</p> <p>1.6 Test your knowledge (quiz)</p>	<p><b><u>Sway Session 2: Physical Activity</u></b></p> <p>2.1 The Benefits of Exercise and Physical Activity Reducing the risk of falling How physically active am I? (quiz)</p> <p>2.2 Building an active lifestyle Aerobic and cardiovascular exercise Physical Activity Recommendations</p> <p>2.3 Exercise, general physical activity, and Joint Pain Planning and recording physical activity Tracking your daily steps</p> <p>2.4 The Group E-Rehab Home Exercise Programme Format of the sessions / equipment Leg strengthening programme</p> <p>2.5 Will I get New Aches and Pains if I exercise?</p> <p>2.6 Physical activity quiz</p>
<p><b><u>Sway Session 3: Goal Setting</u></b></p> <p>3.1 Do my knee symptoms hold me back (quiz)</p> <p>3.2 What are goals</p> <p>3.3 Why and How should I set goals?</p> <p>3.4 SMART goals Example of a SMART goal</p> <p>3.5 Goal Planning and Implementation</p> <p>3.6 Problem Solving Problem solving example</p> <p>3.7 Reward yourself</p> <p>3.8 Goal setting and chronic pain (quiz)</p>	<p><b><u>Sway Session 4: Pacing Skills</u></b></p> <p>4.1 Activity levels and Pain</p> <p>4.2 Flare ups</p> <p>4.3 Balancing Activity and Rest Boom Bust (Overactivity/underactivity) cycle Activity rest cycle</p> <p>4.4 Pacing your activity levels Putting Pacing into practice</p> <p>4.5 Pacing and chronic pain quiz (quiz)</p> <p>4.6 Managing at Work</p>
<p><b><u>Sway Session 5: Communication and Emotional Wellbeing</u></b></p> <p>5.1 How well do I communicate with people? (quiz)</p> <p>5.2 The importance of Effective Communication Making others aware (inc. professionals)</p> <p>5.3 Communication Styles Assertive Communication</p> <p>5.5 The Importance of Emotional Wellbeing</p> <p>5.6 Managing Emotions, Acceptance, and Feeling Positive Getting and Staying Connected Distraction techniques / Mindfulness</p> <p>5.7 Managing Setbacks</p> <p>5.8 Emotions and Chronic Pain (quiz)</p> <p>5.9 Online Arthritis Support</p>	<p><b><u>Sway Session 6: Staying Healthy</u></b></p> <p>6.1 Good Health</p> <p>6.2 Healthy Eating</p> <p>6.3 Getting Enough Sleep Sleep and Pain / Sleeping well</p> <p>6.4 Relax and Unwind</p> <p>6.5 Good Health Quiz (quiz)</p> <p>6.6 Summary</p> <p>6.7 What Happens Next? Continuing exercises and activities</p>
<p><b><u>Home-based Leg Strengthening Exercises</u></b></p> <p><b>Physiotherapist-led group-based exercise classes via Zoom in weeks 1, 2, 3, 5, 7, 9, and 12.</b></p> <p>Weeks 1-6 (3 exercises): a) Sitting knee extension, b) Side steps, c) Calf raises (weeks 1-6).</p> <p>Weeks 7-12 (5 exercises): Exercises a to c plus - d) Mini (wall) squats, e) Chair rises (sit-to-stands).</p> <ul style="list-style-type: none"> <li>• 30 second sit-to-stand test done at the start of every physio-led Zoom class.</li> <li>• Classes include time for discussing the self-directed Sway educational sessions.</li> </ul>	

1  
2 267 **Control arm**  
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4 268 Participants allocated to the control group could receive any usual care intervention, ranging from  
5  
6 269 no healthcare practitioner input to one or two physiotherapy sessions (delivered in-person or  
7  
8 270 remotely by telephone or videoconferencing), to advice and guidance about self-management. The  
9  
10 271 type of intervention that control group participants receive depends on their recruitment path.  
11  
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13 272

14  
15 273 **Enrolment**  
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17 274 Participants are enrolled once they have been screened for eligibility by telephone (visit 1) and their  
18  
19 275 informed, written postal consent has been countersigned by a delegated member of the research  
20  
21 276 team (Supplement 2). Eligible consenting participants complete a postal baseline questionnaire (visit  
22  
23 277 2) prior to randomisation.  
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29 279 **Randomisation and blinding**  
30

31 280 Participants are randomised (by DGW) to one of the three groups using a 1:1:1 allocation ratio.  
32  
33 281 Random allocation sequences with varying block length (3, 6 and 9), stratified by sex, are generated  
34  
35 282 using an external password-protected web-based randomisation system (Sealed Envelope Ltd.  
36  
37 283 London, UK). A dummy randomisation list[34], created using the same settings but different random  
38  
39 284 seed number, was set up and then checked by the trial statistician (EMAH) before the trial  
40  
41 285 randomisation list was created.  
42  
43

44 286

45  
46 287 The nature of this feasibility trial means it is not possible to blind participants, physiotherapists  
47  
48 288 delivering the Group E-Rehab intervention, or the study team managing the trial. However, the trial  
49  
50 289 statistician will remain blinded to group allocation until all preliminary data checks have been  
51  
52 290 performed at a blinded data review meeting and the database has been locked.  
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2 292 **Trial data collection and outcomes**

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4 293 *Follow-up visits*

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7 294 Follow-up postal questionnaires are sent out at three months (visit 3), which is the end of the  
8  
9 295 intervention treatment period, and at nine months (visit 4). Participants who withdraw from the trial  
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11 296 early will not be replaced and will be requested to complete the next scheduled follow-up  
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13 297 questionnaire. The schedule of enrolment and data collected during the trial is detailed in Table 4.  
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16 298

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19 299 *Outcomes*

20  
21 300 Patient-reported outcomes covering pain, function, health-related quality-of-life, coping and  
22  
23 301 catastrophising, and confidence and motivation to do exercises will be measured alongside basic  
24  
25 302 clinical findings at baseline and at the three-month (12-week) and nine-month follow-up time points  
26  
27 303 (Figure 1 and Table 4). These include validated outcome measures used with OA patients and in knee  
28  
29 304 OA clinical trials.[35–38] Global change in overall pain and mobility/function and data on the number  
30  
31 305 of contacts made with hospital and community health services, plus any costs incurred due to their  
32  
33 306 knee pain (e.g. prescription, travel costs to attend appointments), will be collected at the three and  
34  
35 307 nine-month time points. Primary and secondary outcomes have not been specified as this is a  
36  
37 308 feasibility study.  
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44 310 *Data management and monitoring*

45  
46 311 Identifiable data will be locked in a filing cabinet in the Leeds Institute of Rheumatic and  
47  
48 312 Musculoskeletal Medicine (LIRMM) research offices or held in an encrypted file stored on a  
49  
50 313 password-protected University of Leeds server, with access limited to the study team.  
51  
52 314 Pseudonymised data will be entered onto a password-protected Access database, developed in line  
53  
54 315 with the LIRMM Data Quality Management System Standard Operating Procedures. Data will be  
55  
56 316 periodically internally verified and audited. Data will be stored in a de-identified manner for 5 years  
57  
58 317 after the final publication.  
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318



319 **Table 4:** SPIRIT (Standard Protocol Items for Randomized Trials) schedule of enrolment,  
 320 interventions, and assessments.

TIMEPOINT	STUDY PERIOD			
	Enrolment	Randomisation	Follow-Up	Close-Out
	-1	0	3-Months +/- 4 weeks	9-Months +/- 4 weeks
<b>ENROLMENT:</b>				
Initial contact & study information	X			
Eligibility screen	X			
Informed consent	X			
Allocation		X		
<b>INTERVENTIONS:</b>				
Group E-Rehab			←————→	
'My Knee UK' Group			←————→	
Control Group (duration of treatment will be variable)			←-----→	
<b>ASSESSMENTS:</b>				
<b>Clinical information</b>				
Age, gender, ethnicity		X		
Previous joint surgery		X		
Employment & physical activity		X		
Height & weight		X		
History of current knee pain		X		
General health & medication use		X	X	X
<b>Patient-reported outcomes</b>				
Joint pain manikin		X	X	X
Knee pain frequency (5-point scale)		X	X	X
Confidence & motivation to do exercises (11-point NRS)		X	X	X
Global change (7-point Likert scale)			X	X
WOMAC (Pain, function & stiffness)		X	X	X
ASES		X	X	X
HADS		X	X	X
Generic health status (EQ-5D-5L)		X	X	X
Health-related quality of life (SF-12)		X	X	X
Resource use			X	X
Abbreviations: NRS: numeric rating scale. WOMAC: The Western Ontario and McMaster Universities Osteoarthritis Index. ASES: Arthritis Self-Efficacy Scale. HADS: Hospital Anxiety and Depression Scale. EQ-5D-5L: European Quality of Life-Five Dimension-Five Level Scale. SF-12: 12-Item Short Form Survey.				

321

1  
2 322 Physiotherapists will record the time taken to administer and lead the Group E-Rehab exercise  
3  
4 323 classes and if a trial physiotherapist is contacted by a My Knee UK participant for help or advice, this  
5  
6 324 will also be recorded. This data will contribute to estimating the cost of delivering the Group E-  
7  
8 325 Rehab and My Knee UK interventions.  
9

10 326  
11  
12  
13 327 Descriptive data relating to exercise adherence relevant to each treatment arm will be collected at  
14  
15 328 the end of the 12-week intervention phase. The web analytics service Google Analytics[39] will be  
16  
17 329 used to record the number of times each participant accesses the My Knee UK website and the  
18  
19 330 duration of their website access. The weekly number of home-based exercise sessions completed  
20  
21 331 (self-reported in response to the automated SMS message) will also be recorded. Group E-Rehab  
22  
23 332 data will include the number of Zoom exercise classes attended and the number of Sway educational  
24  
25 333 sessions accessed, along with the time spent engaged with each session.  
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29 334

### 30 335 *Nested qualitative study*

31  
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33  
34 336 A sub-sample of consenting participants, purposively sampled by age, sex, and having received the  
35  
36 337 My Knee UK or Group E-Rehab intervention, will undergo individual in-depth remote  
37  
38 338 (videoconference or telephone) interviews where the acceptability of the two e-rehabilitation  
39  
40 339 interventions will be explored. Interviews will focus on participants' experiences of being in the trial  
41  
42 340 and will comprise questions specific to each intervention. It is anticipated around 20 individuals will  
43  
44 341 be interviewed with the final number being determined once data saturation has been reached,  
45  
46 342 which will be when there is consensus amongst the research team that minimal new information is  
47  
48 343 being generated. Participants will be interviewed either on completion of the 3-month follow-up  
49  
50 344 questionnaire (visit 3), or at the end of follow-up on completion of the 9-month questionnaire (visit  
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52 345 4).  
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346  
347 Semi-structured videoconference interviews with the two physiotherapists who delivered the Group  
348 E-Rehab Zoom classes will be conducted. This is to gain insight about the preparation they received,

1  
2 349 thoughts about its acceptability, their experience of delivering the intervention and any barriers to  
3  
4 350 delivering it effectively that they identified.  
5

6 351

## 8 352 **Planned analyses**

10 353 The intention-to-treat participant population will be used. A full statistical analysis plan (SAP V1.0,  
11  
12  
13 354 04/01/2021) was written prior to commencement of recruitment.  
14

15 355

### 17 356 *Sample size*

18  
19  
20 357 A total sample size of 90 participants (30 per arm), based on established principles for a feasibility  
21  
22  
23 358 study[40], will be adequate for evaluating feasibility and collecting sufficient data to inform the  
24  
25 359 sample size in a definitive randomised controlled trial (RCT).  
26

27 360

### 29 361 *Feasibility and proof-of-concept*

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31  
32 362 As a feasibility study, inferential statistics will be limited. Analysis will focus on descriptive statistics,  
33  
34 363 including measures of frequency (e.g. percent), central tendency (e.g. mean, median), and dispersion  
35  
36 364 or variation (e.g. standard deviation, inter-quartile range, confidence interval estimation), rather  
37  
38 365 than formal hypothesis testing. Data will provide an estimate of recruitment and retention rates and  
39  
40 366 the correlation between baseline and follow-up measurements, to inform the sample size required  
41  
42 367 for a definitive RCT. In line with CONSORT[24] the choice of primary outcome for the definitive study  
43  
44 368 will be informed by the results of the feasibility study and guided by a previous study,[10] but  
45  
46 369 candidate variables will be The Western Ontario and McMaster Universities Osteoarthritis Index  
47  
48 370 (WOMAC), pain and physical function domain scores. Published minimum clinically important  
49  
50 371 differences (MCID) reported for the candidate primary outcomes will be used when calculating  
51  
52 372 sample size.[41] If the difference between the groups favours one or both intervention arms over  
53  
54 373 the control arm, and the two-sided 85% confidence interval around the difference includes the  
55  
56 374 MCID, we will proceed to design a definitive trial provided feasibility criteria are met.[42] Attrition  
57  
58  
59 375 will be examined to identify any factors that may be systematically affecting drop-out, and  
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2 376 continuous measures of adherence within each treatment arm will be summarised. The cost of  
3  
4 377 delivering the e-rehabilitation interventions will be estimated and alongside this, a descriptive report  
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6 378 on the use of additional resources (e.g. the type of resources, number of contacts, and any costs  
7  
8 379 incurred) will be produced.  
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10 380

### 11 381 *Safety analyses*

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16 382 Adverse events (AEs) or serious adverse events (SAEs) will be recorded and coded to indicate the  
17  
18 383 major event category but, as this is not a clinical trial of an investigational medicinal product,  
19  
20 384 severity will not be graded. The frequency of all treatment-related AEs and SAEs recorded during the  
21  
22 385 trial period will be displayed as the number of participants experiencing the AEs/SAEs, the  
23  
24 386 percentage of participants, and the number of AEs/SAEs will be presented both overall and by  
25  
26 387 treatment arm.  
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30 388

### 31 389 *Qualitative study*

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34  
35 390 Data derived from the participant and semi-structured physiotherapist interviews will be transcribed  
36  
37 391 verbatim. Transcripts will be analysed using framework analysis.[43]  
38

39 392

### 40 393 **Feasibility trial outcome**

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43  
44 394 Data from the feasibility trial and follow-up nested qualitative study will be integrated to support the  
45  
46 395 case for determining whether one or both e-rehabilitation interventions are feasible, acceptable and  
47  
48 396 have the potential to be implemented in practice. The qualitative and quantitative data will enable  
49  
50 397 the potential for My Knee UK and/or Group E-Rehab to be introduced as alternative models of  
51  
52 398 services delivery to be explored. The feasibility trial will be deemed successful if the results  
53  
54 399 demonstrate that (1) participants and physiotherapists find one or both intervention(s) acceptable  
55  
56 400 (using data from the nested qualitative study), (2) it is possible to calculate a manageable sample  
57  
58 401 size for use in a definitive RCT, (3) attrition at visit 3 (3-months) is no more than 30% and (4) at least  
59  
402 40% of eligible patients are recruited to the trial. If one or both e-rehabilitation interventions are

1  
2 403 acceptable, the intention is to develop the protocol for and conduct a definitive RCT with a health  
3  
4 404 economic component. This will be sufficiently powered for testing the wider use of My Knee UK  
5  
6 405 and/or Group E-Rehab (depending on feasibility trial outcome) as a prescribed treatment for  
7  
8 406 individuals with persistent knee pain.  
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## 15 409 **DISCUSSION**

17  
18 410 The growing prevalence of persistent knee pain and OA requires the development and  
19  
20 411 implementation of effective and accessible treatments that enable these patients to manage their  
21  
22 412 symptoms. These treatments should be convenient for patients and should not overburden local  
23  
24 413 MSK physiotherapy services. Current evidence suggests that for chronic conditions such as OA,  
25  
26 414 digital technologies can be used to deliver self-management programmes electronically.[9,44]  
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31 416 This trial aims to evaluate the feasibility and acceptability of two different e-rehabilitation  
32  
33 417 interventions (Group E-Rehab and My Knee UK) in individuals with persistent knee pain. Education,  
34  
35 418 advice about increasing general physical activity levels, and strengthening exercises that can be  
36  
37 419 tailored to individual needs are pivotal components of both interventions. Muscle strengthening  
38  
39 420 programmes are beneficial in reducing pain and improving physical function in people with knee  
40  
41 421 OA.[45] In this trial, the home-based lower-limb strengthening exercise programme is either  
42  
43 422 prescribed and monitored by a physiotherapist as a group-based intervention using  
44  
45 423 videoconferencing (Group E-Rehab), or it is self-directed (accessed via the My Knee UK website). It is  
46  
47 424 believed that the e-rehabilitation interventions under investigation in this trial will provide patients  
48  
49 425 with access to the digital tools and resources needed for self-managing their knee pain and  
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51 426 symptoms, and that one or both interventions could eventually be implemented within the NHS.  
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2 428 **Ethics and dissemination**  
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4 429 This feasibility trial and current protocol (v5.0, 25/01/2022) was approved by the West of Scotland  
5  
6 430 Research Ethics Committee 5 (REC5), reference number 20/WS/0006 prior to commencing  
7  
8 431 recruitment, which is ongoing. The study is sponsored by the University of Leeds (Research Integrity  
9  
10 432 and Governance), UK and is registered with the ISRCTN (Reference: 15564385; Supplement 3). All  
11  
12 433 individuals assisting with the trial will be informed of any protocol amendments, which will be  
13  
14 434 approved by the Sponsor before being submitted to the REC/HRA for approval. The results will be  
15  
16 435 disseminated to the study grant funder, submitted for publication in peer-reviewed journals and  
17  
18 436 where requested, a summary of the study findings will be disseminated to study participants. No  
19  
20 437 study participants will be identifiable in the study results.  
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25  
26 439 **Data availability statement**  
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28 440 The full protocol and statistical analysis plan will be available via the University of Leeds data  
29  
30 441 repository. The full anonymised trial data set and statistical codes will be available 12 months  
31  
32 442 following publication upon request.  
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## 454 **Competing interests**

455 None declared.

## 457 **Author contributions**

458 RSH, RKN and KLB co-developed the Australian SMS programme and My Knee Exercise website.  
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460 SRK, KLB, CC, EMAH, GAM, MC and DGW designed this protocol. EMAH produced the statistical  
461 analysis plan. The UK exercise and SMS programmes were developed by PGC, CC, DGW and MC,  
462 DGW respectively. DGW designed the UK version of the website (My Knee UK), created the  
463 Microsoft Sway education package, is leading the coordination of the study, and drafted the  
464 manuscript. All authors contributed to manuscript reviewing and editing and approved the final  
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7  
8 475 submit for publication.  
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2 615 **TABLE AND FIGURE TITLES AND LEGENDS**  
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4  
5 616 Table 1: Trial eligibility criteria.  
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7 617 Figure 1: Study flow diagram.  
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9 618 Table 2: Summary of the My Knee UK rehabilitation programme.  
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11 619 Table 3: Summary of the Group E-Rehab rehabilitation programme.  
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13  
14 620 Table 4: SPIRIT (Standard Protocol Items for Randomized Trials) schedule of enrolment,  
15 621 interventions, and assessments.

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17 622 [NRS: numeric rating scale; WOMAC: The Western Ontario and McMaster Universities  
18 623 Osteoarthritis Index; ASES: Arthritis Self-Efficacy Scale; HADS: Hospital Anxiety and  
19 624 Depression Scale; EQ-5D-5L; European Quality of Life-Five Dimension-Five Level Scale; SF-12:  
20 625 12-Item Short Form Survey]  
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26 628 **SUPPLEMENTS**  
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29 629 Supplement 1: Protocol modifications made to mitigate the effects of the Covid-19 Pandemic  
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31 630 Supplement 2: Sample participant consent form for the Phase 2 trial  
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33 631 Supplement 3: Trial registration  
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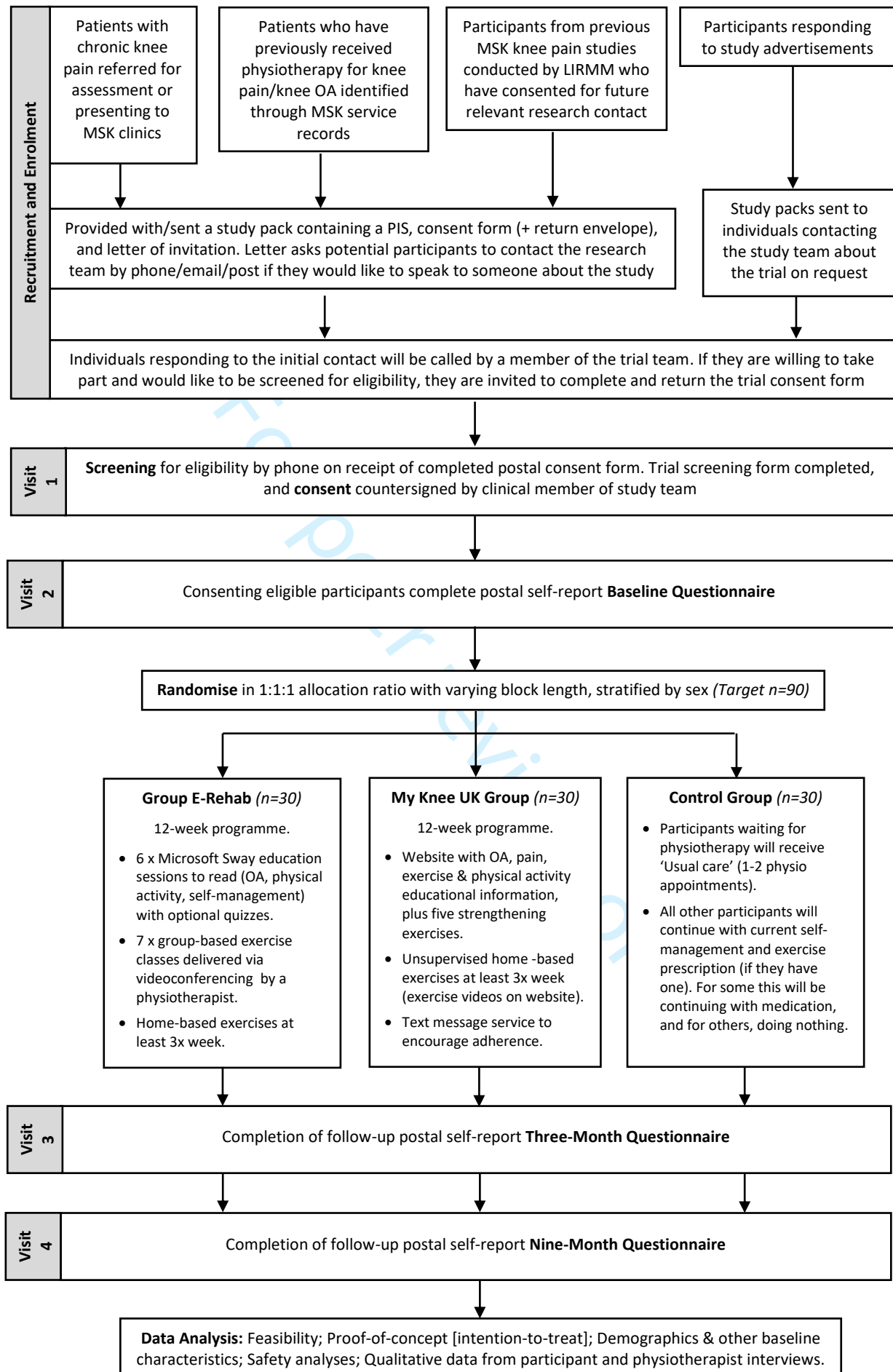
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2 SUPPLEMENT 1  
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45 **Protocol modifications made to mitigate the effects of the Covid-19 Pandemic**  
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- 7 1. Changes arising from the Covid-19 pandemic mean that routine physiotherapy appointments  
8 are now more likely to be remote rather than face-to-face. Currently, most appointments are  
9 taking place over the telephone or in some case, via video consultation, rather than being face-  
10 to-face in a clinic. Prior to starting the recruitment process for the feasibility trial, the protocol  
11 and participant documents were amended to reflect these changes. This means that potential  
12 participants will be fully aware that if they enter the study and are allocated to the control  
13 group, if they are current patients who will receive usual care, then their physiotherapy  
14 appointments are unlikely to be face-to-face, particularly if Covid-19 restrictions are still in  
15 place.  
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- 30 2. Given the current and potential future restrictions arising from the Covid-19 pandemic,  
31 interviews with the physiotherapists and sub-sample of participants from the trial during the  
32 nested qualitative study phase will be done remotely.  
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- 39 3. Current Covid-19 restrictions mean that only skeleton staff members from the research team  
40 were physically going into the office. This would have caused a delay in responding to the initial  
41 postal response to enquiries from potential participants. To avoid this, the invitation letter was  
42 amended slightly so that if anyone receiving the study information is interested in joining the  
43 study, they are asked to contact the study team via email or phone instead of returning a paper  
44 contact form.  
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- 54 4. A delayed start due to Covid-19 has resulted in shortened timeframe for recruitment, with the  
55 risk that reaching the target of 90 participants within the study timeframe would not be  
56 achievable. To mitigate this, additional ways of identifying and recruiting participants were  
57 added to the protocol. This included:  
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- Searching local Trust MSK service records for potentially eligible patients who have previously received physio for knee pain.
- Using Participant identification Centres (PICs) who have the appropriate approval and model agreement in place to carrying out a search of their patient records database to identify individuals that meet a study's eligibility criteria.
- A database search of participants from previous University of Leeds studies who have consented to be contacted about future relevant research studies.
- A media campaign with physical posters/flyers in clinics, waiting rooms or local community centres, and an electronic poster/advert that can be distributed digitally (e.g. email, University or Trust websites), and used via social media.

Participants recruited via MSK waiting lists or clinics (current patients) will continue to receive a physio appointment (usual care) if they are randomised to the control group or if they subsequently withdraw. However, the amendment will affect participants identified via service records, database searches, media campaigns or PICs if they are randomised to the control group or later withdraw from the trial. Participants recruited using these methods (i.e. not via the MSK waiting list or clinics), will be asked to continue with whatever exercises, treatment, or self-management they were doing before joining the trial.

SUPPLEMENT 2

Sample participant consent form for the Phase 2 trial



**UNIVERSITY OF LEEDS**

Leeds Institute of Rheumatic and Musculoskeletal Medicine

2<sup>nd</sup> Floor, Chapel Allerton Hospital

Chapeltown Road, Leeds, LS7 4SA

Email: [e.rehab@leeds.ac.uk](mailto:e.rehab@leeds.ac.uk)

Tel: 0113 392 4965

Participant Identification Number

**CONSENT FORM** (IRAS Reference: 269827)

**Evaluation of electronic-rehabilitation programmes for chronic knee pain**

**Phase 2: Feasibility trial**

Please initial  
each box

1	I confirm that I have read the information sheet dated 18/05/2021 (version 3.0) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2	I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, and without my legal rights or medical care being affected.	
3	I understand that, even if I withdraw from this study, the information already collected from me will be used in analysing the results of this study.	
4	I understand that the group sessions will be recorded and any identifiable audio and visual data from these recordings will be stored securely and not shared.	
5	I understand that the information collected during this study may be used to support other research in the future and may be shared anonymously with other researchers.	
6	I agree to my personal information being stored for the purposes of this study. I understand that any information which could identify me will be kept strictly confidential.	
7	I understand that relevant sections of the data collected during the study, may be looked at by individuals from the University of Leeds (sponsors) or from regulatory authorities where it is relevant to my taking part in this research.	
8	I understand that my GP will be informed about my participation in this study.	
9	I agree to take part in the above study.	

**After initialling the boxes, please print and sign your name (participant), add the date, and fill out the participant contact details on the next page before returning the form.**

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6 Name of Participant (PRINTED)  
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10 **Please remember to fill in your contact details at the bottom of the page.**

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12 The contact slip will be removed and destroyed after we have put your details on to our secure  
13 Subject Screening Log, which is used by the research team for contacting you about the study.  
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23 Name of Researcher  
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30 When completed: 1 for participant; 1 for researcher site file. \*Will be signed by researcher on a different  
31 day.  
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IRAS ID	Project Title	Document Type	Version #	Date	Page
269827	E-rehab for Knee Pain	Phase 2 Trial Patient Consent Form	4.0	10/09/2021	Page 2 of 2

## SUPPLEMENT 3

## Trial registration

Data category	Information
Registry identifying number	ISRCTN15564385
Date of registration	07/02/2020
Prospective/Retrospective	Prospectively registered
Additional identifiers	CPMS 43473, IRAS 269827
Sources of monetary support	Versus Arthritis; National Institute for Health Research (NIHR) (UK)
Sponsor	University of Leeds
Contact information	Dr Dawn Groves-Williams; d.groves-williams@leeds.ac.uk Dr Sarah Kingsbury; s.r.kingsbury@leeds.ac.uk
Short/public title	E-rehab for Knee Pain
Scientific title	Evaluation of electronic-rehabilitation programmes for chronic knee pain
Countries of recruitment	United Kingdom
Condition category	Musculoskeletal Diseases
Condition	Chronic knee pain
Interventions	Access to <b>My Knee UK</b> website containing exercise videos and self-management resources for 12 weeks. Support via SMS messages <b>Group E-Rehab:</b> access to online educational and self-management resources plus 7 online group physiotherapy classes over 12-weeks <b>Control Group:</b> depending on their recruitment path – will receive usual physiotherapy care or continue with usual self-management
Key inclusion and exclusion criteria	Type: Adults $\geq$ 45 years; both sexes; no healthy volunteers Inclusion: knee pain > 3 months and on most days of previous month; activity-related joint pain; pain during walking $\geq$ 4 on an 11-point scale Exclusion: Inflammatory arthritis/gout; Joint replacement in study knee; injection within last month; arthroscopy within last 3-months
Study design	Mixed methods interventional randomised controlled feasibility trial with follow-up interviews Primary: Interventional; Secondary: Randomised controlled trial; Trial setting: Community; Trial type: treatment
Target sample size	90 (30 in each group)
Date of first enrolment	22/04/2021
Recruitment status	Recruiting
Overall trial status	Ongoing
Key outcomes (Primary and secondary outcomes have not been specified due to this being a feasibility study).	Participants and physiotherapists find e-rehabilitation feasible and acceptable, and it can be administered successfully; calculation of a sample size that can be achieved in a main trial; max. of 30% attrition at 3-months; $\geq$ 40-50% of eligible participants are recruited. Patient-reported outcome domains are: pain; quality of life; pain coping and catastrophising; resource use; confidence and motivation to do exercises; global change in overall pain and mobility/function.

# Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

## Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

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In your methods section, say that you used the SPIRIT reporting guidelines, and cite them as:

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		Reporting Item	Page Number
<b>Administrative information</b>			
Title	<a href="#">#1</a>	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	<a href="#">#2a</a>	Trial identifier and registry name. If not yet registered, name of intended registry	4
Trial registration: data set	<a href="#">#2b</a>	All items from the World Health Organization Trial Registration Data Set	Suppl 3
Protocol version	<a href="#">#3</a>	Date and version identifier	21
Funding	<a href="#">#4</a>	Sources and types of financial, material, and other support	23-24
Roles and responsibilities: contributorship	<a href="#">#5a</a>	Names, affiliations, and roles of protocol contributors	1,23

1	Roles and	<a href="#">#5b</a>	Name and contact information for the trial sponsor	22
2	responsibilities:			
3	sponsor contact			
4	information			
5				
6				
7	Roles and	<a href="#">#5c</a>	Role of study sponsor and funders, if any, in study	24
8	responsibilities:		design; collection, management, analysis, and	
9	sponsor and funder		interpretation of data; writing of the report; and the	
10			decision to submit the report for publication, including	
11			whether they will have ultimate authority over any of	
12			these activities	
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17	Roles and	<a href="#">#5d</a>	Composition, roles, and responsibilities of the	8,23
18	responsibilities:		coordinating centre, steering committee, endpoint	
19	committees		adjudication committee, data management team, and	
20			other individuals or groups overseeing the trial, if	
21			applicable (see Item 21a for data monitoring committee)	
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26	<b>Introduction</b>			
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28	Background and	<a href="#">#6a</a>	Description of research question and justification for	6-7
29	rationale		undertaking the trial, including summary of relevant	
30			studies (published and unpublished) examining benefits	
31			and harms for each intervention	
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35	Background and	<a href="#">#6b</a>	Explanation for choice of comparators	7
36	rationale: choice of			
37	comparators			
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39				
40	Objectives	<a href="#">#7</a>	Specific objectives or hypotheses	7
41				
42				
43	Trial design	<a href="#">#8</a>	Description of trial design including type of trial (eg,	3,7
44			parallel group, crossover, factorial, single group),	
45			allocation ratio, and framework (eg, superiority,	
46			equivalence, non-inferiority, exploratory)	
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49	<b>Methods:</b>			
50	<b>Participants,</b>			
51	<b>interventions, and</b>			
52	<b>outcomes</b>			
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55				
56	Study setting	<a href="#">#9</a>	Description of study settings (eg, community clinic,	Fg1
57			academic hospital) and list of countries where data will	
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be collected. Reference to where list of study sites can be obtained

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4	Eligibility criteria	<a href="#">#10</a>	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)
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11	Interventions:	<a href="#">#11a</a>	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered
12	description		
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16	Interventions:	<a href="#">#11b</a>	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)
17	modifications		
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23	Interventions:	<a href="#">#11c</a>	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)
24	adherence		
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28	Interventions:	<a href="#">#11d</a>	Relevant concomitant care and interventions that are permitted or prohibited during the trial
29	concomitant care		
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32	Outcomes	<a href="#">#12</a>	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended
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43	Participant timeline	<a href="#">#13</a>	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)
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50	Sample size	<a href="#">#14</a>	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations
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57	Recruitment	<a href="#">#15</a>	Strategies for achieving adequate participant enrolment to reach target sample size
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**Methods:****Assignment of interventions (for controlled trials)**

Allocation: sequence generation	<a href="#">#16a</a>	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
Allocation concealment mechanism	<a href="#">#16b</a>	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	15
Allocation: implementation	<a href="#">#16c</a>	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	15
Blinding (masking)	<a href="#">#17a</a>	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	15
Blinding (masking): emergency unblinding	<a href="#">#17b</a>	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
<b>Methods: Data collection, management, and analysis</b>			
Data collection plan	<a href="#">#18a</a>	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.	16

Reference to where data collection forms can be found, if not in the protocol

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

1 2 3 4 5 6 7 8	Dissemination policy: authorship	<a href="#">#31b</a> Authorship eligibility guidelines and any intended use of professional writers	31
9 10 11 12	Dissemination policy: reproducible research	<a href="#">#31c</a> Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	22

## 13 Appendices

14 15 16 17 18	Informed consent materials	<a href="#">#32</a> Model consent form and other related documentation given to participants and authorised surrogates	Suppl 2
19 20 21 22 23 24 25	Biological specimens	<a href="#">#33</a> Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

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 28 <https://www.goodreports.org/>, a tool made by the [EQUATOR Network](#) in collaboration with  
 29 [Penelope.ai](#)  
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