

Development of a haemophilia physiotherapy intervention for optimum musculoskeletal health in children

Submission date 07/09/2020	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/11/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 04/11/2020	Condition category Haematological Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Children are born with haemophilia. Females carry the disorder and usually males are affected. It is a disorder affecting 1 in 10,000 people where the blood does not clot normally, leading to bleeding into muscles and joints. As a result, muscles become weak and joints become painful and difficult to move. "Being able to participate in games and activities with their friends" is one of the things that matters most to boys with haemophilia. At present, there is a lack of robust evidence to determine whether muscle strengthening exercise can improve or negatively affect outcomes for young children with haemophilia. With the help of boys with haemophilia, their parents and physiotherapists, the researchers have developed an exercise programme designed to increase muscle strength. This study aims to find out if the exercise programme might have an effect on joint pain and movement participation in games and activities and improve health in the long term.

Who can participate?

Boys aged between 6 and 12 with severe or moderate haemophilia

What does the study involve?

66 boys will be allocated to a group that is asked to complete a 12-week exercise routine to strengthen their leg muscles and another 66 boys to a group that does not do the exercises. The boys will be allocated at random, so that each boy has an equal chance of being in either group. The researchers will monitor the boys throughout the study by measuring their muscle strength, how far they can walk in 6 minutes and time taken to ascend and descend 12 steps. The researchers will also record how physically active the boys are using a wrist band as well as how satisfied they are with their health.

What are the possible benefits and risks of participating?

It is not known whether participants will benefit directly from participating in this study. However, the researchers will collect information which might improve future care for all patients with haemophilia including patients in this study. They do not expect any reactions or side effects of doing the exercises, but they cannot be certain. When muscles are worked harder

than they are used to, or in a different way, soreness in muscles may occur 1-2 days after exercise. This is common when starting an exercise programme and some people may notice some discomfort or aching in their muscles 1-2 days after doing exercises.

Where is the study run from?

This research is being organised by the Haemophilia Centre, East Kent Hospitals University NHS Foundation Trust. However, participants can participate at their local Haemophilia Centre.

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

September 2019 to September 2023

Who is funding the study?

National Institute for Health Research (NIHR) (UK)

Who is the main contact?

Dr David Stephensen

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Contact information

Type(s)

Scientific

Contact name

Dr David Stephensen

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Contact details

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

282478

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Study information

Scientific Title

Single-blinded two-arm pragmatic randomised controlled trial of an exercise intervention versus usual care in children with haemophilia

Acronym

DOLPHIN-II

Study objectives

A 12-week exercise intervention increases muscle strength of the dominant knee extensors more than usual care at 24 weeks in children with haemophilia aged 6-12 years.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 03/11/2020, South West - Cornwall & Plymouth Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)2071048071; cornwallandplymouth.rec@hra.nhs.uk), REC ref: 20/SW/0154

Study design

Single-blinded two-arm pragmatic randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Children with haemophilia

Interventions

Randomisation of eligible participants will be performed with the online randomisation service <http://sealedenvelope.com/>. Utilising the secure, centralised and independent service, participants will be randomly allocated into one of the two groups (treatment group 1: 12-week muscle strengthening exercise intervention; treatment group 2: usual physiotherapy care for 12

weeks) on a ratio of 1:1. Allocation will be stratified by centre to ensure the same numbers of participants at each site are allocated to the two groups. The unblinded principal investigator at each site will be issued with a password to access the service to create a new randomisation for study participants. The trial manager will oversee randomisations by site and over time.

Intervention Type

Behavioural

Primary outcome measure

Muscle strength of the dominant knee extensors measured using maximum voluntary isometric contraction at baseline, 12 and 24 weeks

Secondary outcome measures

1. Muscle strength of the ankle plantarflexors and non-dominant knee extensors measured using maximum voluntary isometric contraction at baseline, 12 and 24 weeks
2. Physical function measured using the 6-minute timed walk, timed up and down stairs, triple hop and vertical jump tests at baseline, 12 and 24 weeks
3. Physical activity measured using daily step counts, sedentary time, time spent in moderate and vigorous-intensity physical activity using a wearable activity tracker at baseline, 12 and 24 weeks
4. Quality of life and QALY measured using the EuroQol-5D (EQ-5D) and Child Health Utility 9D (CHU9D) at baseline, 12 and 24 weeks
5. Safety and adherence assessed using adverse events, pain and exercise counts at 12 weeks
6. Intervention practicalities assessed using semi-structured interviews at the end of the intervention at 12 weeks

Overall study start date

01/09/2019

Completion date

30/09/2023

Eligibility

Key inclusion criteria

1. Diagnosis of severe or moderate haemophilia and registered with a UK Haemophilia Centre
2. Aged 6 – 12 years
3. Inhibitor or non-inhibitor
4. Able to follow simple verbal instructions and provide informed consent

Participant type(s)

Patient

Age group

Child

Lower age limit

6 Years

Upper age limit

12 Years

Sex

Male

Target number of participants

132

Key exclusion criteria

1. Children 13 years or older (boys aged 13 years or older are excluded due to confounding effects of non-linear increases in neuromuscular maturation and muscle strength that occur in boys during puberty and adolescence)
2. von Willebrand disease
3. Past history of fracture or trauma to the lower limb
4. Past history of orthopaedic surgery of the lower limb
5. Past history of acquired brain injury
6. Past history of any other disturbance of the central nervous system
7. Joint or muscle bleed in the lower limb in the past 6 weeks
8. Presence of lower limb pain
9. Participants who are unable to fully comply with verbal instructions

Date of first enrolment

01/01/2021

Date of final enrolment

01/03/2023

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Kent Haemophilia Centre

East Kent Hospitals University NHS Foundation Trust

Canterbury

United Kingdom

CT1 3NG

Sponsor information

Organisation

East Kent Hospitals University NHS Foundation Trust

Sponsor details

Kent Haemophilia Centre
Canterbury
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+44 (0)1227866481
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Sponsor type

Hospital/treatment centre

Website

<http://www.ekhuft.nhs.uk/patients-and-visitors/>

ROR

<https://ror.org/02dqqj223>

Funder(s)**Funder type**

Government

Funder Name

Research for Patient Benefit Programme - NIHR201588

Alternative Name(s)

NIHR Research for Patient Benefit Programme, RfPB

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications**Publication and dissemination plan**

The researchers will upload the study protocol once REC/HRA approved. So that people hear about what they learn in the study, the researchers will report the findings to other researchers

using journals, relevant healthcare professionals through face to face meetings, and children with haemophilia and their families through newsletters and presentations at Haemophilia Society meetings.

Intention to publish date

01/03/2024

Individual participant data (IPD) sharing plan

The dataset will not be made available. The study involves participants with a rare condition, and although the data will be anonymised, some participant-level data may result in deanonymisation. Data will be held on a secure database by the sponsor.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No