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

Dawn Groves-Williams, Gretl A McHugh, Kim L Bennell, Christine Comer, Elizabeth M A Hensor, Mark Conner, Rachel K Nelligan, Rana S Hinman, Sarah R Kingsbury, Philip G Conaghan

ABSTRACT

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

Methods and analysis This protocol describes a non-blinded, randomised feasibility trial with three parallel groups. The trial aims to recruit 90 participants (45 years or older) with a history of persistent knee pain consistent with a clinical diagnosis of knee osteoarthritis. Participants will be randomly assigned in a 1:1:1 allocation ratio. The ‘My Knee UK’ intervention arm will receive a self-directed unsupervised internet-based home exercise programme plus short message service support (targeting exercise behaviour change) for 12 weeks; the ‘Group E-Rehab’ intervention arm will receive group-based physiotherapist-prescribed home exercises delivered via videoconferencing accompanied by internet-interactive educational sessions for 12 weeks; the control arm will receive usual physiotherapy care or continue with their usual self-management (depending on their recruitment path). Feasibility variables, patient-reported outcomes and clinical findings measured at baseline, 3 and 9 months will be assessed and integrated with qualitative interview data from a subset of Group E-Rehab and My Knee UK participants. If considered feasible and acceptable, a definitive randomised controlled trial can be conducted to investigate the clinical effectiveness and cost-effectiveness of one or both interventions with a view to implementation in routine care.

Ethics and dissemination The trial was approved by the West of Scotland Research Ethics Committee 5 (Reference: 20/WS/0006). The results of the study will be disseminated to study participants, the study grant funder and will be submitted for publication in peer-reviewed journals.

Trial registration number ISRCTN15564385.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study does not require any face-to-face contact as the interventions are accessed and/or delivered remotely.
⇒ The digital health interventions being investigated have been tailored to the needs of individuals with persistent knee pain based on feedback from patient and public involvement and expert review groups conducted during phase I.
⇒ Data will be collected and analysed using a mixed methods approach to provide a greater understanding of the feasibility and acceptability of the two digital health interventions.
⇒ Participants, physiotherapists and the trials staff administering the study cannot be blinded; however, the trial statistician will remain blinded to group allocation until the database has been locked.
⇒ The interventions require participants to have an active email account, mobile phone and access to a computer or tablet with Internet access suitable for receiving/making video calls.

INTRODUCTION

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

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

Digital health interventions for knee pain have been developed and delivered by physiotherapists in Australia; and there is evidence to suggest they can improve knee pain and function9 15 and are generally accepted by patients with knee OA.16 Such digital health interventions may be useful in other large health services (such as in the UK) as an alternative to ‘in person’ clinic appointments, particularly where physiotherapy services are overstretched17 and waiting times are prolonged due to the COVID-19 pandemic,18 or where individuals are unable to attend physiotherapy sessions due to mobility problems and/or lack of transport.19–21

Aims and objectives
This trial aims to evaluate the feasibility and acceptability of two different electronic-rehabilitation (e-rehabilitation) interventions in individuals with persistent knee pain. One comprises a self-directed internet-based home exercise programme with exercise behaviour change support provided via automated short message service (SMS) (‘My Knee UK’). The second is a group-based home exercise programme with internet-interactive education sessions (‘Group E-Rehab’), where the home exercise programme is prescribed and monitored by a physiotherapist using videoconferencing. The trial will also explore the effect of each e-rehabilitation programme on pain and other symptoms compared with the control arm and provide a report on any additional resources (eg, additional National Health Service (NHS)/private healthcare services) used by participants during the trial.

METHODS

Trial design
This is an unblinded, single-centre, randomised feasibility trial with three parallel arms (two e-rehabilitation treatment arms and one control arm). The study protocol was designed to conform to the Standard Protocol Items: Recommendations for Interventional Trials guidelines22 23 and the extension of the Consolidated Standards of Reporting Trials (CONSORT) statement for randomised pilot and feasibility trials.24 The feasibility trial (phase II) opened to recruitment in March 2021 and the planned study end date is June 2023. Trial phases are outlined in figure 1.

In line with the recently published CONSERVE 2021 Statement and guidelines,45 several protocol changes were made in response to the COVID-19 pandemic (online supplemental 1).

Patient and public involvement
Members of the National Institute for Health Research Leeds Biomedical Research Centre Patient and Public Involvement (PPI) group provided input into the trial design and outcome measures through focus group discussions during the funding application stages. PPI was subsequently used to provide input into the refinement of the two e-rehabilitation programmes during the first phase of the study. Additionally, two PPI representatives are members of the project advisory group and help review content and assist with key decisions throughout the trial.

Participants
The target population is adults with persistent knee pain who meet the eligibility criteria (table 1). Potential participants have either been referred to musculoskeletal (MSK) services for assessment or have previously received physiotherapy for persistent knee pain; are participants from past studies that have consented to future contact; have responded to a media campaign advertising for volunteers (figure 1).

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

My Knee UK
This is a 12-week internet-based home exercise intervention that was modified from ‘My Knee Exercise’ (https://mykneeexercise.org.au), a 24-week intervention created and trialled in Australia by Nelligan et al.15 26 This intervention provides guidance, via a website, for participants to undertake an unsupervised, self-directed lower limb strengthening programme supported by online OA educational information and advice (table 2). The strengthening programme was reduced from the 24-week Australian version to what was considered a less burdensome 12-week programme by clinical members of the research team.27 The exercise programme was reviewed and refined by the research team and PPI members of the project advisory group, with input from an MSK physiotherapist expert review group.

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

Participants receive exercise-related behaviour change messages throughout the My Knee UK intervention via automated SMS delivered to their mobile phones (SMS Solutions Australia, Melbourne, Australia). The SMS

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**Figure 1** Study flow diagram. LIRMM, Leeds Institute of Rheumatic and Musculoskeletal Medicine; MSK, musculoskeletal; OA, osteoarthritis; PIS, Participant Information Sheet.
library uses behaviour change theory (BCT) to identify and address key barriers to and facilitators of home-exercise programme adherence and has been shown to increase adherence to unsupervised home-based strengthening exercises. The 24-week SMS script, developed by Nelligan et al with input from academics, physiotherapists and consumers, was modified for use with the 12-week My Knee UK intervention by increasing the frequency of facilitator messages (from between 0 and 2 to between 1 and 3 per week), enabling the full BCT message library to be used (table 2).

Group E-Rehab

Group E-Rehab is a 12-week e-rehabilitation intervention comprising six internet-interactive education sessions and the same five lower limb strengthening exercises as My Knee UK. However, unlike those allocated to My Knee UK, Group E-Rehab participants receive seven group-based exercise sessions delivered remotely by a physiotherapist (table 3) via the videoconferencing platform Zoom (Zoom Video Communications, San Jose, USA) in weeks 1, 2, 3, 5, 7, 9 and 12 (table 3). The physiotherapist demonstrates/teaches the leg strengthening exercises (limited to three exercises in the first three classes), and conducts a 30 s chair sit-to-stand test remotely at

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**Table 1** Trial eligibility criteria

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
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<tbody>
<tr>
<td>Adults ≥45 years</td>
<td>Inflammatory arthritis (including gout)</td>
</tr>
<tr>
<td>Knee pain in ≥3 months and on most days of previous month</td>
<td>A joint replacement in the study knee</td>
</tr>
<tr>
<td>Knee pain during walking ≥4 on an 11-point numerical rating scale</td>
<td>An injection into the study knee joint within the last month</td>
</tr>
<tr>
<td>Activity-related knee joint pain</td>
<td>An arthroscopy of the study knee joint in the last 3 months</td>
</tr>
<tr>
<td>Has a mobile phone, active email account and computer with internet access suitable for receiving and making video calls if required</td>
<td>Unable to comply with the study protocol</td>
</tr>
</tbody>
</table>

**Table 2** Summary of the My Knee UK rehabilitation programme

<table>
<thead>
<tr>
<th>Webpage tab</th>
<th>Contents</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Home</td>
<td>Introductory video (from PCG)</td>
</tr>
<tr>
<td></td>
<td>How to use the website and beginning your programme</td>
</tr>
<tr>
<td></td>
<td>‘Contact us’ for help tab</td>
</tr>
<tr>
<td>2.2. Understanding knee osteoarthritis (OA)</td>
<td></td>
</tr>
<tr>
<td>2.3. Understanding knee pain</td>
<td></td>
</tr>
<tr>
<td>2.4. Knee pain treatments</td>
<td></td>
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<tr>
<td>2.5. Exercise as treatment</td>
<td></td>
</tr>
<tr>
<td>2.6. Recommended exercise</td>
<td></td>
</tr>
<tr>
<td>2.7. Managing exercise pain</td>
<td></td>
</tr>
<tr>
<td>2.8. How to start in the exercise</td>
<td></td>
</tr>
<tr>
<td>3.2. How to start your knee exercises</td>
<td></td>
</tr>
<tr>
<td>3.3. Organise your exercise equipment</td>
<td></td>
</tr>
<tr>
<td>3.4. Tips for starting and sticking to exercise</td>
<td></td>
</tr>
<tr>
<td>3.5. Your mobile phone text message support</td>
<td></td>
</tr>
<tr>
<td><strong>Exercise programme one (weeks 1–6)</strong></td>
<td></td>
</tr>
<tr>
<td>Exercise instructions and videos (including self-tailoring exercise guides)</td>
<td></td>
</tr>
<tr>
<td>(1) Sitting knee extension, (2) side steps, (3) calf raises</td>
<td></td>
</tr>
<tr>
<td><strong>Exercise programme two (weeks 7–12)</strong></td>
<td></td>
</tr>
<tr>
<td>Exercise instructions and videos (including self-tailoring exercise guides)</td>
<td></td>
</tr>
<tr>
<td>(1) Sitting knee extension, (2) side steps, (3) calf raises, (4) mini (wall) squats, (5) chair raises (sit to stands)</td>
<td></td>
</tr>
<tr>
<td>4.2. Why increase physical activity?</td>
<td></td>
</tr>
<tr>
<td>4.3. How to increase physical activity</td>
<td></td>
</tr>
<tr>
<td>4.4. Track your daily steps</td>
<td></td>
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<tr>
<td>4.5. Activity pacing</td>
<td></td>
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<tr>
<td>4.6. Make a physical activity plan</td>
<td></td>
</tr>
<tr>
<td>4.7. Record your progress</td>
<td></td>
</tr>
<tr>
<td>4.8. Physical activity success stories (videos)</td>
<td></td>
</tr>
<tr>
<td>5. My knee tools</td>
<td>Contains all the resources used throughout the website in one place</td>
</tr>
</tbody>
</table>

**Examples of facilitator and barrier behaviour change messages**

**Facilitator**

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.

**Barrier**

(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 and 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.
the start of each class as a baseline measure and indication of progress. The physiotherapist monitors the sit-to-stand assessment alongside exercise quality, technique and effort during the classes, and uses these measures to tailor the exercises to meet each participant’s needs. Group sessions last 45–60 min, and each group contains four to seven participants.

Interactive educational sessions developed for the Group E-Rehab intervention, available through the digital presentation programme Microsoft Sway, cover knee OA self-management and include optional quizzes with automated feedback, plus self-assessment questionnaires to make the sessions more personalised (table 3). Participants are advised that, although they can access the Sway education sessions in any order and at their leisure during the 12-week intervention, working through all six in the first 6 weeks will give them more opportunities to ask questions and/or discuss the contents during the online exercise classes. The physiotherapist provides dedicated time for this during each online class as well as reminding participants to engage with the education sessions and encouraging them to do their exercises at least three times each week. Participants are emailed exercise logbooks and physical activity planners to download.

Two Leeds Community MSK and Rehabilitation Service physiotherapists with current registration to practice in the UK were identified to deliver the Group E-Rehab intervention based on their clinical skills and experience. In preparation for the trial, both attended an external viewing training course (Et al Training, Leeds, UK). To facilitate consistent delivery of the intervention, particularly the exercise component,
the physiotherapists completed practice Zoom classes and follow a comprehensive guidance document (written and provided by the study advanced practice physiotherapist (CC) and DG-W).

Control arm
Participants allocated to the control group could receive any usual care intervention, ranging from no healthcare practitioner input to one or two physiotherapy sessions (delivered in-person or remotely by telephone or videoconferencing), to advice and guidance about self-management. The type of intervention that control group participants receive depends on their recruitment path.

Enrolment
Participants are enrolled once they have been screened for eligibility by telephone (visit 1) and their informed, written postal consent has been countersigned by a delegated member of the research team (online supplemental 2). Eligible consenting participants complete a postal baseline questionnaire (visit 2) prior to randomisation.

Randomisation and blinding
Participants are randomised (by DG-W) to one of the three groups using a 1:1:1 allocation ratio. Random allocation sequences with varying block length (3, 6 and 9), stratified by sex, are generated using an external password-protected web-based randomisation system (Sealed Envelope, London, UK). A dummy randomisation list, created using the same settings but different random seed number, was set up and then checked by the trial statistician (EMAH) before the trial randomisation list was created.

The nature of this feasibility trial means it is not possible to blind participants, physiotherapists delivering the Group E-Rehab intervention or the study team managing the trial. However, the trial statistician will remain blinded to group allocation until all preliminary data checks have been performed at a blinded data review meeting and the database has been locked.

Trial data collection and outcomes

Follow-up visits
Follow-up postal questionnaires are sent out at 3 months (visit 3), which is the end of the intervention treatment period, and at 9 months (visit 4). Participants who withdraw from the trial early will not be replaced and will be requested to complete the next scheduled follow-up questionnaire. The schedule of enrolment and data collected during the trial is detailed in table 4.

Outcomes
Patient-reported outcomes covering pain, function, health-related quality of life, coping and catastrophising, and confidence and motivation to do exercises will be measured alongside basic clinical findings at baseline and at the 3-month (12 weeks) and 9-month follow-up timepoints (figure 1 and table 4). These include validated outcome measures used with patients with OA and in knee OA clinical trials. Global change in overall pain and mobility/function and data on the number of contacts made with hospital and community health services, plus any costs incurred due to their knee pain (eg, prescription, travel costs to attend appointments), will be collected at the 3-month and 9-month timepoints. Primary and secondary outcomes have not been specified as this is a feasibility study.

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

Physiotherapists will record the time taken to administer and lead the Group E-Rehab exercise classes and if a trial physiotherapist is contacted by a My Knee UK participant for help or advice, this will also be recorded. These data will contribute to estimating the cost of delivering the Group E-Rehab and My Knee UK interventions.

Descriptive data relating to exercise adherence relevant to each treatment arm will be collected at the end of the 12-week intervention phase. The web analytics service Google Analytics will be used to record the number of times each participant accesses the My Knee UK website and the duration of their website access. The weekly number of home-based exercise sessions completed (self-reported in response to the automated SMS message) will also be recorded. Group E-Rehab data will include the number of Zoom exercise classes attended and the number of Sway educational sessions accessed, along with the time spent engaged with each session.

Nested qualitative study
A subsample of consenting participants, purposively sampled by age, sex and having received the My Knee UK or Group E-Rehab intervention, will undergo individual in-depth remote (videoconference or telephone) interviews where the acceptability of the two e-rehabilitation interventions will be explored. Interviews will focus on participants’ experiences of being in the trial and will comprise questions specific to each intervention. It is anticipated around 20 individuals will be interviewed with the final number being determined once data saturation has been reached, which will be when there is consensus among the research team that minimal new information is being generated. Participants will be interviewed either on completion of the 3-month follow-up questionnaire (visit 3), or at the end of follow-up on completion of the 9-month questionnaire (visit 4).
Semistructured videoconference interviews with the two physiotherapists who delivered the Group E-Rehab Zoom classes will be conducted. This is to gain insight about the preparation they received, thoughts about its acceptability, their experience of delivering the intervention and any barriers to delivering it effectively that they identified.
Planned analyses
The intention-to-treat participant population will be used. A full statistical analysis plan (SAP V.1.0, 04 January 2021) was written prior to commencement of recruitment.

Sample size
A total sample size of 90 participants (30 per arm), based on established principles for a feasibility study, will be adequate for evaluating feasibility and collecting sufficient data to inform the sample size in a definitive randomised controlled trial (RCT).

Feasibility and proof of concept
As a feasibility study, inferential statistics will be limited. Analysis will focus on descriptive statistics, including measures of frequency (eg, per cent), central tendency (eg, mean, median) and dispersion or variation (eg, SD, IQR, CI estimation), rather than formal hypothesis testing. Data will provide an estimate of recruitment and retention rates and the correlation between baseline and follow-up measurements, to inform the sample size required for a definitive RCT. In line with CONSORT41 the choice of primary outcome for the definitive study will be informed by the results of the feasibility study and guided by a previous study, but candidate variables will be The Western Ontario and McMaster Universities Osteoarthritis Index, pain and physical function domain scores. Published minimum clinically important differences (MCID) reported for the candidate primary outcomes will be used when calculating sample size.42 If the difference between the groups favours one or both intervention arms over the control arm, and the two-sided 85% CI around the difference includes the MCID, we will proceed to design a definitive trial provided feasibility criteria are met.41 Attrition will be examined to identify any factors that may be systematically affecting drop-out, and continuous measures of adherence within each treatment arm will be summarised. The cost of delivering the e-rehabilitation interventions will be estimated and alongside this, a descriptive report on the use of additional resources (eg, the type of resources, number of contacts and any costs incurred) will be produced.

Safety analyses
Adverse events (AEs) or serious adverse events (SAEs) will be recorded and coded to indicate the major event category but, as this is not a clinical trial of an investigational medicinal product, severity will not be graded. The frequency of all treatment-related AEs and SAEs recorded during the trial period will be displayed as the number of participants experiencing the AEs/SAEs, the percentage of participants and the number of AEs/SAEs will be presented both overall and by treatment arm.

Qualitative study
Data derived from the participant and semistructured physiotherapist interviews will be transcribed verbatim. Transcripts will be analysed using framework analysis.42

Feasibility trial outcome
Data from the feasibility trial and follow-up nested qualitative study will be integrated to support the case for determining whether one or both e-rehabilitation interventions are feasible, acceptable and have the potential to be implemented in practice. The qualitative and quantitative data will enable the potential for My Knee UK and/or Group E-Rehab to be introduced as alternative models of service delivery to be explored. The feasibility trial will be deemed successful if the results demonstrate that (1) participants and physiotherapists find one or both intervention(s) acceptable (using data from the nested qualitative study), (2) it is possible to calculate a manageable sample size for use in a definitive RCT, (3) attrition at visit 3 (3 months) is no more than 30% and (4) at least 40% of eligible patients are recruited to the trial. If one or both e-rehabilitation interventions are acceptable, the intention is to develop the protocol for and conduct a definitive RCT with a health economic component. This will be sufficiently powered for testing the wider use of My Knee UK and/or Group E-Rehab (depending on feasibility trial outcome) as a prescribed treatment for individuals with persistent knee pain.

DISCUSSION
The growing prevalence of persistent knee pain and OA requires the development and implementation of effective and accessible treatments that enable these patients to manage their symptoms. These treatments should be convenient for patients and should not overburden local MSK physiotherapy services. Current evidence suggests that for chronic conditions, such as OA, digital technologies can be used to deliver self-management programmes electronically.9 43 This trial aims to evaluate the feasibility and acceptability of two different e-rehabilitation interventions (Group E-Rehab and My Knee UK) in individuals with persistent knee pain. Education, advice about increasing general physical activity levels and strengthening exercises that can be tailored to individual needs are pivotal components of both interventions. Muscle strengthening programmes are beneficial in reducing pain and improving physical function in people with knee OA.44 In this trial, the home-based lower-limb strengthening exercise programme is either prescribed and monitored by a physiotherapist as a group-based intervention using videoconferencing (Group E-Rehab) or it is self-directed (accessed via the My Knee UK website). It is believed that the e-rehabilitation interventions under investigation in this trial will provide patients with access to the digital tools and resources needed for self-managing their knee pain and symptoms, and that one or both interventions could eventually be implemented within the NHS.

Ethics and dissemination
This feasibility trial and current protocol (v.5.0, 25 January 2022) was approved by the West of Scotland
Research Ethics Committee 5 (REC5), reference number 20/WS/0006 prior to commencing recruitment, which is ongoing. The study is sponsored by the University of Leeds (Research Integrity and Governance), UK and is registered with the ISRCTN (online supplemental 3). All individuals assisting with the trial will be informed of any protocol amendments, which will be approved by the Sponsor before being submitted to the REC/HRA for approval. The results will be disseminated to the study grant funder, submitted for publication in peer-reviewed journals and where requested, a summary of the study findings will be disseminated to study participants. No study participants will be identifiable in the study results.

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**Contributors** RSH, RKN and KLB codeveloped the Australian SMS programme and My Knee Exercise website. Funding was secured by PGC (lead applicant) and GAM, SRK, LH, KLB and CC (coapplicants). PGC, SRK, KLB, CC, LH, GAM, MC and DG-W designed this protocol. LH produced the statistical analysis plan. The exercise and SMS programmes were developed by PGC, CC, DG-W and MC, DG-W respectively. DG-W designed the UK version of the website (My Knee UK), created the Microsoft Sway education package, is leading the coordination of the study and drafted the manuscript. All authors contributed to manuscript reviewing and editing and approved the final version.

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**Competing interests** None declared.

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**REFERENCES**


SUPPLEMENT 1

Protocol modifications made to mitigate the effects of the Covid-19 Pandemic

1. Changes arising from the Covid-19 pandemic mean that routine physiotherapy appointments are now more likely to be remote rather than face-to-face. Currently, most appointments are taking place over the telephone or in some case, via video consultation, rather than being face-to-face in a clinic. Prior to starting the recruitment process for the feasibility trial, the protocol and participant documents were amended to reflect these changes. This means that potential participants will be fully aware that if they enter the study and are allocated to the control group, if they are current patients who will receive usual care, then their physiotherapy appointments are unlikely to be face-to-face, particularly if Covid-19 restrictions are still in place.

2. Given the current and potential future restrictions arising from the Covid-19 pandemic, interviews with the physiotherapists and sub-sample of participants from the trial during the nested qualitative study phase will be done remotely.

3. Current Covid-19 restrictions mean that only skeleton staff members from the research team were physically going into the office. This would have caused a delay in responding to the initial postal response to enquiries from potential participants. To avoid this, the invitation letter was amended slightly so that if anyone receiving the study information is interested in joining the study, they are asked to contact the study team via email or phone instead of returning a paper contact form.

4. A delayed start due to Covid-19 has resulted in shortened timeframe for recruitment, with the risk that reaching the target of 90 participants within the study timeframe would not be achievable. To mitigate this, additional ways of identifying and recruiting participants were added to the protocol. This included:
• 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
2nd Floor, Chapel Allerton Hospital
Chapeltown Road, Leeds, LS7 4SA
Email: 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**

<table>
<thead>
<tr>
<th></th>
<th>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.</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>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.</td>
</tr>
<tr>
<td>3</td>
<td>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.</td>
</tr>
<tr>
<td>4</td>
<td>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.</td>
</tr>
<tr>
<td>5</td>
<td>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.</td>
</tr>
<tr>
<td>6</td>
<td>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.</td>
</tr>
<tr>
<td>7</td>
<td>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.</td>
</tr>
<tr>
<td>8</td>
<td>I understand that my GP will be informed about my participation in this study.</td>
</tr>
<tr>
<td>9</td>
<td>I agree to take part in the above study.</td>
</tr>
</tbody>
</table>

After initialising 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.
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 Participant (PRINTED) Date Signature

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: _____________________________________ ________________

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## SUPPLEMENT 3

### Trial registration

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<thead>
<tr>
<th>Data category</th>
<th>Information</th>
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<tr>
<td>Registry identifying number</td>
<td>ISRCTN15564385</td>
</tr>
<tr>
<td>Date of registration</td>
<td>07/02/2020</td>
</tr>
<tr>
<td>Prospective/Retrospective</td>
<td>Prospectively registered</td>
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<tr>
<td>Additional identifiers</td>
<td>CPMS 43473, IRAS 269827</td>
</tr>
<tr>
<td>Sources of monetary support</td>
<td>Versus Arthritis; National Institute for Health Research (NIHR) (UK)</td>
</tr>
<tr>
<td>Sponsor</td>
<td>University of Leeds</td>
</tr>
<tr>
<td>Contact information</td>
<td>Dr Dawn Groves-Williams; <a href="mailto:d.groves-williams@leeds.ac.uk">d.groves-williams@leeds.ac.uk</a></td>
</tr>
<tr>
<td></td>
<td>Dr Sarah Kingsbury; <a href="mailto:s.r.kingsbury@leeds.ac.uk">s.r.kingsbury@leeds.ac.uk</a></td>
</tr>
<tr>
<td>Short/public title</td>
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<tr>
<td>Scientific title</td>
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<td>Condition category</td>
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<tr>
<td>Condition</td>
<td>Chronic knee pain</td>
</tr>
</tbody>
</table>

| Interventions          | Access to My Knee UK website containing exercise videos and self-management resources for 12 weeks. Support via SMS messages |
| Group E-Rehab:         | access to online educational and self-management resources plus 7 online group physiotherapy classes over 12-weeks |
| Control Group:         | depending on their recruitment path – will receive usual physiotherapy care or continue with usual self-management |

| Key inclusion and exclusion criteria | Type: Adults ≥ 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 ≥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; ≥ 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. |