ISRCTN15564385 https://doi.org/10.1186/ISRCTN15564385

E-rehab for Knee Pain

Submission date
27/01/2020

Recruitment status
No longer recruiting

Registration date
07/02/2020

Overall study status
Completed

Last Edited
12/08/2025

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Chronic knee pain is a common problem. It can happen for a number of reasons, and it can make it difficult to walk and function in everyday life. The knee joint is complex, and a range of factors can lead to damage and pain. When the components of the knee are not working properly, pain, inflammation, and other symptoms can occur.
This study, which is funded by Versus Arthritis, aims to evaluate how feasible and acceptable two electronic rehabilitation (e-rehabilitation) programmes are when used to treat patients with chronic knee pain. The acceptability and experiences of the physiotherapists delivering the interventions will also be explored. The study will build on and expand for use in the UK, e-rehabilitation programmes that have been developed in Australia.

Who can participate?
Adults aged > 45 years with chronic knee pain who have access to the internet at home and on their smartphone.

What does the study involve?
Patients with knee pain who meet the inclusion criteria will be recruited from the Leeds Community Healthcare Musculoskeletal Service or service records/databases, or will respond to adverts. They will then be randomised to receive one of the two e-rehabilitation programmes (Group E-Rehab or MyKneeExercise), or they will be placed in the control group. Participants will be informed of their randomisation allocation via email or telephone. The 'Group E-Rehab' intervention is an Internet-delivered physiotherapist-prescribed home exercise programme, and physiotherapists will be trained to deliver this. The 'MyKneeExercise' intervention is home web-based and no physiotherapist input is required to deliver this e-rehabilitation programme. The feasibility and acceptability of these interventions will then be explored using data collected through questionnaires and interviews, and the study will assess the potential use of the e-rehabilitation programmes by physiotherapists in community care settings.

What are the possible benefits and risks of participating?
Taking part in this study may or may not directly benefit participants but it will help researchers to see whether treating individuals with chronic knee pain using the Internet is feasible. If it is, then a larger scale study may follow.

There are no risks associated with taking part in this study, there is just the slight inconvenience of being asked to complete three study questionnaires and for some, also taking part in an the interview to get their views and opinions about the rehabilitation programme.

Where is the study run from?
Leeds Community Healthcare NHS Trust (UK)

When is the study starting and how long is it expected to run for?
January 2020 to June 2023

Who is funding the study?
1. Versus Arthritis (UK)
2. National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Dawn Groves-Williams
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
269827

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 43473, IRAS 269827

Study information

Scientific Title
Evaluation of electronic-rehabilitation programmes for chronic knee pain

Study objectives
Electronic-rehabilitation programmes can be delivered to individuals with chronic knee pain and is acceptable to individuals and health professionals.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/01/2020, West of Scotland REC 5 (West of Scotland Research Ethics Service Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE; +44 (0)141 314 0213; WoSREC5@ggc.scot.nhs.uk), ref: 20/WS/0006

Study design
Mixed methods interventional randomized controlled trial with follow-up interviews

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Chronic knee pain

Interventions
Current interventions as of 11/10/2021:
One or more of the following recruitment methods will be used. i) Potential participants will be identified either at the point of referral or when they present with knee pain to a physiotherapist at the Leeds Musculoskeletal Services. ii) Individuals identified as having experienced and been treated for knee pain through their Musculoskeletal Service records. iii) The study team will contact consenting participants from previous musculoskeletal studies involving knee pain to briefly outline the study, including eligibility criteria, to them. iv) A media campaign may be run at relevant sites, including via social media, to aid recruitment. All potential participants will receive a letter from the clinical team about the study, together with a copy of the PIS and a consent form.

Patients who would like to take part in the study will be initially screened for general eligibility, and then subsequently consented before clinical screening for inclusion/exclusion criteria. Consent will be requested to make audio-visual recordings of the Group rehab sessions. Potential participants who are not happy to consent to the sessions being recorded may not be eligible for this intervention. Participants who are eligible to take part will be randomly allocated into one of three groups in a 1:1:1 allocation ratio. They will receive either standard physiotherapy care (Control Group), a web-based home exercise programme with a motivational text support system (MyKneeExercise), or a group Internet-delivered physiotherapist prescribed home exercise programme with additional Internet-interactive educational sessions (Group E-Rehab). It is proposed that there will be 30 participants in each group. Participants will be informed of their randomisation allocation via email or telephone.

Participants receiving the Group E-Rehab intervention will be given online access to standard education material and will be asked to complete four Internet-interactive educational modules. These will be completed at the participants own pace. The exercise aspect of this intervention will be delivered by a physiotherapist. This will consist of approximately seven group Skype /Zoom sessions delivered once a fortnight to groups of 4-7 participants, each lasting 45- 60 minutes. Participants will be given an introduction/'technical lesson' to familiarise them with Skype/Zoom, and the physiotherapist will perform an assessment (Skype/Zoom visit 1). Individuals receiving Group E-Rehab will be given a lower-limb strengthening home exercise programme to do, which should be completed by the individual or group participants three times per week. It is proposed that two physiotherapists will be needed to deliver the Group E-Rehab intervention to 30 participants in total. Physiotherapists who are involved with the study will attend a one-day training course; and will be provided with a specific exercise manual.

Participants receiving the MyKneeExercise will be provided with a web-based home exercise programme and support to do physiotherapy prescribed exercises at their own pace, three times a week over 12 weeks. The programme contains various lower limb strengthening exercises (e.g. hamstring curl, knee extension, calf raises), and the website contains evidence-based information and videos for each exercise and general OA information and advice. Participants will be asked to complete an exercise log and will receive motivational text messages (2-5 per week), where they will also be asked to report their adherence to the exercise programme. The website has been trialled with patients in Australia, however, any participant who is not managing the programme will be able to request a single appointment with a physiotherapist by completing the 'make an appointment' page on the MyKneeExercise website.

The interactive/electronic elements of the programmes and the physiotherapist training materials (for Group E-Rehab) will be developed and refined during Phase 1 of the study.

Depending on where the participant has been recruited from, the control group will either receive usual care via Leeds Community Health musculoskeletal services, or they will continue with their usual self-management. For some, this may mean that they do nothing. Usual care normally consists of 1 to 2 physiotherapy sessions and being provided with an exercise sheet to continue with the exercises/rehabilitation at home. However, if COVID-19 restrictions are in place, or clinical practice remains changed, then usual care physiotherapy may be conducted remotely rather than face-to-face.

All participants will be asked to complete a questionnaire (covering topics such as pain, function, health status, quality of life) at baseline and after 3 and 9 months. To learn more about the individuals who are taking part in the study, additional information and basic demographic details such as age, sex, ethnicity, medical history (including a history of chronic knee pain), joints affected (using a joint manikin), employment, and medications, will be collected at baseline. A resource use questionnaire to collect data in order to generate an estimate of the cost of delivering the interventions will also be used. The questionnaires will be sent by post.

Qualitative data collection:
On completion of the 3-month or 9-month follow-up questionnaire, a sub-sample of participants from the two e-rehabilitation intervention study arms will be contacted and asked their views about the specific intervention they received as well as their experience of being in the study. This will be done remotely or by telephone, and will last approximately 45 minutes. Around 20 participants will be interviewed; the final number will be determined once data saturation has been reached.

The two physiotherapists who delivered the Skype/Zoom Group E-Rehab intervention will both be asked for feedback about their experience of the preparation, delivery and potential/actual barriers to the e-rehabilitation programme using semi-structured online interviews.

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Previous interventions from 04/12/2020 to 11/10/2021:
Patients referred to the LCH musculoskeletal service with chronic knee pain will be provided with information about the study and invited to take part. The study will be advertised to current patients by having posters/leaflets in clinics, and additional potential participants will be identified from current/past chronic knee pain referral lists to the service. Potential participants will either be handed (if in a musculoskeletal clinic), or sent an invitation letter from LCH Trust, and they will also receive a contact form containing contact details for the research team at the University of Leeds, and a Participant Information Sheet.

Patients who would like to take part in the study will be initially screened for general eligibility, and then subsequently consented before clinical screening for inclusion/exclusion criteria. Consent will be requested to make audio-visual recordings of the Group rehab sessions. Potential participants who are not happy to consent to the sessions being recorded may not be eligible for this intervention. Participants who are eligible to take part will be randomly allocated into one of three groups in a 1:1:1 allocation ratio. They will receive either standard physiotherapy care (Control Group), a web-based home exercise programme with motivational text support system (MyKneeExercise), or a group Internet-delivered physiotherapist prescribed

home exercise programme with additional Internet-interactive educational sessions (Group E-Rehab). It is proposed that there will be 30 participants in each group. Participants will be informed of their randomisation allocation via email or telephone.

Participants receiving the Group E-Rehab intervention will be given online access to standard education material and will be asked to complete four Internet-interactive educational modules. These will be completed at the participants own pace. The exercise aspect of this intervention will be delivered by a physiotherapist. This will consist of approximately seven group Skype /Zoom sessions delivered once a fortnight to groups of 5-6 participants, each lasting 45- 60 minutes. Participants will be given an introduction/'technical lesson' to familiarise them with Skype/Zoom, and the physiotherapist will perform an assessment (Skype/Zoom visit 1). Individuals receiving Group E-Rehab will be given a lower-limb strengthening home exercise programme to do, which should be completed by the individual or group participants three times per week. It is proposed that two physiotherapists will be needed to deliver the Group E-Rehab intervention to 30 participants in total. Physiotherapists who are involved with the study will attend a one-day training course; and will be provided with a specific exercise manual.

Participants receiving the MyKneeExercise will be provided with a web-based home exercise programme and support to do physiotherapy prescribed exercises at their own pace, three times a week over 12 weeks. The programme contains various lower limb strengthening exercises (e.g. hamstring curl, knee extension, calf raises), and the website contains evidence-based information and videos for each exercise and general OA information and advice. Participants will be asked to complete an exercise log and will receive motivational text messages (2-5 per week), where they will also be asked to report their adherence to the exercise programme. The web site has been trialled with patients in Australia, however, any participant who is not managing the programme will be able to request a single appointment with a physiotherapist by completing the 'make an appointment' page on the MyKneeExercise website.

The interactive/electronic elements of the programmes and the physiotherapist training materials (for Group E-Rehab) will be developed and refined during Phase 1 of the study.

The control group will receive one/two physiotherapy sessions (this may not be face-to-face); and will be provided with an exercise sheet so they can continue with the exercises and rehabilitation at home.

All participants will be asked to complete a questionnaire (covering topics such as pain, function, health status, quality of life) at baseline and after 3 and 9 months. To learn more about the individuals who are taking part in the study, additional information and basic demographic details such as age, sex, ethnicity, medical history (including history of chronic knee pain), joints affected (using a joint manikin), employment, and medications, will be collected at baseline. A resource use questionnaire to collect data in order to generate an estimate of the cost of delivering the interventions will also be used. The questionnaires will be sent by post.

Qualitative data collection:
On completion of the 9-month follow-up questionnaire, a sub-sample of participants from the two e-rehabilitation intervention study arms will be contacted and asked their views about the specific intervention they received as well as their experience of being in the study. This will be done remotely or by telephone, and will last approximately 45 minutes. Around 20 participants will be interviewed; the final number will be determined once data saturation has been reached.

The two physiotherapists who delivered the Skype/Zoom Group E-Rehab intervention will both be asked for feedback about their experience of the preparation, delivery and potential/actual barriers to the e-rehabilitation programme using semi-structured online interviews.

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Original interventions:
Patients referred to the LCH musculoskeletal service with chronic knee pain will be provided with information about the study and invited to take part. The study will be advertised to current patients by having posters/leaflets in clinics, and additional potential participants will be identified from current/past chronic knee pain referral lists to the service. Potential participants will either be handed (if in a musculoskeletal clinic), or sent an invitation letter from LCH Trust, and they will also receive a contact form containing contact details for the research team at the University of Leeds, and a Participant Information Sheet.

Patients who would like to take part in the study will be initially screened for general eligibility, and then subsequently consented before clinical screening for inclusion/exclusion criteria. Consent will be requested to make audio-visual recordings of the Group rehab sessions. Potential participants who are not happy to consent to the sessions being recorded may not be eligible for this intervention. Participants who are eligible to take part will be randomly allocated into one of three groups in a 1:1:1 allocation ratio. They will receive either standard physiotherapy care (Control Group), a web-based home exercise programme with motivational text support system (MyKneeExercise), or a group Internet-delivered physiotherapist prescribed home exercise programme with additional Internet-interactive educational sessions (Group E-Rehab). It is proposed that there will be 30 participants in each group. Participants will be informed of their randomisation allocation via email or telephone.

Participants receiving the Group E-Rehab intervention will be given online access to standard education material and will be asked to complete four Internet-interactive educational modules. These will be completed at the participants own pace. The exercise aspect of this intervention will be delivered by a physiotherapist. This will consist of approximately seven group Skype /Zoom sessions delivered once a fortnight to groups of 5-6 participants, each lasting 45- 60 minutes. Participants will be given an introduction/'technical lesson' to familiarise them with Skype/Zoom, and the physiotherapist will perform an assessment (Skype/Zoom visit 1). Individuals receiving Group E-Rehab will be given a lower-limb strengthening home exercise programme to do, which should be completed by the individual or group participants three times per week. It is proposed that two physiotherapists will be needed to deliver the Group E-Rehab intervention to 30 participants in total. Physiotherapists who are involved with the study will attend a one-day training course; and will be provided with a specific exercise manual.

Participants receiving the MyKneeExercise will be provided with a web-based home exercise programme and support to do physiotherapy prescribed exercises at their own pace, three times a week over 12 weeks. The programme contains various lower limb strengthening exercises (e.g. hamstring curl, knee extension, calf raises), and the website contains evidence-based information and videos for each exercise and general OA information and advice. Participants will be asked to complete an exercise log and will receive motivational text messages (2-5 per week), where they will also be asked to report their adherence to the exercise programme. The web site has been trialled with patients in Australia, however, any participant who is not managing the programme will be able to request a single appointment with a physiotherapist by completing the 'make an appointment' page on the MyKneeExercise website.

The interactive/electronic elements of the programmes and the physiotherapist training materials (for Group E-Rehab) will be developed and refined during Phase 1 of the study.

The control group will receive one/two physiotherapy sessions; and will be provided with an exercise sheet so they can continue with the exercises and rehabilitation at home.

All participants will be asked to complete a questionnaire (covering topics such as pain, function, health status, quality of life) at baseline and after three and nine months. To learn more about the individuals who are taking part in the study, additional information and basic demographic details such as age, sex, ethnicity, medical history (including history of chronic knee pain), joints affected (using a joint manikin), employment, and medications, will be collected at baseline. A resource use questionnaire to collect data in order to generate an estimate of the cost of delivering the interventions will also be used. The questionnaires will be sent by post.

Qualitative data collection:
On completion of the nine-month follow-up questionnaire, a sub-sample of participants from the two e-rehabilitation intervention study arms will be contacted and asked their views about the specific intervention they received as well as their experience of being in the study. This will be done using face-to-face interviews or by telephone, and will last approximately 45 minutes. Around 20 participants will be interviewed; the final number will be determined once data saturation has been reached.

The two physiotherapists who delivered the Skype/Zoom Group E-Rehab intervention will both be asked for feedback about their experience of the preparation, delivery and potential/actual barriers to the e-rehabilitation programme using semi-structured face-to-face interviews.

Intervention Type
Other

Primary outcome measure
Current primary outcome measures as of 25/04/2022:
This study uses measures of proof of concept/feasibility and patient-reported outcomes. As this is a feasibility study, it is to be noted that primary and secondary outcomes do not need to be specified.

The criteria for success of the feasibility study are:
1. Demonstration that participants and physiotherapists find e-rehabilitation acceptable and can be administered successfully
2. Calculation of a sample size from the feasibility study that can be achieved in a main trial
3. At most 30% attrition at 3 months
4. At least 40-50% of eligible patients recruited into the study

Patient-reported outcomes are:
1. Pain measured using a joint pain manikin, 5-point scale (frequency of pain), a medication use questionnaire, and Part 1 of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), at baseline, and at 3 and 9 months
2. Quality of life measured using the 12-Item Short Form Survey (SF-12), and EQ-5D-5L (EuroQoL Group) questionnaires at baseline, and at 3 and 9 months
3. Pain catastrophising and coping assessed using the Hospital Anxiety and Depression Scale (HADS) and 8-point Arthritis Self-Efficacy Scale (ASES-8) at baseline, and at 3 and 9 months
4. Resource use measured with a ‘Use of Hospital/Community Services’ questionnaire at baseline, and at 3 and 9 months

5. Confidence (no confidence to very confident) and motivation (no motivation to very motivated) to do exercises, measured using an 11-point numeric rating scale at baseline, and at 3 and 9 months
6. Global change (overall pain and mobility/function), measured using a 7-point Likert scale (much worse to much better), and data from WOMAC Parts 2 & 3 at 3 and 9 months

Previous primary outcome measures:
Feasibility of two different e-rehabilitation programmes:
1. Demonstration that participants and physiotherapists find e-rehabilitation acceptable and can be administered successfully
2. Calculation of a sample size from the feasibility study that can be achieved in a main trial
3. At most 30% attrition at 3 months
4. At least 40-50% of eligible patients recruited into the study

Secondary outcome measures
Current secondary outcome measures as of 25/04/2022:
As mentioned above, this is a feasibility study and therefore, it is acceptable not to specify primary and secondary outcomes.

Previous secondary outcome measures:
1. Pain is measured using a joint pain manikin, 5-point scale (frequency of pain), a medication use questionnaire, and Part 1 of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), at baseline, and at three and nine months
2. Quality of life is measured using the 12-Item Short Form Survey (SF-12), and EQ-5D-5L (EuroQoL Group) questionnaires at baseline, and at 3 and 9 months
3. Pain catastrophising and coping is assessed using the Hospital Anxiety and Depression Scale (HADS) and 8-point Arthritis Self-Efficacy Scale (ASES-8) at baseline, and at 3 and 9 months
4. Resource use will be measured with a 'Use of Hospital/Community Services' questionnaire at baseline, and at 3 and 9 months
5. Global change (overall pain and mobility/function) is measured using a 7-point Likert scale (much worse to much better), and data from WOMAC Parts 2 & 3 at 3 and 9 months

Overall study start date
27/01/2020

Completion date
30/06/2023

Eligibility

Key inclusion criteria
1. Adults > 45 years
2. Chronic knee pain > 3 months and on most days of previous month
3. Knee pain during walking ≥4 on an 11-point numerical rating scale
4. Activity-related joint pain
5. Has a mobile phone, active email account, and computer with Internet access suitable for receiving/making Skype/Zoom video calls if required

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 90; UK Sample Size: 90

Total final enrolment
90

Key exclusion criteria
1. Inflammatory arthritis including gout
2. Joint replacement in the study knee
3. An injection (e.g. steroid) into the study knee joint within the last month
4. An arthroscopy (i.e. keyhole surgery) of the study knee joint in the last three months
5. Enrolled in another research study involving an intervention for OA treatment or management
6. Unable to comply with the study protocol
7. Unable to understand written and spoken English

Date of first enrolment
01/03/2021

Date of final enrolment
30/06/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Leeds Community Healthcare NHS Trust
Stockdale House
8 Victoria Road
Leeds
United Kingdom
LS6 1PF

Sponsor information

Organisation

University of Leeds

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Sponsor type
University/education

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ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Charity

Funder Name
Versus Arthritis

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
National Institute for Health Research (NIHR) (UK)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/12/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Prof. Philip Conaghan (P.Conaghan@leeds.ac.uk) following publication, which will be approx. mid-2022. The data will be fully anonymised and with consent from participants for sharing.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		03/06/2022	30/06/2022	Yes	No
HRA research summary			26/07/2023	No	No