

Evaluating the acceptability and usability of a digital self-management intervention (smartphone application) to support the non-surgical treatment of Perthes' Disease

Submission date 20/10/2023	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 19/12/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 22/12/2023	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Perthes' disease is a condition that results in the collapse of a child's hip bone, affecting their ability to run, and play sports and some children even find walking difficult. There is lots of uncertainty around the treatment of Perthes' disease and a lack of consistent advice between Perthes' disease specialists. This can cause considerable anxiety to the parents of children with Perthes' disease. With the support of children with Perthes' disease, their families and clinicians, a digital intervention (an app) has been developed. This is the final study within an overarching project to test an app, designed to support self-management.

Who can participate?

Children aged between 5 and 16 years old who were diagnosed with Perthes' Disease between one and five years ago

What does the study involve?

The study will recruit ten children from three sites (30 total) to use the app for six weeks. Information will be collected before and after using the app, focussing on app usage, quality of life and impact of the condition on the child/family. The study will also test how acceptable the app is to children with Perthes' disease and their families. There will also be a sub-study where some participants will be asked more specific questions about their interaction with the app to gain insight into the reasons why different elements of the app were/were not as acceptable as others. 12-15 of the participants who used the app will be invited to take part in focus groups to discuss their experience of using the app in more detail.

The results of this study will be shared so that it is accessible to all. Articles will be published in medical journals and information will be shared with groups who support children with Perthes' disease, as well as through social media. The results will be fed back in a 'fun' child-friendly way, using videos and electronic leaflets to make sure the answers are available to everyone.

What are the possible benefits and risks of participating?

There are no significant benefits or risks to taking part in this study. The benefit of taking part is that the participants will have an opportunity to try a novel intervention in the management of a debilitating condition and provide insight that could improve the care of children with the condition in the future. The main risk is the burden of time for the participants taking part, to account for this, funding has been acquired in line with NIHR guidance to compensate participants for their time.

Where is the study run from?

University of Leeds (UK)

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

June 2023 to May 2024

Who is funding the study?

National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?

Mr Adam Galloway, adamgalloway@nhs.net (UK)

Study website

<https://www.leedsth.nhs.uk/a-z-of-services/leeds-childrens-hospital-clinical-research-team/current-studies/non-stop/>

Contact information

Type(s)

Public, Scientific, Principal Investigator

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

330507

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

IRAS 330507, CPMS 59738

Study information

Scientific Title

Evaluating the acceptability and usability of a digital self-management intervention (smartphone application) to support the non-surgical treatment of Perthes' Disease

Acronym

Testing the NON-STOP app

Study objectives

1. To test the acceptability of implementing the NON-STOP intervention with children with Perthes' Disease and their families
2. Understand the user experience of children with Perthes' Disease when using the NON-STOP intervention

Ethics approval required

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Ethics approval(s)

Approved 30/11/2023, West Midlands Research Ethics Committee (Meeting held by video-conference via Zoom, -, -, United Kingdom; +44 (0)207 104 8357; edgbaston.rec@hra.nhs.uk), ref: 23/WM/0251

Study design

Mixed methods with observational and qualitative components

Primary study design

Interventional

Secondary study design

Nested-qualitative

Study setting(s)

Home, Hospital

Study type(s)

Other

Participant information sheet**Health condition(s) or problem(s) studied**

Perthes' Disease

Interventions

Testing of a new self-management intervention to support management

Intervention Type

Other

Primary outcome measure

Log-ins, type of data accessed, and time used measured using App use metrics at the end of the study

Secondary outcome measures

1. Physical health function measured using the Patient-Reported Outcomes Measurement Information System: Mobility tool (PROMIS Mobility including QoL assessment) before and after app use
2. Child activity levels measured using the Child Physical Activity Questionnaire (CPAQ) pre and post-app testing period
3. App acceptability measured using the Health Information Technology Usability Evaluation Scale (Health-ITUES) after the app testing period

Overall study start date

01/06/2023

Completion date

31/05/2024

Eligibility

Key inclusion criteria

1. Diagnosed with Perthes' Disease between one and five years ago
2. Aged between 5 and 16 years old
3. Access to a smart device

Participant type(s)

Service user

Age group

Child

Lower age limit

5 Years

Upper age limit

16 Years

Sex

Both

Target number of participants

30

Key exclusion criteria

1. Unable to communicate verbally in English
2. The child has undergone surgery for Perthes' Disease in the last 6 weeks

Date of first enrolment

02/01/2024

Date of final enrolment

31/03/2024

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

NIHR Leeds Clinical Research Facility

Leeds Teaching Hospitals NHS Trust

Leeds

United Kingdom

LS1 3EX

Sponsor information

Organisation

University of Leeds

Sponsor details

Woodhouse Lane

Leeds

England

United Kingdom

LS2 9JT

+44 (0)113 3437587

governance-ethics@leeds.ac.uk

Sponsor type

University/education

Website

<http://www.leeds.ac.uk/>

ROR

<https://ror.org/024mrx33>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health and Care 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

Planned publication in a high-impact and peer-reviewed journal

Intention to publish date

31/12/2024

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publicly available repository from the lead researcher's institute (University of Leeds)

IPD sharing plan summary

Stored in publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.2		14/11/2023	No	Yes
Participant information sheet	version 1.2		14/11/2023	No	Yes
Participant information sheet	nested qualitative study version 1.2		14/11/2023	No	Yes

Participant information sheet	nested qualitative study version 1.2	14/11/2023	No	Yes
Protocol file	version 1.0	14/11/2023	No	No