

# Exercise for pain management in haemophilia

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| <b>Submission date</b><br>18/05/2021   | <b>Recruitment status</b><br>No longer recruiting     | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>09/07/2021 | <b>Overall study status</b><br>Completed              | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>10/10/2024       | <b>Condition category</b><br>Haematological Disorders | <input type="checkbox"/> Individual participant data  |

## Plain English summary of protocol

### Background and study aims

Haemophilia is a rare inherited bleeding disorder. If left untreated, those with a severe form of the condition bleed into their joints and muscles. After many repeated bleeds, joints become damaged by a condition known as haemophilic arthritis. For most adults over 40 years old with severe haemophilia, effective treatment was not readily available when they were growing up. As a result many have multiple joints affected by painful haemophilic arthritis. This affects quality of life and physical activity. Chronic pain because of this joint damage is a problem for many people with haemophilia, but evidence for effective pain management options is lacking. In other types of arthritis, exercise is effective for pain management, but it is unclear if it could work for people with haemophilia. This study was developed and created with people with haemophilia. The aim is to evaluate if the study can be done (feasibility), what the participants think about taking part in it, and to assess if the outcomes the researchers have chosen are useful.

### Who can participate?

Adults aged 18 years and over, with a diagnosis of severe haemophilia A or B and chronic pain.

### What does the study involve?

The intervention will be 12 sessions delivered over 6 weeks using telerehabilitation. Participants will do the exercises in their own home with their haemophilia physiotherapist leading the session over webcam. Exercises will be personalised to each person's own abilities. Each week there will be one individual exercise session and one group exercise session (30-35 minutes each). Weeks 1, 3 and 5 will have a group knowledge sharing and discussion session before the group exercise (30-40 minutes). Participants will complete short questionnaires about their pain, physical function and quality of life at the start and end of the 6-week session and again 12 weeks after finishing the sessions. Participants will also be asked to participate in a short interview after they finish the exercise intervention, where they will be asked to share their experiences of taking part in the study.

### What are the possible benefits and risks of participating?

It is unknown if people participating in this study will benefit from doing so. The researchers do not expect any serious side effects or serious consequences from taking part in this study. Some people may experience an increase in their pain after exercise and this may be a normal effect of doing a new activity. The researchers cannot fully eliminate the potential for the exercise to

provoke a joint bleed, although they have safety measures in place to reduce this risk as much as possible. The findings from this study will help inform the design of follow up studies with larger numbers of people.

Where is the study run from?

The Royal Free London NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?

January 2021 to May 2023

Who is funding the study?

National Institute for Health Research (NIHR) (UK)

Who is the main contact?

Paul McLaughlin

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## Contact information

**Type(s)**

Scientific

**Contact name**

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## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number**

294992

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

## Study information

### Scientific Title

Physiotherapist-led telerehabilitation and exercise intervention for the management of chronic pain in people with severe haemophilia: a non-randomised, mixed methods feasibility study

### Acronym

REMAP-Haemophilia

### Study objectives

The primary objective of this study is to test the feasibility of a remote (telerehabilitation) physiotherapy-led exercise-based rehabilitation programme in people with severe haemophilia who have chronic joint pain.

The secondary objective is to collect preliminary data (before and after) on intended patient-reported outcome measures relating to pain, quality of life, function and self-efficacy.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approved 13/07/2021, East Midlands – Nottingham 2 Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 203 443 6294; nottingham2.rec@hra.nhs.uk), ref: 21/EM/0161

### Study design

Multi-site uncontrolled before and after feasibility study with embedded qualitative study

### Primary study design

Interventional

### Secondary study design

Non randomised study

### Study setting(s)

Home

### Study type(s)

Treatment

### Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

### Health condition(s) or problem(s) studied

Chronic pain in people with severe haemophilia

### Interventions

This is a feasibility study design with no randomisation included.

The intervention consists of a 12-session, low impact, moderate-intensity exercise programme. Each participant will have a personalised programme delivered to them by their own haemophilia physiotherapist. Using an interval training approach, it will include lower and upper body strengthening and general cardiovascular activity, with an additional exercise added every 2 weeks. Each session will last no longer than 30 minutes. The programme will be delivered virtually using a telerehabilitation approach. Each week will have a 1:1 session as well as a group exercise session (max. 5 people). In addition, there will be three knowledge sharing and discussion sessions with the topics of pain with haemophilia, physical activity with haemophilia, arthritis and pain and pacing with pain. The study design incorporates behaviour change techniques. Participants will be asked to record weekly short self-evaluations in a diary for the duration of the exercise intervention.

Assessments will be carried out at three timepoints: baseline, end of exercise sessions (6 weeks) and 12 weeks after timepoint 2.

Following completion of the 6-week exercise component, participants will be asked to participate in an individual semi-structured interview. This is in keeping with the feasibility design and is to investigate their views and experiences of taking part in the study.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

The feasibility aspects of the intervention will be evaluated as follows:

1. Recruitment rate (% uptake)
2. Adherence rate to the intervention procedures
3. Acceptability of the intervention
4. Attrition due to the intervention
5. Safety of the intervention
6. Loss to follow up

All will be evaluated from data from screening/recruitment logs, attendance records, participant diaries, participant interviews and review of any recorded adverse events at the end of the study intervention

## **Secondary outcome measures**

Measured at baseline, week 6 and week 18:

1. Severity and impact of pain measured using the Brief Pain Inventory (BPI)
2. Confidence to be active even with pain measured using the Pain Self Efficacy Questionnaire (PSEQ)
3. Health-related quality of life measured using the EQ 5D 5L questionnaire
4. Pain and quality of life with arthritic joint pain measured using the Musculoskeletal Health Questionnaire (MSK-HQ)
5. Impact of haemophilia on perceived physical function measured using the Haemophilia Activities List (HAL)
6. Self-reporting functional goals for rehabilitation measured using the Patient-Specific Functional Scale (PSFS)
7. Rating change in one's own clinical status measured by Patient Global Impression of Change (PGIC)

## **Overall study start date**

01/01/2021

**Completion date**

31/05/2023

## Eligibility

**Key inclusion criteria**

1. People with severe haemophilia A or B (with or without an inhibitor)
2. Aged 18 years and over
3. Self-reported symptoms of chronic pain associated with haemophilic arthropathy (any joint)
4. Willing and able to give informed consent for participation in this study
5. Able to follow instructions
6. Have a good command of written and spoken English
7. Registered at a UK located haemophilia comprehensive care centre with a named physiotherapist
8. Have access to a laptop/tablet at home and sufficient internet connection

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Male

**Target number of participants**

15

**Total final enrolment**

10

**Key exclusion criteria**

1. Mild or moderate haemophilia A or B
2. Any other inherited bleeding disorder
3. A diagnosis of chronic pain that is not associated with haemophilic arthropathy
4. Severe and/or unstable cardiovascular disease
5. Severe and/or unstable pulmonary disease
6. Uncontrolled diabetes mellitus

**Date of first enrolment**

01/07/2021

**Date of final enrolment**

01/12/2022

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre****Royal Free Hospital**

Royal Free London NHS Foundation Trust

Pond St

London

United Kingdom

NW3 2QG

**Study participating centre****The Royal London Hospital**

Barts Health NHS Trust

80 Newark St

London

United Kingdom

E1 2ES

**Study participating centre****Basingstoke and North Hampshire Hospital**

Hampshire Hospitals NHS Foundation Trust

Aldermaston Rd

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**Sponsor information****Organisation**

Royal Free London NHS Foundation Trust

**Sponsor details**

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**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.royalfree.nhs.uk/>

**ROR**

<https://ror.org/04rtdp853>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

National Institute for Health Research

**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**

The protocol will be uploaded once approvals have been received and finalised. Results from this study will be published (open access) in a peer-reviewed journal that targets physiotherapists, physical therapists, physiatrists and physicians in haemophilia and other inherited bleeding disorders. Findings will be disseminated to patient groups such as the UK Haemophilia Society and European Haemophilia Consortium via newsletters and presentations.

**Intention to publish date**

01/12/2023

**Individual participant data (IPD) sharing plan**

The data-sharing plans for the current study are unknown and will be made available at a later date.

**IPD sharing plan summary**

Data sharing statement to be made available at a later date

**Study outputs**

| Output type                          | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|--------------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">HRA research summary</a> |         |              | 28/06/2023 | No             | No              |
| <a href="#">Results article</a>      |         | 08/10/2024   | 10/10/2024 | Yes            | No              |